

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(D)  
of the Securities Exchange Act of 1934**

**June 15, 2023  
Date of report (Date of earliest event reported)**

**MEI Pharma, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-50484**  
(Commission  
File Number)

**51-0407811**  
(IRS Employer  
Identification No.)

**11455 El Camino Real, Suite 250  
San Diego, California**  
(Address of principal executive offices)

**92130**  
(Zip Code)

**Registrant's telephone number, including area code (858) 369-7100**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of Each Class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common stock, \$0.0000002 par value	MEIP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01 Regulation FD Disclosure**

On June 15, 2023, MEI Pharma, Inc. (the “Company”) and Infinity Pharmaceuticals, Inc. (“Infinity”) issued a joint press release announcing a pre-recorded joint video webcast that will be available at 8:00 am Eastern Time on June 19, 2023, which will provide an update on the pending Merger (as defined below) and an overview of the combined company. As previously disclosed, on February 22, 2023, the Company, Infinity, and Meadow Merger Sub, Inc., a wholly owned subsidiary of the Company (“Merger Sub”), entered into an Agreement and Plan of Merger whereby Merger Sub will merge with and into Infinity, with Infinity being the surviving entity as a wholly owned subsidiary of the Company (the “Merger”). Copies of the press release and investor presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, to this Form 8-K and incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the foregoing information, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for the purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall such information, including Exhibits 99.1 and 99.2, be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

***Important Information about the Merger and Where to Find It***

This communication relates to a proposed transaction between Infinity and the Company. In connection with the proposed merger, the Company filed with the SEC a registration statement on Form S-4 that includes a joint proxy statement of the Company and Infinity (the “Joint Proxy Statement/Prospectus”) that also constitutes a prospectus of the Company. The registration statement on Form S-4 was declared effective by the SEC on June 6, 2023. The Company and Infinity have each filed and mailed the Joint Proxy Statement/Prospectus to their respective stockholders. INVESTORS AND THE COMPANY’S AND INFINITY’S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF THE COMPANY AND INFINITY WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED MERGER AND THE PARTIES TO THE PROPOSED MERGER. Investors and stockholders may obtain a free copy of the Joint Proxy Statement/Prospectus and other documents containing important information about the Company and Infinity from the SEC’s website at [www.sec.gov](http://www.sec.gov). The Company and Infinity make available free of charge at [www.meipharma.com](http://www.meipharma.com) and [www.infi.com](http://www.infi.com), respectively (in the “Investors” and “Investors/Media” sections, respectively), copies of materials they file with, or furnish to, the SEC.

***Participants in the Solicitation***

The Company, Infinity and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of the Company and Infinity in connection with the proposed merger. Securityholders may obtain information regarding the names, affiliations and interests of the Company’s and Infinity’s directors and executive officers in the Joint Proxy Statement/Prospectus which may be obtained free of charge from the SEC’s website at [www.sec.gov](http://www.sec.gov), the Company’s investor website at <https://www.meipharma.com/investors> and Infinity’s investor website at <https://investors.infi.com/>.

***No Offer or Solicitation***

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

#### Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations of the management of the Company and Infinity that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “should,” “plan,” “could,” “continue,” “target,” “contemplate,” “estimate,” “forecast,” “guidance,” “predict,” “possible,” “potential,” “pursue,” “likely,” and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding: the expected timing of the closing of the proposed merger; the ability of the parties to complete the proposed merger considering the various closing conditions; the expected benefits of the proposed merger, including estimations of anticipated cost savings and cash runway; the competitive ability and position of the combined company; the potential, safety, efficacy, and regulatory and clinical progress of the combined company’s product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and the expectations surrounding potential regulatory submissions, approvals and timing thereof; the sufficiency of the combined company’s cash, cash equivalents and short-term investments to fund operations; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from the Company’s and Infinity’s plans, estimates or expectations could include, but are not limited to: (i) the risk that the proposed merger may not be completed in a timely manner or at all, which may adversely affect the Company’s and Infinity’s businesses and the price of their respective securities; (ii) uncertainties as to the timing of the consummation of the proposed merger and the potential failure to satisfy the conditions to the consummation of the proposed merger, including obtaining stockholder and regulatory approvals; (iii) the proposed merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement, pendency or completion of the proposed merger on the ability of the Company or Infinity to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom the Company or Infinity does business, or on the Company’s or Infinity’s operating results and business generally; (v) the Company’s or Infinity’s respective businesses may suffer as a result of uncertainty surrounding the proposed merger and disruption of management’s attention due to the proposed merger; (vi) the outcome of any legal proceedings related to the proposed merger or otherwise, or the impact of the proposed merger thereupon; (vii) the Company or Infinity may be adversely affected by other economic, business, and/or competitive factors; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement and the proposed merger; (ix) restrictions during the pendency of the proposed merger that may impact the Company’s or Infinity’s ability to pursue certain business opportunities or strategic transactions; (x) the risk that the Company or Infinity may be unable to obtain governmental and regulatory approvals required for the proposed merger, or that required governmental and regulatory approvals may delay the consummation of the proposed merger or result in the imposition of conditions that could reduce the anticipated benefits from the proposed merger or cause the parties to abandon the proposed merger; (xi) risks that the anticipated benefits of the proposed merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (xii) the impact of legislative, regulatory, economic, competitive and technological changes; (xiii) risks relating to the value of the Company shares to be issued in the proposed merger; (xiv) the risk that integration of the proposed merger post-closing may not occur as anticipated or the combined company may not be able to achieve the benefits expected from the proposed merger, as well as the risk of potential delays, challenges and expenses associated with integrating the combined company’s existing businesses; (xv) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of the Company’s and Infinity’s traded securities; (xvi) the impact of the COVID-19 pandemic on the Company’s and Infinity’s industry and individual companies, including on counterparties, the supply chain, the execution of clinical development programs, access to financing and the allocation of government resources; (xvii) final data from pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; (xviii) costs and delays in the development and/or U.S. Food and Drug Administration (“FDA”) approval, or the failure to obtain such approval, of the combined company’s product candidates; (xix) regulatory authorities may not agree with the design or results of clinical studies and as a result future clinical studies may be subject to holds; (xx) uncertainties or differences in interpretation in clinical trial results; (xxi) the combined company’s inability to maintain or enter into, and the risks resulting from dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any product candidates; and (xxii) the ability of the Company or Infinity to protect and enforce intellectual property rights; and (xxiii) the unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as the Company’s and Infinity’s response to any of the aforementioned factors. Additional factors that may affect the future results of the Company and Infinity are set forth in their respective filings with the United States Securities and Exchange Commission (the “SEC”), including the section entitled “Risk Factors” in the Registration Statement on Form S-4 that was declared effective by the SEC on June 6, 2023 and each of the Company’s and Infinity’s most recently filed Annual Reports on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). See in particular the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2022 in Part I, Item 1A, “Risk Factors,” and Infinity’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, in Part I, Item 1A, “Risk Factors.” The risks and uncertainties described above and in the SEC filings cited above are not exclusive and further information concerning the Company and Infinity and their respective businesses, including factors that potentially could materially affect their respective businesses, financial conditions or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Any such forward-looking statements represent management’s reasonable estimates and beliefs as of the date of this filing. While the Company and Infinity may elect to update such forward-looking statements at some point in the future, they disclaim any obligation to do so, other than as may be required by law, even if subsequent events cause their views to change.

This Form 8-K contains hyperlinks to information that is not deemed to be incorporated by reference.

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**Item 9.01 Exhibits.****(d) Exhibits**

Exhibit No.	Description
99.1	Joint Press Release of the Company, dated June 15, 2023.
99.2	Investor Presentation of Infinity Pharmaceuticals, Inc. and MEI Pharma, Inc. dated June 19, 2023.
104.1	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

June 20, 2023

**MEI PHARMA, INC.**

By: /s/ David M. Urso  
Name: David M. Urso  
Title: President and Chief Executive Officer



**MEI Pharma and Infinity Pharmaceuticals Host Video Webcast Providing Overview and Update on Pending Merger to Advance Three Promising Clinical Oncology Candidates**

*Event Available at 8:00 a.m. Eastern Time on June 19, 2023*

**SAN DIEGO, CA. and CAMBRIDGE, MA., June 15, 2023** – MEI Pharma, Inc. (Nasdaq: MEIP) (“MEI”), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, and Infinity Pharmaceuticals, Inc. (Nasdaq: INFI) (“Infinity”), a clinical-stage biotechnology company developing eganelisib, a first-in-class, oral, immuno-oncology macrophage reprogramming drug candidate, announced today that the companies will host a recorded joint video webcast that will be available at 8:00 am Eastern Time on June 19, 2023. On the webcast Mr. David Urso will provide an update on the pending merger and an overview of the combined company, which joins the expertise and resources of MEI and Infinity to advance a robust pipeline of three clinical-stage oncology drug candidates.

In addition to presentations from the executive management from MEI and Infinity on the three programs, the webcast includes commentary and discussion with Dr. Ezra Cohen, a recognized expert in the treatment of squamous cell carcinoma of the head & neck (SCCHN) and recently the Chief, Division of Hematology-Oncology, and Associate Director of Clinical Science at UC San Diego Moores Cancer Center. Following the prepared presentations, Dr. Nick Abbott, most recently the senior sell side biotech analyst at Wells Fargo Securities will ask questions of the presenters, Dr. Robert Ilaria, Dr. Ezra Cohen and Dr. Richard Ghahie.

The combined company’s development pipeline consists of three differentiated programs. All three clinical-stage development programs have the potential, in combination with current therapies, to overcome known resistance mechanisms and meaningfully improve patient outcomes:

- Eganelisib, an oral immuno-oncology macrophage reprogramming product candidate, which is planned to be evaluated in combination with the PD-1 targeted checkpoint inhibitor pembrolizumab (KEYTRUDA®) in patients with head and neck squamous cell carcinoma (HNSCC);
- Voruciclib, an oral CDK9 inhibitor, currently being studied in combination with venetoclax (VENCLEXTA®) in patients with hematologic malignancies; and
- ME-344, a novel tumor selective mitochondrial inhibitor targeting the OXPHOS pathway, to be evaluated in combination with bevacizumab (AVASTIN®) in patients with relapsed colorectal cancer.



#### **Video Webcast Information**

You can access the video webcast under the investor relations section of MEI's website on the "Events and Presentation" page at [www.meipharma.com](http://www.meipharma.com), or under the investor relations page of Infinity's website on its "Events and Presentation" page at [www.infi.com](http://www.infi.com). The pre-recorded video webcast will be archived for at least 30 days after the conclusion of the event.

#### **About MEI Pharma**

MEI Pharma, Inc. (Nasdaq: MEIP) is a pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated mechanisms of action intended to address unmet medical needs and deliver improved benefits to patients, either as standalone treatments or in combination with other therapeutic options. For more information, please visit [www.meipharma.com](http://www.meipharma.com). Follow us on Twitter @MEI\_Pharma and on LinkedIn.

#### **About Infinity Pharmaceuticals**

Infinity Pharmaceuticals, Inc. (Nasdaq: INFI) is a clinical-stage biotechnology company developing eganelisib (IPI-549), a potential first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic which is designed to address a fundamental biologic mechanism of immune suppression in cancer in multiple clinical studies. For more information on Infinity, please refer to Infinity's website at [www.infi.com](http://www.infi.com).

#### **Important Information about the Merger and Where to Find It**

This communication relates to a proposed transaction between Infinity) and MEI. In connection with the proposed merger, MEI filed with the SEC a registration statement on Form S-4 that includes a joint proxy statement of MEI and Infinity (the "Joint Proxy Statement/Prospectus") that also constitutes a prospectus of MEI. The registration statement on Form S-4 was declared effective by the SEC on June 6, 2023. MEI and Infinity have each filed and mailed the Joint Proxy Statement/Prospectus to their respective stockholders. INVESTORS AND MEI'S AND INFINITY'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF MEI AND INFINITY WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED MERGER AND THE PARTIES TO THE PROPOSED MERGER. Investors and stockholders may obtain a free copy of the Joint Proxy Statement/Prospectus and other documents containing important information about MEI and Infinity from the SEC's website at [www.sec.gov](http://www.sec.gov). MEI and Infinity make available free of charge at [www.meipharma.com](http://www.meipharma.com) and [www.infi.com](http://www.infi.com), respectively (in the "Investors" and "Investors/Media" sections, respectively), copies of materials they file with, or furnish to, the SEC.

**Participants in the Solicitation**

MEI, Infinity and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of MEI and Infinity in connection with the proposed merger. Securityholders may obtain information regarding the names, affiliations and interests of MEI's and Infinity's directors and executive officers in the Joint Proxy Statement/Prospectus which may be obtained free of charge from the SEC's website at [www.sec.gov](http://www.sec.gov), MEI's investor website at <https://www.meipharma.com/investors> and Infinity's investor website at <https://investors.infi.com/>.

**No Offer or Solicitation**

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

**Cautionary Statement Regarding Forward-Looking Statements**

Certain statements contained in this filing may be considered forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations of the management of MEI and Infinity that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding: the expected timing of the closing of the proposed merger; the ability of the parties to complete the proposed merger considering the various closing conditions; the expected benefits of the proposed merger, including estimations of anticipated cost savings and cash runway; the competitive ability and position of the combined company; the potential, safety, efficacy, and regulatory and clinical progress of the combined company's product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and the expectations surrounding potential regulatory submissions, approvals and timing thereof; the sufficiency of the combined



company's cash, cash equivalents and short-term investments to fund operations; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from MEI's and Infinity's plans, estimates or expectations could include, but are not limited to: (i) the risk that the proposed merger may not be completed in a timely manner or at all, which may adversely affect MEI's and Infinity's businesses and the price of their respective securities; (ii) uncertainties as to the timing of the consummation of the proposed merger and the potential failure to satisfy the conditions to the consummation of the proposed merger, including obtaining stockholder and regulatory approvals; (iii) the proposed merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement, pendency or completion of the proposed merger on the ability of MEI or Infinity to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom MEI or Infinity does business, or on MEI's or Infinity's operating results and business generally; (v) MEI's or Infinity's respective businesses may suffer as a result of uncertainty surrounding the proposed merger and disruption of management's attention due to the proposed merger; (vi) the outcome of any legal proceedings related to the proposed merger or otherwise, or the impact of the proposed merger thereupon; (vii) MEI or Infinity may be adversely affected by other economic, business, and/or competitive factors; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement and the proposed merger; (ix) restrictions during the pendency of the proposed merger that may impact MEI's or Infinity's ability to pursue certain business opportunities or strategic transactions; (x) the risk that MEI or Infinity may be unable to obtain governmental and regulatory approvals required for the proposed merger, or that required governmental and regulatory approvals may delay the consummation of the proposed merger or result in the imposition of conditions that could reduce the anticipated benefits from the proposed merger or cause the parties to abandon the proposed merger; (xi) risks that the anticipated benefits of the proposed merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (xii) the impact of legislative, regulatory, economic, competitive and technological changes; (xiii) risks relating to the value of MEI shares to be issued in the proposed merger; (xiv) the risk that integration of the proposed merger post-closing may not occur as anticipated or the combined company may not be able to achieve the benefits expected from the proposed merger, as well as the risk of potential delays, challenges and expenses associated with integrating the combined company's existing businesses; (xv) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of MEI's and Infinity's traded securities; (xvi) the impact of the COVID-19 pandemic on MEI's and Infinity's industry and individual companies, including on counterparties, the supply chain, the execution of clinical development programs, access to financing and the allocation of government resources; (xvii) final data from pre-clinical studies and completed clinical trials may differ

materially from reported interim data from ongoing studies and trials; (xviii) costs and delays in the development and/or U.S. Food and Drug Administration (“FDA”) approval, or the failure to obtain such approval, of the combined company’s product candidates; (xix) regulatory authorities may not agree with the design or results of clinical studies and as a result future clinical studies may be subject to holds; (xx) uncertainties or differences in interpretation in clinical trial results; (xxi) the combined company’s inability to maintain or enter into, and the risks resulting from dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any product candidates; and (xxii) the ability of MEI or Infinity to protect and enforce intellectual property rights; and (xxiii) the unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as MEI’s and Infinity’s response to any of the aforementioned factors. Additional factors that may affect the future results of MEI and Infinity are set forth in their respective filings with the United States Securities and Exchange Commission (the “SEC”), including the section entitled “Risk Factors” in the Registration Statement on Form S-4 that was declared effective by the SEC on June 6, 2023 and each of MEI’s and Infinity’s most recently filed Annual Reports on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). See in particular MEI’s Annual Report on Form 10-K for the fiscal year ended June 30, 2022 in Part I, Item 1A, “Risk Factors,” and Infinity’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, in Part I, Item 1A, “Risk Factors.” The risks and uncertainties described above and in the SEC filings cited above are not exclusive and further information concerning MEI and Infinity and their respective businesses, including factors that potentially could materially affect their respective businesses, financial conditions or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Any such forward-looking statements represent management’s reasonable estimates and beliefs as of the date of this press release. While MEI and Infinity may elect to update such forward-looking statements at some point in the future, they disclaim any obligation to do so, other than as may be required by law, even if subsequent events cause their views to change.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference.



**Infinity Contact**

Melissa Hackel  
Tel: 617-453-1117

Morrow Sodali, LLC  
Tel: (800) 662-5200  
[INFI@info.morrowsodali.com](mailto:INFI@info.morrowsodali.com)

**MEI Pharma Contacts**

David A. Walsey  
Tel: 858-369-7104  
[investor@meipharma.com](mailto:investor@meipharma.com)

Joele Frank, Wilkinson Brimmer Katcher  
Dan Katcher / Aaron Palash  
Tel: 212-355-4449  
[MEIP-jf@joelefrank.com](mailto:MEIP-jf@joelefrank.com)



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MEI Pharma & Infinity Pharmaceuticals Merger and Clinical Program Update

JUNE 2023

## TODAY'S AGENDA

### Welcome and Overview

- David Urso, President & CEO (MEIP and combined company)

### Eganelisib

- Dr. Robert Ilaria, Jr., Chief Medical Officer (INFI and combined company)
- Dr. Ezra Cohen
  - Chief Medical Officer, Oncology, Tempus Most recently, Chief, Division of Hematology-Oncology, and Associate Director of Clinical Science at UC San Diego Moores Cancer Center
- Nick Abbott, PhD.
  - Former sellside analyst with 35 years biotech experience, most recently at Wells Fargo

### Voruciclib & ME-344

- Dr. Richard Ghalie, Chief Medical Officer (MEIP)
- Nick Abbott, PhD

### Conclusion

- David Urso, President & CEO



**A Transaction with  
Potential to Create  
Significant Opportunities  
and Build Value**

## Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this presentation may be considered forward-looking statements within the meaning of the federal securities law. Such statements are based upon current plans, estimates and expectations of the management of MEI and Infinity that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding: the expected timing of the closing of the proposed merger; the ability of the parties to complete the proposed merger considering the various closing conditions; the expected benefits of the proposed merger, including estimations of anticipated cost savings and cash runway; the competitive ability and position of the combined company; the potential, safety, efficacy, and regulatory and clinical progress of the combined company's product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and the expectations surrounding potential regulatory submissions, approvals and timing thereof; the sufficiency of the combined company's cash, cash equivalents and short-term investments to fund operations; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from MEI's and Infinity's plans, estimates or expectations could include, but are not limited to: (i) the risk that the proposed merger may not be completed in a timely manner or at all, which may adversely affect MEI's and Infinity's businesses and the price of their respective securities; (ii) uncertainties as to the timing of the consummation of the proposed merger and the potential failure to satisfy the conditions to the consummation of the proposed merger, including obtaining stockholder and regulatory approvals; (iii) the proposed merger may involve unexpected costs, liabilities or delays; (iv) the effect of the announcement, pendency or completion of the proposed merger on the ability of MEI or Infinity to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom MEI or Infinity does business, or on MEI's or Infinity's operating results and business generally; (v) MEI's or Infinity's respective businesses may suffer as a result of uncertainty surrounding the proposed merger and disruption of management's attention due to the proposed merger; (vi) the outcome of any legal proceedings related to the proposed merger or otherwise, or the impact of the proposed merger thereupon; (vii) MEI or Infinity may be adversely affected by other economic, business, and/or competitive factors; (viii) the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement and the proposed merger; (ix) restrictions during the pendency of the proposed merger that may impact MEI's or Infinity's ability to pursue certain business opportunities or strategic transactions; (x) the risk that MEI or Infinity may be unable to obtain governmental and regulatory approvals required for the proposed merger, or that required governmental and regulatory approvals may delay the consummation of the proposed merger or result in the imposition of conditions that could reduce the anticipated benefits from the proposed merger or cause the parties to abandon the proposed merger; (xi) risks that the anticipated benefits of the proposed merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; (xii) the impact of legislative, regulatory, economic, competitive and technological changes; (xiii) risks relating to the value of MEI shares to be issued in the proposed merger; (xiv) the risk that integration of the proposed merger post-closing may not occur as anticipated or the combined company may not be able to achieve the benefits expected from the proposed merger, as well as the risk of potential delays, challenges and expenses associated with integrating the combined company's existing businesses; (xv) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of MEI's and Infinity's traded securities; (xvi) the impact of the COVID-19 pandemic on MEI's and Infinity's industry and individual companies, including on counterparties, the supply chain, the execution of clinical development programs, access to financing and the allocation of government resources; (xvii) final data from pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; (xviii) costs and delays in the development and/or U.S. Food and Drug Administration ("FDA") approval, or the failure to obtain such approval, of the combined company's product candidates; (xix) regulatory authorities may not agree with the design or results of clinical studies and as a result future clinical studies may be subject to holds; (xx) uncertainties or differences in interpretation in clinical trial results; (xxi) the combined company's inability to maintain or enter into, and the risks resulting from dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any product candidates; and (xxii) the ability of MEI or Infinity to protect and enforce intellectual property rights; and (xxiii) the unpredictability and severity of catastrophic events, including, but not limited to, acts of terrorism or outbreak of war or hostilities, as well as MEI's and Infinity's response to any of the aforementioned factors. Additional factors that may affect the future results of MEI and Infinity are set forth in their respective filings with the United States Securities and Exchange Commission (the "SEC"), including the section entitled "Risk Factors" in the Registration Statement on Form S-4 that was declared effective by the SEC on June 6, 2023 and each of MEI's and Infinity's most recently filed Annual Reports on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). See in particular MEI's Annual Report on Form 10-K for the fiscal year ended June 30, 2022 in Part I, Item 1A, "Risk Factors," and Infinity's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, in Part I, Item 1A, "Risk Factors." The risks and uncertainties described above and in the SEC filings cited above are not exclusive and further information concerning MEI and Infinity and their respective businesses, including factors that potentially could materially affect their respective businesses, financial conditions or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Any such forward-looking statements represent management's reasonable estimates and beliefs as of the date of this presentation. While MEI and Infinity may elect to update such forward-looking statements at some point in the future, they disclaim any obligation to do so, other than as may be required by law, even if subsequent events cause their views to change.

This presentation contains hyperlinks to information that is not deemed to be incorporated by reference.



## Additional Information

### **Important Information about the Merger and Where to Find It**

This communication relates to a proposed transaction between Infinity Pharmaceuticals, Inc. ("Infinity") and MEI Pharma, Inc. ("MEI"). In connection with the proposed merger, MEI filed with the SEC a registration statement on Form S-4 that includes a joint proxy statement of MEI and Infinity (the "Joint Proxy Statement/Prospectus") that also constitutes a prospectus of MEI. The registration statement on Form S-4 was declared effective by the SEC on June 6, 2023. MEI and Infinity have each filed and mailed the Joint Proxy Statement/Prospectus to their respective stockholders. INVESTORS AND MEI'S AND INFINITY'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF MEI AND INFINITY WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED MERGER AND THE PARTIES TO THE PROPOSED MERGER. Investors and stockholders may obtain a free copy of the Joint Proxy Statement/Prospectus and other documents containing important information about MEI and Infinity from the SEC's website at [www.sec.gov](http://www.sec.gov). MEI and Infinity make available free of charge at [www.meipharma.com](http://www.meipharma.com) and [www.infi.com](http://www.infi.com), respectively (in the "Investors" and "Investors/Media" sections, respectively), copies of materials they file with, or furnish to, the SEC.

### **Participants in the Solicitation**

MEI, Infinity and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of MEI and Infinity in connection with the proposed merger. Securityholders may obtain information regarding the names, affiliations and interests of MEI's and Infinity's directors and executive officers in the Joint Proxy Statement/Prospectus which may be obtained free of charge from the SEC's website at [www.sec.gov](http://www.sec.gov), MEI's investor website at <https://www.meipharma.com/investors> and Infinity's investor website at <https://investors.infi.com/>.

### **No Offer or Solicitation**

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.





## TODAY'S AGENDA

### Welcome and Overview

- David Urso, President & CEO (MEIP and combined company)

### Eganelisib

- Dr. Robert Ilaria, Jr., Chief Medical Officer (INFI and combined company)
- Dr. Ezra Cohen
  - Chief Medical Officer, Oncology, Tempus Most recently, Chief, Division of Hematology-Oncology, and Associate Director of Clinical Science at UC San Diego Moores Cancer Center
- Nick Abbott, PhD.
  - Former sellside analyst with 35 years biotech experience, most recently at Wells Fargo

### Voruciclib & ME-344

- Dr. Richard Ghalie, Chief Medical Officer (MEIP)
- Nick Abbott, PhD

### Conclusion

- David Urso, President & CEO



A Transaction with  
Potential to Create  
Significant Opportunities  
and Build Value



## A Combined Company with Significant Opportunities for Value Creation



Three differentiated, promising, clinical candidates based on solid science and data\*

Pipeline led by planned eganelisib Phase 2 Study in Squamous cell carcinoma of the head & neck (SCCHN)

Voruciclib + Venclexta® P1 Study: Initial Results ~YE 2023

ME-344 + Avastin® P1 Study: Initial Results ~YE 2023

Eganelisib + Keytruda® P2 Study: Initial Safety/Efficacy 2H 2024



Utilize understandings of biology to overcome resistance mechanisms of standard of care therapies

Advance potential first-in-class programs to value creating transactions or commercialization



Anticipated Cash at closing of ~\$100M expected to fund operations to mid-2025 and clinical data over the next ~6-24 months



Experienced Leadership Team

\*Dates refer to expected timelines.

# Leadership with Extensive Industry and Oncology Drug Development Expertise

## EXECUTIVE LEADERSHIP

David Urso | *Chief Executive Officer*

Robert Ilaria Jr., MD | *Chief Medical Officer*

Stéphane Peluso PhD | *Chief Scientific Officer*

## BOARD

David Urso

Norman C. Selby (Chair)

Charles V. Baltic III, JD

Richard Gaynor, MD

Daniel Gold, PhD

Sujay Kango

Adelene Perkins

Thomas Reynolds, MD, PhD



### 3 Clinical-Stage Oncology Programs Expected to be Funded Through Mid-2025

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3	Initial Clinical Data*
<b>Eganelisib</b> Oral PI3K Gamma Inhibitor	Head & Neck Squamous Cell Carcinoma <sup>1</sup> 1L Recurrent	KEYTRUDA®				2H 2024
<b>Voruciclib</b> Oral CDK9 Inhibitor	Acute Myeloid Leukemia Relapsed/refractory (2L+)	VENCLEXTA®				~YE 2023
<b>ME-344</b> Mitochondrial Inhibitor	Colorectal Cancer <sup>2</sup> Relapsed	AVASTIN®				~YE 2023

1. Study in planning.  
2. Study pending initiation.

\* Expected timing.



## Transaction Summary

### SPECIAL MEETING DATES

- MEI and Infinity Special Meetings Scheduled for July 14, 2023

### TRANSACTION STRUCTURE

- Stock-for-stock merger: Infinity stockholders will receive shares of MEI common stock
- Infinity will become a wholly owned subsidiary of MEI pharma
- Pro forma outstanding equity of the combined company post-closing: Approximately 58% MEI and approximately 42% Infinity
- Combined company will continue to trade on Nasdaq under a new name: Kimbrx Therapeutics

### APPROVALS AND CLOSING

- Expected transaction closing by mid 2023
- Approved by both companies' boards
- Projected approximately \$100 million in cash, cash equivalents, and short-term investments at closing
- Subject to approval by stockholders of both companies, as well as customary closing conditions and regulatory approvals



### 3 Clinical-Stage Oncology Programs Expected to be Funded Through Mid-2025

INVESTIGATIONAL AGENTS	THERAPEUTIC AREA	COMBINATION	PHASE 1/1B	PHASE 2	PHASE 3	Initial Clinical Data*
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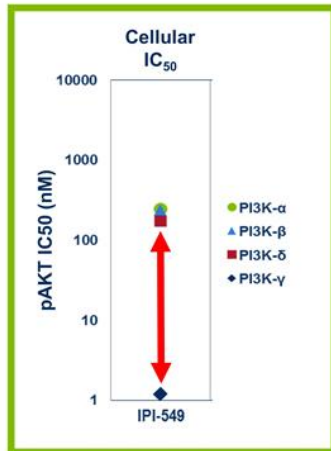
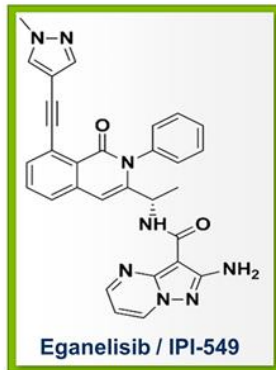
\* Expected timing.



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Eganelisib: First-in-Class PI3K- $\gamma$  Inhibitor for Next Generation  
Macrophage Reprogramming Cancer Immunotherapy

# Eganelisib is a First-in-Class, Potent and Selective PI3K- $\gamma$ Inhibitor with a Strong Scientific Foundation as Next Generation Cancer Immunotherapy



**LETTER** **nature**  
doi:10.1038/nature19834

## PI3K $\gamma$ is a molecular switch that controls immune suppression

Megan M. Kaneda<sup>1</sup>, Karen S. Messer<sup>1,2</sup>, Natacha Balainirina<sup>1</sup>, Hongying Li<sup>1,2</sup>, Christopher J. Leem<sup>1</sup>, Sara Gorjestani<sup>1</sup>, Gyungwhi Woo<sup>1</sup>, Abraham V. Nguyen<sup>1</sup>, Camila C. Figueiredo<sup>1,3</sup>, Philippe Foubert<sup>1</sup>, Michael C. Schmidt<sup>1</sup>, Melissa Pink<sup>4</sup>, David G. Winkler<sup>4</sup>, Matthew Rausch<sup>4</sup>, Vito J. Palombella<sup>4</sup>, Jeffery Kutok<sup>4</sup>, Karen McGovern<sup>4</sup>, Kelly A. Frazer<sup>5,6</sup>, Xuefeng Wu<sup>1</sup>, Michael Karin<sup>7</sup>, Roman Sasik<sup>8</sup>, Ezra E. W. Cohen<sup>1,9</sup> & Judith A. Varner<sup>1,9,10</sup>

Macrophages play critical, but opposite, roles in acute and chronic inflammation and cancer<sup>1–5</sup>. In response to pathogenic or injury, inflammatory macrophages express cytokines that stimulate upon exposure to pathogenic stimuli (Fig. 1b and Extended Data Fig. 11–k), suggesting that PI3K $\gamma$  inhibits macrophage inflammatory responses and might also do so in the tumour microenvironment.

**LETTER** **nature**  
doi:10.1038/nature20554

## Overcoming resistance to checkpoint blockade therapy by targeting PI3K $\gamma$ in myeloid cells

Olivier De Henau<sup>1</sup>, Matthew Rausch<sup>2</sup>, David Winkler<sup>2</sup>, Luis Felipe Campesato<sup>3</sup>, Cailian Liu<sup>4</sup>, Daniel Hirschhorn-Cymerman<sup>1</sup>, Sadna Buthi<sup>1</sup>, Arun Ghosh<sup>1</sup>, Melissa Pink<sup>2</sup>, Jeremy Tchaicha<sup>1</sup>, Mark Douglas<sup>1</sup>, Thomas Fährstén<sup>1</sup>, Sujata Sharma<sup>1</sup>, Jennifer Proctor<sup>1</sup>, Nicole Kosmider<sup>2</sup>, Kerry White<sup>2</sup>, Howard Stern<sup>2</sup>, John Soglia<sup>1</sup>, Julian Adams<sup>1</sup>, Vito J. Palombella<sup>1</sup>, Karen McGovern<sup>2</sup>, Jeffery L. Kutok<sup>2</sup>, Jedd D. Wolchok<sup>1,5</sup> & Taha Merghoub<sup>1,6</sup>

Recent clinical trials using immunotherapy have demonstrated its potential to control cancer by disinhibiting the immune system. Immune checkpoint blocking (ICB) antibodies against cytotoxic-T-lymphocyte-associated protein 4 or programmed but contain more activated CD8<sup>+</sup> T cells (Fig. 1b, c). Additionally, CD8<sup>+</sup> T cells express more granzyme B in the B16-F10 model. They also express higher levels of PD-1 and GILM (Fig. 1c, data not shown), which might explain their sensitivity to ICB. Furthermore, myeloid

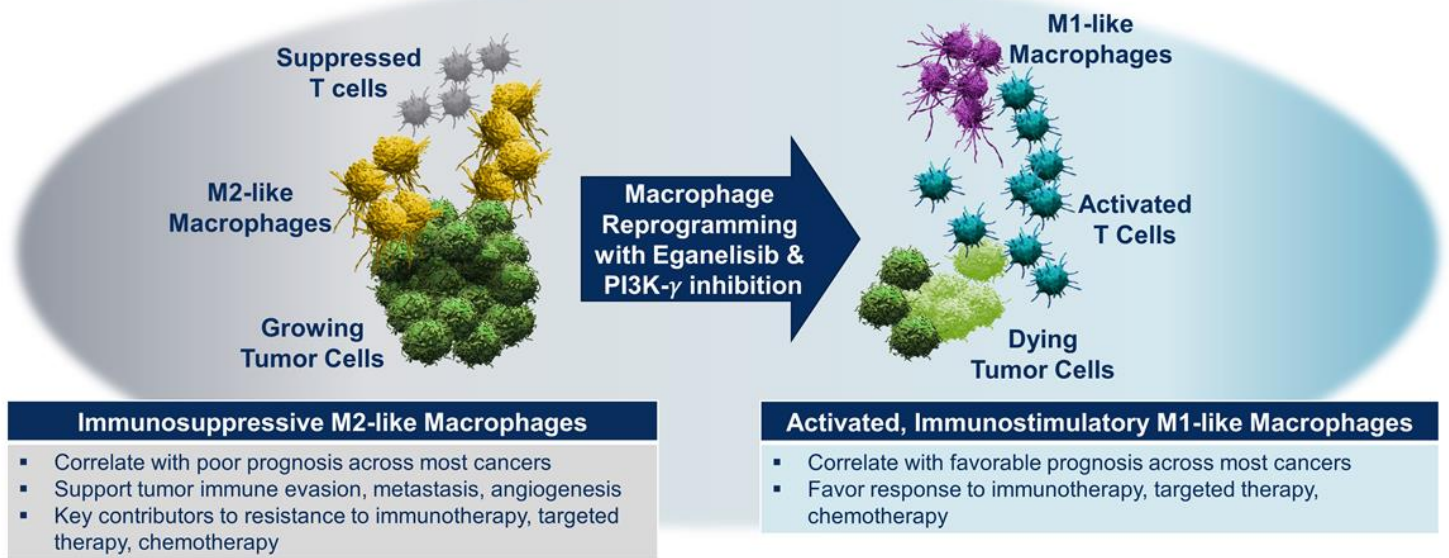


Evans et al *ACS Med Chem Let* 2016 7 862  
McGovern et al. *AACR-NCI-EORTC* 2015 #A192

Kaneda et al. *Nature* 2016 539 437  
De Henau et al. *Nature*, 2016 539 443



# Reprogramming Tumor Associated Macrophages for Cancer Immunotherapy





# PI3K- $\gamma$ is Uniquely Differentiated from Other PI3K Isoforms

PI3K- $\gamma$	VS	PI3K- $\delta$	PI3K- $\beta$	PI3K- $\alpha$
Myeloid cells		B cells and T-cells	Ubiquitous	Ubiquitous
Immune cell trafficking <b>Macrophage polarization</b>		B-cell and T-cell activation and function	Platelet activation Insulin signaling	Insulin signaling
KO viable, immunodeficiency and immunopathology phenotype		KO viable, immunodeficiency and immunopathology phenotype	Embryonic lethal	Embryonic lethal
Macrophage reprogramming for immunotherapy in solid tumors		B-cell malignancies	PTEN-deleted solid tumors	PI3K- $\alpha$ mutated solid tumors
Eganelisib		ZYDELIG® COPIKTRA® UKONIQ®	GSK2636771	PIQRAY®
Reversible hepatotoxicity, rash, pyrexia to date		Infections, colitis / diarrhea, cutaneous reaction, pneumonitis, hepatotoxicity	Gr3 hypophosphatemia and hypocalcemia, rash, fatigue	Cutaneous reaction, hyperglycemia, pneumonitis / interstitial lung disease, diarrhea



# MARIO Clinical Program Demonstrates Eganelisib Clinical Activity and Safety Across Multiple Combinations and Tumor Types



	PHASE 1	PHASE 1B	PHASE 2	KEY STUDY DATA
<b>MARIO-275</b> Bristol Myers Squibb 2 <sup>nd</sup> Line Urothelial Cancer in combination with Opdivo				ITT mOS of 15.4 mos vs 7.9 mos on Control Arm with HR of 0.62 <sup>1</sup>
<b>MARIO-3</b> Genentech Frontline Metastatic TNBC in combination with Tecentriq and Abraxane				PD-L1(+) Pts 37.5% 1-year PFS <sup>2</sup> PD-L1(-) Pts 34.7% 1-year PFS <sup>2</sup>
<b>ARC-2</b> TNBC and Ovarian Cancer in combination with etrumadenant and Doxil®				TNBC ORR: 25% vs. 9% <sup>3</sup> Ovarian ORR: 75% vs. 14% <sup>3</sup>
<b>MARIO-1</b> Bristol Myers Squibb Checkpoint inhibitor refractory HNSCC and Melanoma in combination with Opdivo				SCCHN ORR (≤ 2 lines): 20% <sup>4</sup> Melanoma ORR (≤ 2 lines): 21% <sup>5</sup>



1. Tomczak et al. ASCO GU 2021; 2. October 8, 2022 Data Snapshot 3. Gardner O et al. SABCS 2020 Triplet Arm (Eganelisib + Etrumadenant + Doxil) versus Doublet Arm (Etrumadenant + Doxil); Doxil® is a registered trademark of Baxter Healthcare Corporation. 4. Cohen et al. SITC 2020; 5. Postow et al. SITC 2020

# MARIO Clinical Program Demonstrates Eganelisib Clinical Activity and Safety Across Multiple Combinations and Tumor Types



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<b>ARC-2</b> ARCUS BIOSCIENCES TNBC and Ovarian Cancer in combination with etrumadenant and Doxil®				TNBC ORR: 25% vs. 9% <sup>3</sup> Ovarian ORR: 75% vs. 14% <sup>3</sup>
<b>MARIO-1</b> Bristol Myers Squibb Checkpoint inhibitor refractory HNSCC and Melanoma in combination with Opdivo				SCCHN ORR (≤ 2 lines): 20% <sup>4</sup> Melanoma ORR (≤ 2 lines): 21% <sup>5</sup>



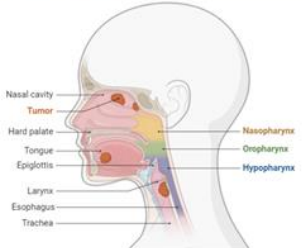
1. Tomczak et al. ASCO GU 2021; 2. October 8, 2022 Data Snapshot 3. Gardner O et al. SABCS 2020 Triplet Arm (Eganelisib + Etrumadenant + Doxil) versus Doublet Arm (Etrumadenant + Doxil); Doxil® is a registered trademark of Baxter Healthcare Corporation. 4. Cohen et al. SITC 2020; 5. Postow et al. SITC 2020

# Squamous Cell Carcinoma of the Head and Neck (SCCHN) The Patient Experience And Eganelisib Potential

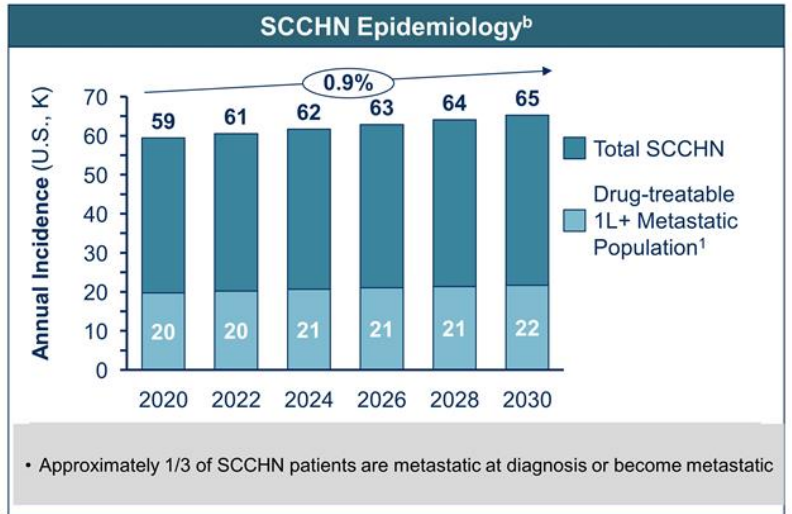
## SCCHN Overview

### SCCHN Background

Squamous cell carcinoma accounts for **~90% of all head and neck cancers**, with an annual incidence of **~60 K** per year (U.S.)



- Key risk factors include tobacco and alcohol use, as well as HPV infection
  - Incidence of HPV-caused SCCHN is increasing over time
- Men are over twice as likely to be diagnosed with SCCHN as women



<sup>1</sup> Drug-treatable population is defined as "the number of patients per year who become eligible for drug treatment at particular stages of disease and/or for particular lines of therapy," according to Clarivate DRG. Source: <sup>a</sup> SEER; <sup>b</sup> Clarivate DRG, Nov. 2021; ClearView Analysis.

# Current Landscape in R/M HNSCC

**FIRST  
LINE**

**SECOND  
LINE**

**THIRD  
LINE +**

# Current Landscape in R/M HNSCC

## FIRST LINE

Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

## SECOND LINE

## THIRD LINE +

2023 ASCO  
ANNUAL MEETING

#ASCO23

PRESENTED BY: Ezra Cohen, MD

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R/M= Recurrent/Metastatic

ASCO  
AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER

# Current Landscape in R/M HNSCC

## FIRST LINE

### Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

### Anti-PD1 + chemotherapy

- PDL1 nil or unknown
- Greater tumor burden

## SECOND LINE

## THIRD LINE +



# Current Landscape in R/M HNSCC

## FIRST LINE

### Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

### Anti-PD1 + chemotherapy

- PDL1 nil or unknown
- Greater tumor burden

### Chemotherapy +/- EGFRi

- aPD-1 unavailable or not preferred

## SECOND LINE

## THIRD LINE +



# Current Landscape in R/M HNSCC

## FIRST LINE

### Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

### Anti-PD1 + chemotherapy

- PDL1 nil or unknown
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### Chemotherapy +/- EGFRi

- aPD-1 unavailable or not preferred

## SECOND LINE

### Standard UNDEFINED

Dependent on 1<sup>st</sup> line therapy and performance status

- aPD1 naïve → aPD1
- Chemotherapy naïve → chemotherapy single or doublet
- aEGFRi naïve → cetuximab +/- chemotherapy

## THIRD LINE +

# Current Landscape in R/M HNSCC

## FIRST LINE

### Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

### Anti-PD1 + chemotherapy

- PDL1 nil or unknown
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- aPD1 naïve → aPD1
- Chemotherapy naïve → chemotherapy single or doublet
- aEGFRi naïve → cetuximab +/- chemotherapy

## THIRD LINE +

### Standard UNDEFINED

Dependent on 2<sup>nd</sup> line therapy and performance status (often deteriorating)

- Single agent

# Current Landscape in R/M HNSCC

## FIRST LINE

Anti-PD1 Monotherapy

- PDL1+
- Lesser tumor burden

Anti-PD1 + chemotherapy

- PDL1 nil or unknown
- Greater tumor burden

Chemotherapy +/- EGFRi

- aPD-1 unavailable or not preferred

## SECOND LINE

### Standard UNDEFINED

Dependent on 1<sup>st</sup> line therapy and performance status

- aPD1 naïve → aPD1
- Chemotherapy naïve → chemotherapy single or doublet
- aEGFRi naïve → cetuximab +/- chemotherapy

## THIRD LINE +

### Standard UNDEFINED

Dependent on 2<sup>nd</sup> line therapy and performance status (often deteriorating)

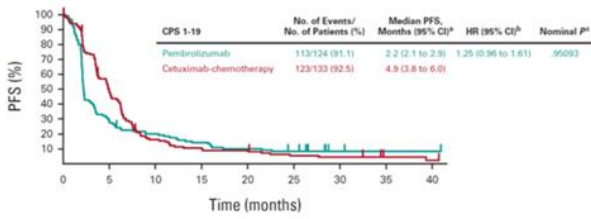
- Single agent

M o l e c u l a r T e s t i n g

C l i n i c a l T r i a l

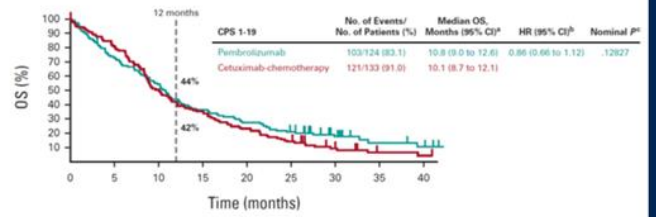
# Pembrolizumab Monotherapy PFS and OS from Keynote-048 in Frontline SCCHN patients with CPS1-19% and CPS >20%

PFS, CPS 1-19<sup>1</sup>



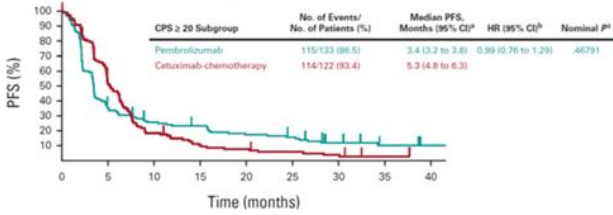
No. at risk:	124	36	24	17	12	9	2	1	1
Pembrolizumab	124	36	24	17	12	9	2	1	1
Cetuximab-chemotherapy	133	62	20	13	11	6	5	2	1

OS, CPS 1-19<sup>1</sup>



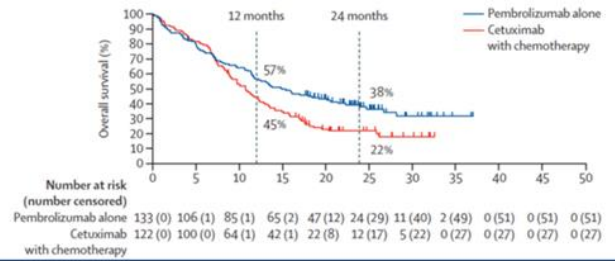
No. at risk:	124	90	67	47	31	19	8	3	2
Pembrolizumab	124	90	67	47	31	19	8	3	2
Cetuximab-chemotherapy	133	107	67	47	31	19	8	3	2

PFS, CPS ≥20<sup>1</sup>



No. at risk:	133	46	32	28	21	18	10	5	2
Pembrolizumab	133	46	32	28	21	18	10	5	2
Cetuximab-chemotherapy	122	61	22	12	9	6	4	1	0

OS, CPS ≥20<sup>2</sup>



Number at risk (number censored)	0	5	10	15	20	25	30	35	40	45	50
Pembrolizumab alone	133 (0)	106 (1)	85 (1)	65 (2)	47 (12)	24 (29)	11 (40)	2 (49)	0 (51)	0 (51)	0 (51)
Cetuximab with chemotherapy	122 (0)	100 (0)	64 (1)	42 (1)	22 (8)	12 (17)	5 (22)	0 (27)	0 (27)	0 (27)	0 (27)

1. Burtneß et al, J. Clin. Oncol. 2022; 2. Burtneß et al, Lancet 2019

# Current Landscape in R/M HNSCC

## FIRST LINE

Anti-PD1 Monotherapy

- PDL1+
- Lesser

Anti-PD1 + chemotherapy

Chemotherapy +/- EGFRi

- aPD-1 unavailable or not preferred

**MARIO-8: Egan + Pembro**  
**Potential IO/IO Chemo Free Regimen in Patients with CPS 1-19% and CPS>20%**

## SECOND LINE

Standard UNDEFINED

Dependent on 1<sup>st</sup> line therapy and performance status

- aPD1 naïve → aPD1
- Chemotherapy naïve → chemotherapy single or doublet
- aEGFRi naïve → cetuximab +/- chemotherapy

## THIRD LINE +

Standard UNDEFINED

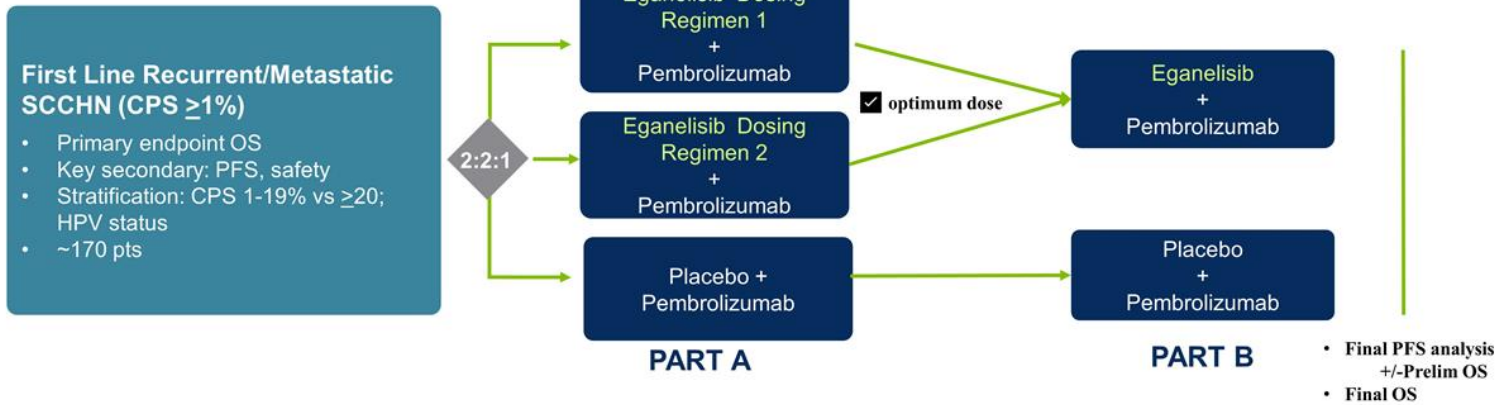
Dependent on 2<sup>nd</sup> line therapy and performance status (often deteriorating)

- Single agent

M o l e c u l a r T e s t i n g

C l i n i c a l T r i a l

# MARIO-8 Randomized Phase 2 Study in SCCHN: Optimizing Eganelisib Dosing in Combination with Pembrolizumab



- Using an adaptive design in Part A, the eganelisib dosing regimen decision will be based on available efficacy and safety data from approximately 40-70 patients
- Peripheral blood biomarker and PK data may also influence dose choice



A background image showing several spherical virus particles with prominent surface spikes, resembling coronaviruses, rendered in a light, semi-transparent style. The particles are scattered across the upper portion of the page.

## MARIO-1: Phase 1 Clinical Study



# MARIO-1: Phase 1/1b Study of Eganelisib Alone and in Combination With Nivolumab in Advanced Solid Tumors (N=224 Patients)

Monotherapy Dose Escalation



Monotherapy Expansion  
All Solid Tumors

Combination Dose Escalation  
Eganelisib+ Nivolumab



Combination  
Expansion

NSCLC

Melanoma

SCCHN

TNBC

Mesothelioma

Adrenocortical Carcinoma

MDSC High

Immediate prior checkpoint  
inhibitor-resistant

Checkpoint inhibitor-naïve

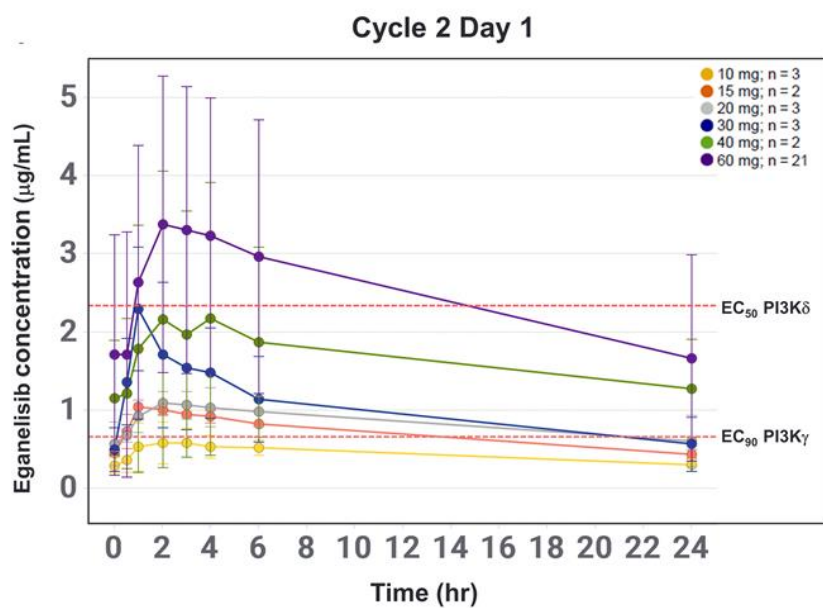
Checkpoint inhibitor-independent

Checkpoint non-responsive tumors





# Sustained inhibition above the PI3K- $\gamma$ EC<sub>90</sub> and below PI3K- $\delta$ EC<sub>50</sub> at Eganelisib doses up to 40 mg



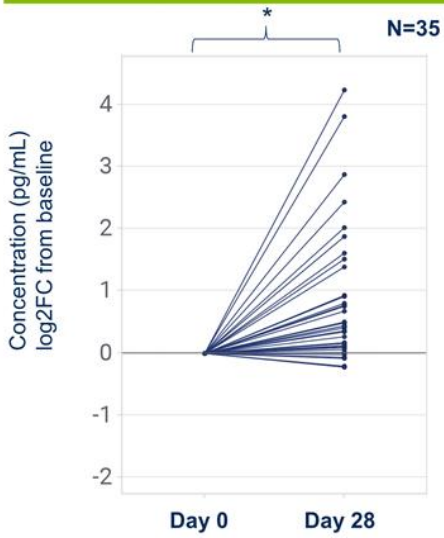
**Note:**

EC<sub>50</sub>/EC<sub>90</sub> from ex-vivo whole blood PD assay  
PI3K $\delta$ :pAKT (S473) in CD19+ B cells  
PI3K $\gamma$ :pAKT (T308) in CD14+ Monocytes  
Error bars indicate standard deviation



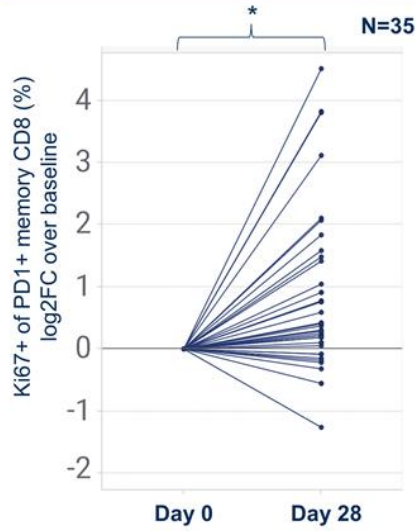
# Eganelisib Monotherapy Leads to Immune Activation in Peripheral Blood

## IFN- $\gamma$ Responsive Cytokines CXCL10



Similar results for CXCL9 (not shown)

## T Cell Reinvigoration



\*p<.05 T-Test  
all dose groups combined for monotherapy

## IFN- $\gamma$ Responsive Genes

Genes	p-value	log <sub>2</sub> FC at Day 28
GBP5	$3.0 \times 10^{-6}$	1.2
GBP1	$1.4 \times 10^{-4}$	.98
GBP4	$3.9 \times 10^{-4}$	.73
GBP6	$5.3 \times 10^{-4}$	1.2
STAT1	$2.3 \times 10^{-3}$	.58
FCGR1A	$2.9 \times 10^{-3}$	1.1
ICAM1	$1.5 \times 10^{-2}$	.45
IRF1	$3.3 \times 10^{-2}$	.31
TRIM21	$4.7 \times 10^{-2}$	.30

N=18

Confidential

# Eganelisib Monotherapy Well Tolerated with No Grade $\geq 3$ Treatment Related Adverse Events up Through 40 mg Dose

Treatment-related Adverse Events Occurring in at Least 5% of Patients or with Any Event of Grade 3 or Higher <sup>a</sup> in the Eganelisib Monotherapy Cohort	Eganelisib dose escalation (Part A) n (%)						Eganelisib dose expansion (Part D: 60 mg) (n=20) n (%)	
	10–30 mg (n=12)		40 mg (n=4)		60 mg (n=3)		Any grade	G $\geq 3^b$
	Any grade	G $\geq 3$	Any grade	G $\geq 3$	Any grade	G $\geq 3^b$		
Any treatment-related TEAE	6 (50)	-	3 (75)	-	2 (67)	2 (67)	14 (70)	8 (40)
AST increased	1 (8)	-	2 (50)	-	1 (33)	1 (33)	9 (45)	6 (30)
ALT increased			2 (50)	-	1 (33)	1 (33)	8 (40)	6 (30)
Pruritus			1 (25)	-			4 (20)	-
Fatigue	1 (8)	-	1 (25)	-			3 (15)	-
Rash maculopapular	1 (8)	-	1 (25)	-			3 (15)	1 (5)
Headache	2 (17)	-					1 (5)	-
Blood ALP increased					1 (33)	-	2 (10)	2 (10)
Dyspnea							2 (10)	1 (5)
Amylase increased	1 (8)	-					1 (5)	-
Lipase increased	1 (8)	-					1 (5)	-
WBC decreased			1 (25)	-			1 (5)	-
Blood bilirubin increased							1 (5)	1 (5)
Rash							1 (5)	1 (5)
Hypercalcemia					1 (33)	1 (33)		



<sup>a</sup>All events were grade 3 except for grade 4 increases in ALT and bilirubin that both occurred in the same patient.  
<sup>b</sup>No grade  $\geq 3$  events occurred during the DLT observation period (first treatment cycle).

# No GR ≥ 3 Hepatic Treatment Related Adverse Events with Eganelisib + Nivolumab up Through 30 mg Eganelisib Dose

## Treatment-related Adverse Events Occurring in at Least 5% Of Patients in the Eganelisib + Nivolumab Combination Therapy Cohort<sup>a</sup>

n (%)	Eganelisib dose escalation + nivolumab (Part C)						Eganelisib + nivolumab dose expansion (Parts E-H) 40 mg (n=149)	
	20 mg (n=7)		30 mg (n=12)		40 mg (n=12)		Any grade	G ≥ 3 <sup>d</sup>
	Any grade	G ≥ 3	Any grade	G ≥ 3 <sup>b</sup>	Any grade	G ≥ 3 <sup>c</sup>		
Any treatment-related TEAE	4 (57)	1 (14)	9 (75)	4 (33)	9 (75)	5 (42)	110 (74)	58 (39)
Rash <sup>e</sup>	1 (14)	1(14)	5 (42)	1 (8)	8 (67)	3 (25)	77 (52)	21 (14)
AST increased			1 (8)	-	5 (42)	5 (42)	39 (26)	21 (14)
ALT increased			1 (8)	-	5 (42)	4 (33)	36 (24)	16 (11)
Fatigue					2 (17)	-	28 (19)	-
Nausea	1 (14)	-	1 (8)				21 (14)	2 (1)
Pyrexia			1 (8)	-	1 (8)	-	21 (14)	2 (1)
Blood ALP increased					2 (17)	-	13 (9)	6 (4)
Decreased appetite							12 (8)	-
Diarrhea			2 (17)	-	1 (8)	-	9 (6)	1 (1)
Vomiting	1 (14)	-	1 (8)	-	1 (8)	-	9 (6)	2 (1)
Chills							10 (7)	1 (1)
Arthralgia							9 (6)	-
Myalgia							9 (6)	-

## Rapid reversal of GR3 hepatic events

Patients receiving any dose of eganelisib + nivolumab (N=185)

- ≥ GR3 treatment-related hepatic rate = 18%
- Median time of onset of first hepatic event = 43 days
- Median duration of GR3 was 8.5 days (Q3 =19 days; max = 38 days)

<sup>a</sup>Eganelisib was administered once daily and nivolumab as 240 mg Q2W or 480 mg Q4W.

<sup>b</sup>Grade 3 events of dermatitis acneiform (n=1), joint effusion (n=1), and lipase increased (n=1) not shown.

<sup>c</sup>All events were grade 3 except for grade 4 ALT increased (n=1). Grade 3 event of abdominal pain (n=1), not shown.

<sup>d</sup>All events were grade 3 except for grade 4 AST increased (n=1), transaminases increased (n=1), and lymphocyte count decreased (n=1).

<sup>e</sup>Includes preferred terms pruritis, rash, rash macular, and rash maculopapular.



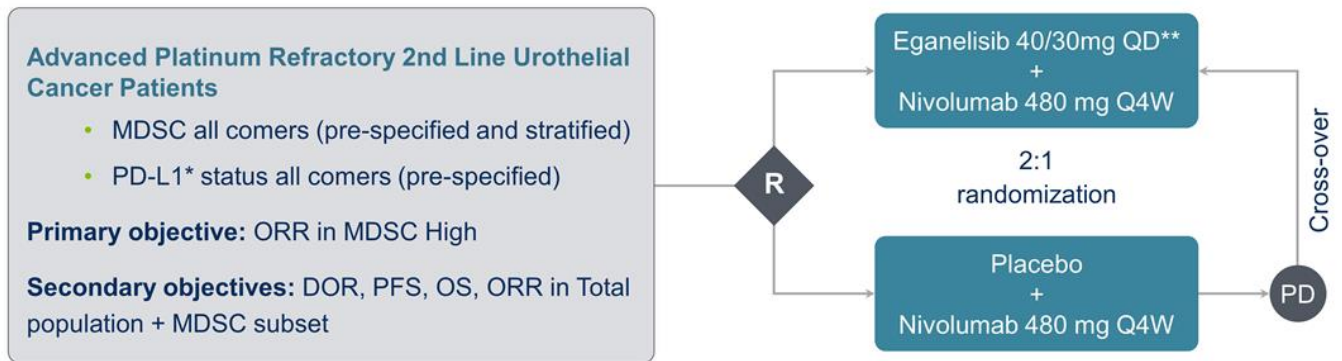


## MARIO-275

Addition of Eganelisib to Standard of Care Opdivo  
in I/O Naïve Urothelial Cancer Patients

# MARIO-275: Addition of Eganelisib to Standard of Care Nivolumab in I/O Naïve Urothelial Cancer Patients, Including PD-L1(-) Patients

## FDA Fast-Track Designation



DOR, duration of response; MDSC, myeloid-derived suppressor cells; ORR, overall response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; Q4W, once every four weeks; QD, once a day

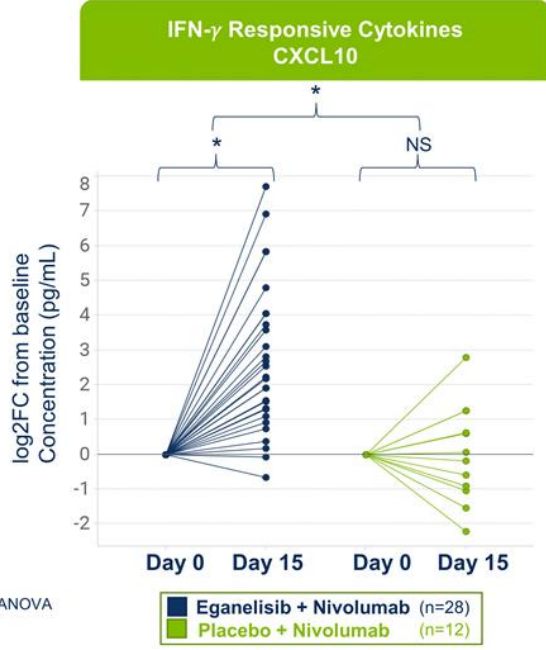
\*PD-L1 expression measured in baseline/archival tumor biopsies with Dako PD-L1 immunohistochemical 28-8 pharmDx kit approved for nivolumab in UC, except 2 biopsies tested with 22C3 PD-L1 antibody prior to study (Tumor Proportion Score  $\geq 1\%$  cutoff for PD-L1(+))

\*\*Infinity voluntarily paused enrollment in May 2020 and implemented a dose reduction of eganelisib from 40mg QD to 30mg QD to address reversible liver enzyme elevations.

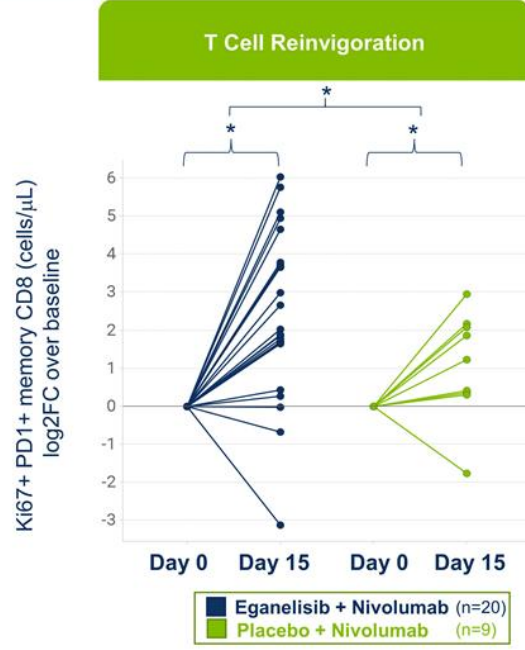




# Increased Immune Activation with Eganelisib + Nivolumab vs Nivolumab Alone in Peripheral Blood



Similar results for CXCL9 (not shown)



## Hepatic TEAEs

Preferred Term (PT)	Egan + Nivo N=33, n (%)	Placebo + Nivo N=16, n (%)	Total N=49, n (%)
<b>Patients with &gt;=1 hepatic TEAE</b>	<b>7 (21.2)</b>	<b>0</b>	<b>7 (14.3)</b>
Alanine aminotransferase increased	2 (6.1)	0	2 (4.1)
Aspartate aminotransferase increased	1 (3.0)	0	1 (2.0)
Hypertransaminasaemia	2 (6.1)	0	2 (4.1)
Hepatotoxicity	2 (6.1)	0	2 (4.1)
Hepatic cytolysis	1 (3.0)	0	1 (2.0)

## Non-Hepatic TEAEs

Preferred Term (PT)	Egan + Nivo N=33, n (%)	Placebo + Nivo N=16, n (%)	Total N=49, n (%)
<b>Patients with &gt;=1 non-hepatic TEAE</b>	<b>5 (15.2)</b>	<b>2 (12.5)</b>	<b>7 (14.3)</b>
Asthenia	2 (6.1)	0	2 (4.1)
Amylase increased	1 (3.0)	0	1 (2.0)
Lipase increased	1 (3.0)	0	1 (2.0)
Cardiac failure chronic	1 (3.0)	0	1 (2.0)
Diarrhoea	1 (3.0)	0	1 (2.0)
Decreased appetite	1 (3.0)	0	1 (2.0)
Hyperglycaemia	0	1 (6.3)	1 (2.0)
Ketoacidosis	0	1 (6.3)	1 (2.0)
Pemphigoid	0	1 (6.3)	1 (2.0)

## Hepatic TEAEs

- No Hy's Law
- No grade 5 hepatic TEAE
- All hepatic Grade  $\geq 3$  TEAEs resolved in the combination arm except 2
  - One patient had grade 3 hepatotoxicity and subsequently died due to disease progression
  - One patient had grade 3 non-treatment-related ALP increased after treatment discontinuation for disease progression.

### Mitigation:

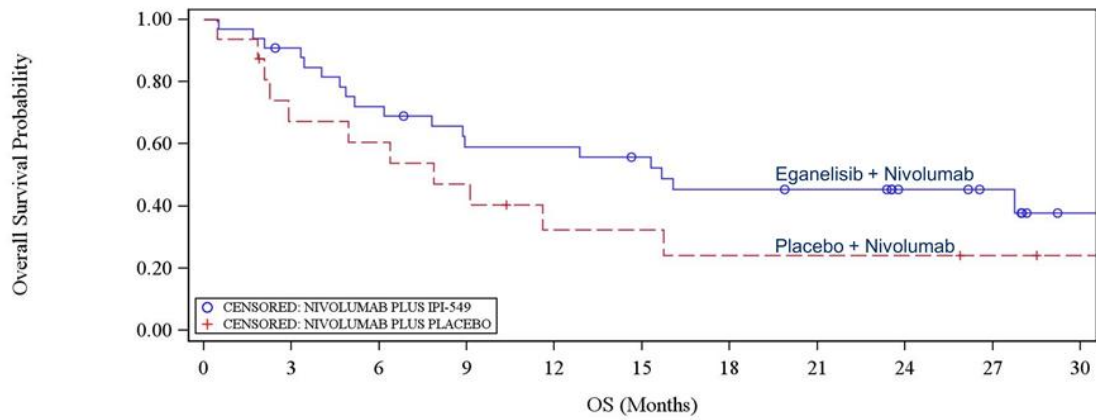
- Dose reduced to 30 mg for MARIO-275 (same dose as used for MARIO-3 (combo with atezo/nab-pac))
- Increased, earlier LFT monitoring to allow earlier intervention





Overall Survival Results: ITT

HR of 0.58 (0.2737, 1.2394) Indicating 42% Reduction of Risk of Death



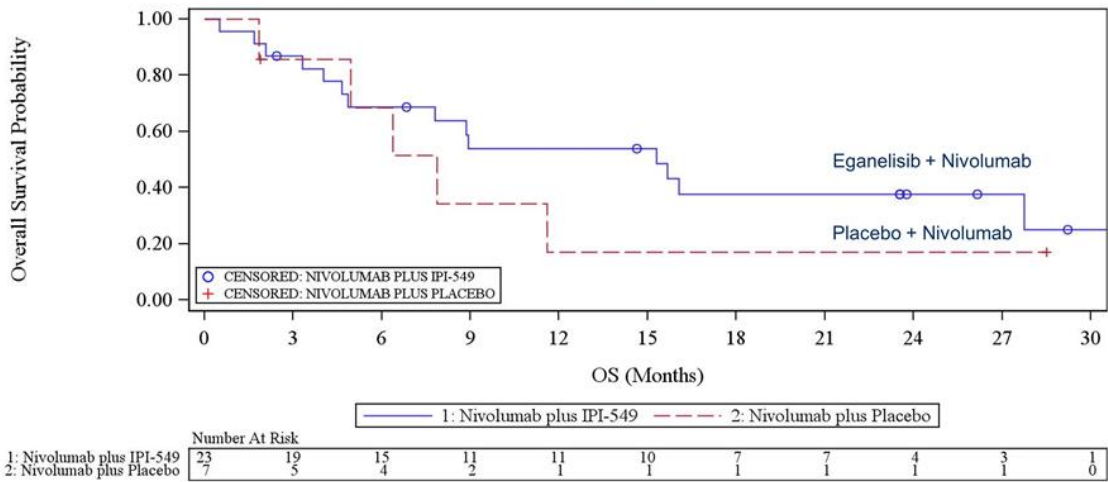
	Number At Risk										
	0	3	6	9	12	15	18	21	24	27	30
1: Nivolumab plus IPI-549	33	29	23	18	18	16	13	12	8	6	1
2: Nivolumab plus Placebo	16	10	9	7	4	4	3	3	3	2	1


Data Snapshot 29 July 2022

**PD-L1(-) Two-Year Landmark Survival Analysis: 38% of Patients in the Eganelisib Plus Nivolumab Arm Are Alive vs 17% of Patients in the Nivolumab Control Arm**

**Overall Survival Results: PD-L1(-)**

**HR of 0.59 (0.2081, 1.6796) Indicating 41% Reduction of Risk of Death**

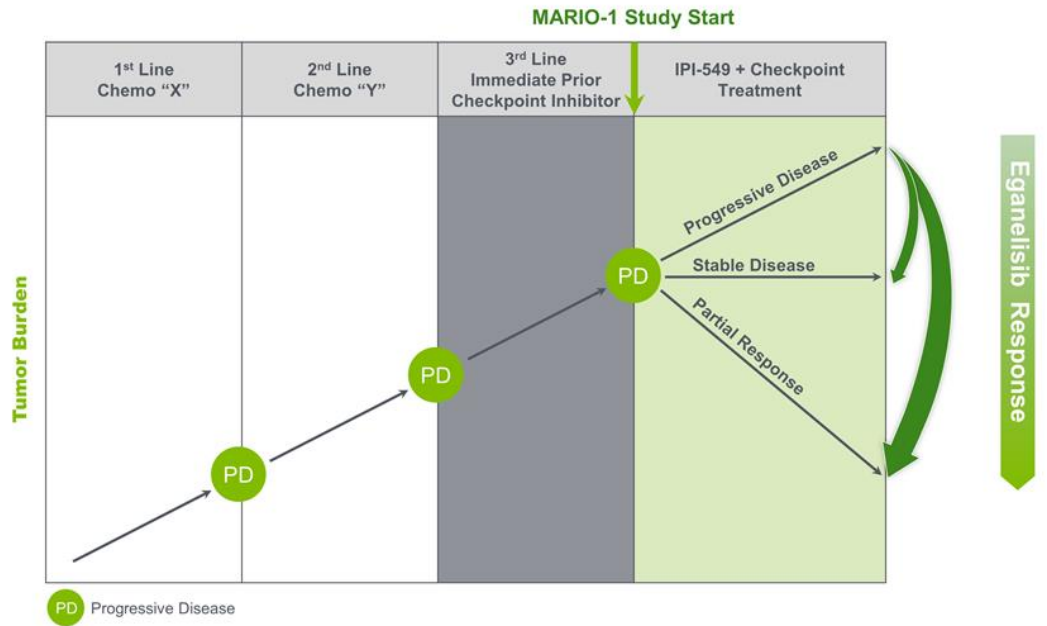




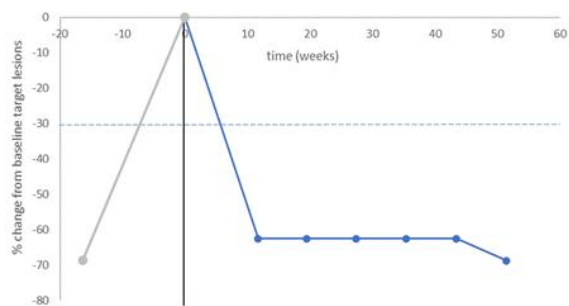
SCCHN Clinical Data (MARIO-1) and Key Elements of the  
Planned Randomized Trial of Eganelisib + Pembro vs  
Pembro as First line treatment for Relapsed/metastatic  
SCCHN (MARIO-8)

# MARIO-1: Eganelisib + Nivolumab Combination in Patients Having Progressed on Immediate Prior CPI Therapy

- Study Concept:
  - Design examines the activity of eganelisib in patients not expected to respond to checkpoint inhibitor due to immediate prior therapeutic failure

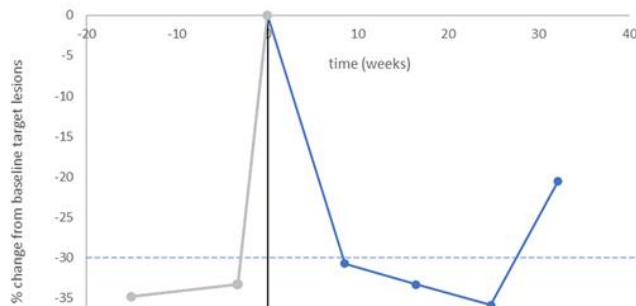


# Overcoming Resistance to CPI in MARIO-1 SCCHN Patients Who Progressed on Immediate Prior Checkpoint Inhibitor Therapy



**Start of MARIO-1 Therapy**  
After Progression on Immediately Prior CPI

- **Patient A:** stage IV disease at study entry
- Refractory to pembrolizumab after 15 months (best response PR)
- 63% tumor reduction
- PFS: 11 months



**Start of MARIO-1 therapy**  
After Progression on Immediately Prior CPI

- **Patient B:** stage IV disease at study entry
- Refractory to pembrolizumab after 5 months (best response SD)
- 36% tumor reduction
- PFS: 7 months



# In the SCCHN Cohort in MARIO-1, Eganelisib + Nivolumab Had a Manageable Safety Profile at the 40 mg Eganelisib dose

## Most Common TEAEs (All Grade) in ≥15% of Patients (N=21)

Preferred Term / Grouped Term	TEAE (All)	Tx-Related TEAE (All)
Fatigue	13 (61.9)	9 (42.9)
Skin *	11 (52.4)	9 (42.9)
Pyrexia	9 (42.9)	3 (14.3)
Decreased Appetite	9 (42.9)	3 (14.3)
Hepatic **	6 (28.6)	5 (23.8)
Weight Decreased	6 (28.6)	0
Nausea	6 (28.6)	4 (19.0)
Diarrhea	6 (28.6)	0
Dyspnea	5 (23.8)	2 (9.5)
Abdominal Pain	5 (23.8)	2 (9.5)
Vomiting	4 (19.0)	2 (9.5)
Myalgia	4 (19.0)	2 (9.5)
Dizziness	4 (19.0)	1 (4.8)
Constipation	4 (19.0)	1 (4.8)
Headache	4 (19.0)	0

## Grade 3 and above TEAEs in ≥ 5% of Patients (N=21)

Preferred Term / Grouped Term	TEAE (≥ Grade 3)	Tx-Related TEAE (≥ Grade 3)
Hepatic ** ^	5 (23.8)	4 (19.0)
Anemia	3 (14.3)	1 (4.8)
Skin *	2 (9.5)	2 (9.5)
Abdominal Pain	2 (9.5)	1 (4.8)
Nausea	2 (9.5)	1 (4.8)
Sepsis	2 (9.5)	0

\* Skin grouped terms: pruritis, rash, rash erythematous, rash macular, rash morbilliform, rash pruritic, urticaria

\*\* Hepatic grouped terms: alanine aminotransferase increased, aspartate aminotransferase increased, alkaline phosphatase increased, blood bilirubin increased, liver function test increased, transaminases increased

^ 1 Grade 4 transaminases increased, no Hy's law criteria met

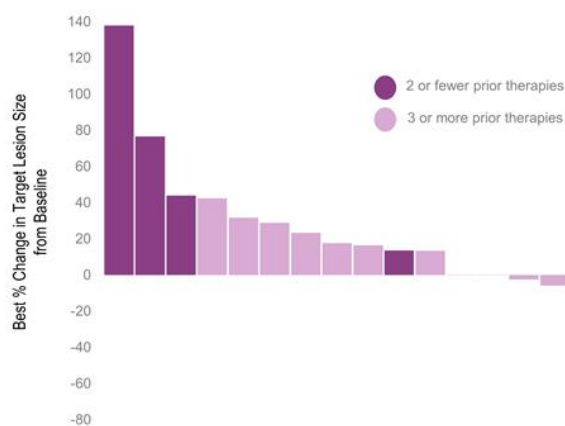
Database Lock Date  
13 Dec 2021



## MARIO-1 SCCHN Cohort

	Total N = 21	≤ 2 Prior Lines N = 11	≥ 3 Prior Lines N = 10
<b>Best Overall Response</b>			
Partial Response (PR), n	2	2	0
Stable Disease (SD), n	7	2	5
Progressive Disease (PD), n	10	5	5
Not evaluable, n	2	2	0
<b>Overall Response Rate (ORR) (PR), n (%)</b>	2 (9.5)	2 (18.2)	0 (0)
<b>Disease Control Rate (DCR) (PR + SD), n (%)</b>	9 (42.9)	4 (36.4)	5 (50.0)
<b>Progression Free Survival (PFS in Months), Median (95%)</b>	3.7 (1.9, 5.5)	5.3 (1.9, 11.1)	3.6 (0.5, 4.5)

- Keynote-048 (Burtness et al Lancet 2019)
  - mPFS for pembro monotherapy in recurrent/metastatic pts = 2.3 months
  - mPFS for pembro monotherapy in recurrent/metastatic pts with CPS ≥ 1 = 3.2 months
- MARIO-1 Database lock 13 Dec 2021

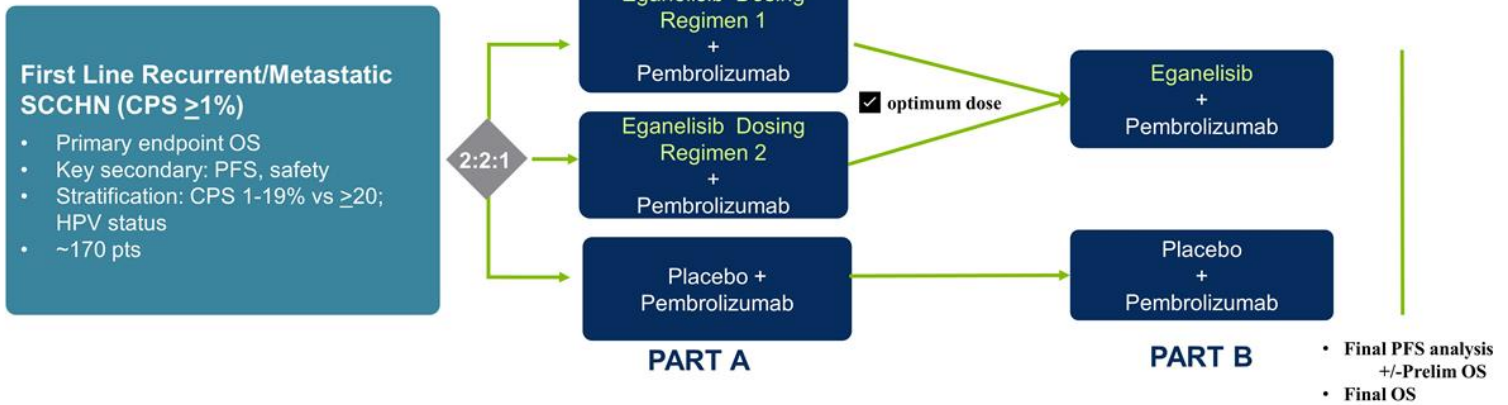


Cohen et al, SITC 2020 Data Snapshot 30 November 2020





# MARIO-8 Randomized Phase 2 Study in SCCHN: Optimizing Eganelisib Dosing in Combination with Pembrolizumab



- Estimated study start Q3 2023
- Using an adaptive design in Part A, the eganelisib dosing regimen decision will be based on available efficacy and safety data from approximately 40-70 patients expected in 2H 2024





## Summary

Encouraging data from heavily pretreated patients with advanced/metastatic head & neck squamous cell cancer, whose tumors had progressed on immediate prior ICI treatment, supports further development of eganelisib in this tumor type

Data supports potentially greater activity in earlier lines of treatment: first line recurrent/metastatic SCCHN in combination with pembrolizumab

FDA feedback has been received and Infinity plans to move forward with a randomized Phase 2 study in this indication that includes eganelisib dosing optimization\*

Estimated Study start in Q3 2023, with dosing decision expected in 2H 2024

\*Subject to submission of the final study protocol to the FDA and responses to FDA comments.



## Q&A Participants



### **Nick Abbott, PhD**

Principal, Abbott Biotech Consultancy  
Most recently, Senior Analyst Equity Research,  
Wells Fargo Corporate and Investment Banking



### **Ezra Cohen, MD, FRCPSC, FASCO**

Chief Medical Officer, Oncology, Tempus  
Most recently, Chief, Division of Hematology-Oncology, and  
Associate Director of Clinical Science at UC San Diego Moores  
Cancer Center



### **Robert Ilaria, Jr, MD**

Chief Medical Officer, Infinity Pharmaceuticals  
Previously, BMS and Celgene, with leading roles on the CTLA-4 and  
PD-1 drug development teams





# Q & A

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Voruciclib: Oral CDK9 Inhibitor



Scientific Rationale & Mechanism of Action

## Voruciclib is an Orally Administered CDK9 Inhibitor: Targeting Cell Proliferation Regulation

CDK9 Regulates  
Two Important Cell  
Proliferation Drivers

- **Mcl-1** – Pro-survival protein in the BCL-2 family
- **Myc** – Oncoprotein that drives growth and proliferation in many tumor types

Increased Mcl-1 is associated with poor prognosis in AML and CLL and is an established venetoclax resistance mechanism

- Venetoclax inhibits BCL2 but can lead to stabilization of Mcl-1
- Voruciclib inhibits Mcl-1 via CDK9 inhibition

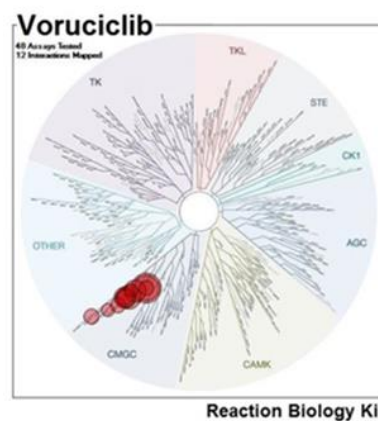
MYC gene is over expressed in many cancers, including those with KRAS mutations

- Inhibition of CDK9 leads to reduced transcription and stability of Myc
- Voruciclib downregulates Myc via CDK9 inhibition



## Voruciclib is an Oral, Selective and Specific CDK9 Inhibitor

- Cyclin dependent kinases (CDK) bind with cyclins to regulate the cell cycle and transcription
- Voruciclib inhibits CDK9
  - Higher specificity and longer residence time on target vs CDK 4, 6 & 1
  - Greater selectivity against CDKs relative to other kinases





Preclinical Studies Show Synergy with Venetoclax



## Hypothesis

**Increased Mcl-1 is an established venetoclax resistance mechanism and is associated with poor outcomes in AML and CLL**

—  
Venetoclax inhibits BCL2 but can lead to stabilization of Mcl-1

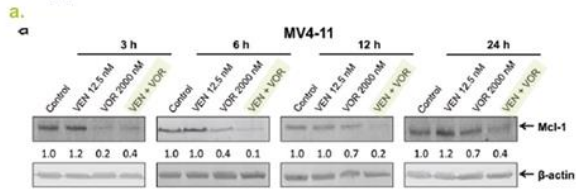
—  
Voruciclib inhibits MCL1 gene transcription via CDK9 inhibition

—  
Inhibition of MCL1 can restore sensitivity to venetoclax

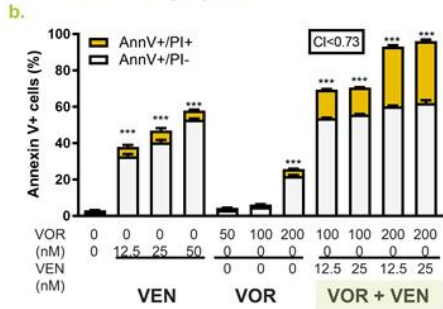


# Voruciclib Synergizes with Venetoclax in AML Murine Xenograft Model

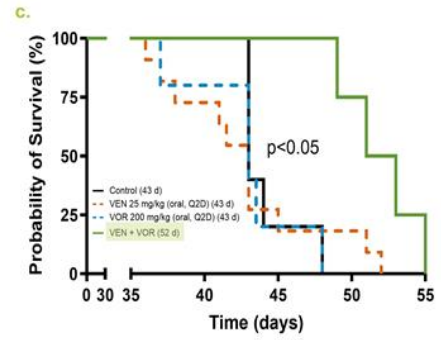
## Suppresses Mcl-1 Level



## Increases Apoptosis



## Extends Survival in MV4-11 Tumor

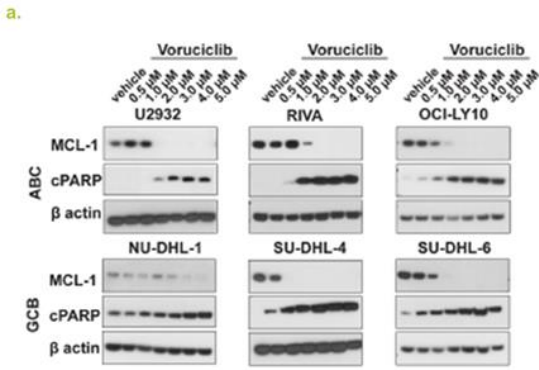


Luedtke, et al. Signal Transduct Ther (2020)

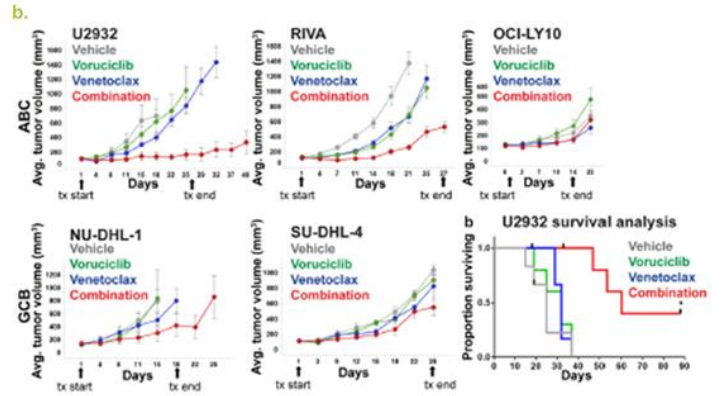


# Voruciclib Synergizes with Venetoclax in Multiple Models, Including High Risk DLBCL Murine Xenograft Models

## Suppresses Mcl-1 Level



## Inhibits Tumor Growth



Dey et al. Nature Sci Rep 2017





Clinical Studies in Solid Tumors

## Key Findings in 2 Monotherapy Phase 1 Studies in Solid Tumors

### 68 PTS ENROLLED IN 2 DOSE ESCALATION/EXPANSION STUDIES EVALUATING 2 DOSING SCHEDULES

---

#### SAFETY

- Maximum Tolerated Dose (MTD)
    - 600 mg on intermittent dosing of 14 days on/7 days off
    - 350 mg on continuous daily dosing
    - Most common adverse events (AE) involved the gastrointestinal tract
  - No neutropenia
  - No pulmonary toxicity
  - No effect on QTc
- 

#### EFFICACY

- Intermittent dosing: 1 patient with partial response and 8 with stable diseases lasting 2 to 6 months
- Daily dosing: 12 patients with stable disease lasting a median of 15 weeks

Solid tumor studies by prior sponsor (Piramal) as a CDK 4-6 inhibitor



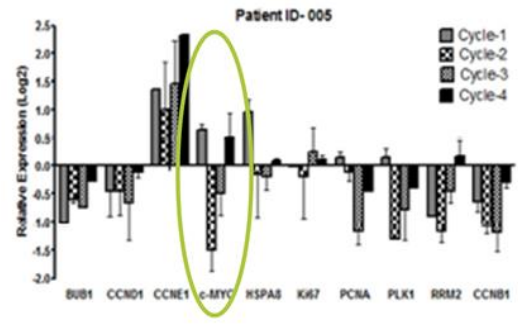
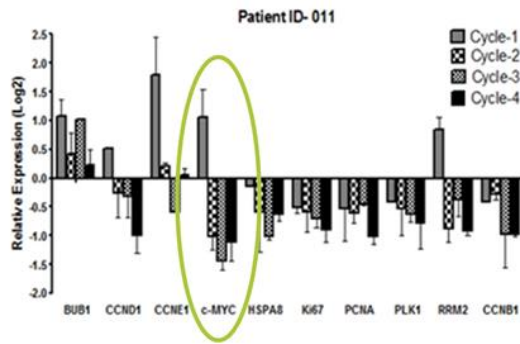
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MEIP Anticipates  
Therapeutic Voruciclib  
Dose in Combination with  
Venetoclax is 100-200 mg  
Intermittently

# Decreased c-MYC Expression Observed in Phase 1 Study in Solid Tumors

10 gene biomarkers evaluated in blood in daily dosing study

c-MYC expression decreased in ~60% patients tested (n=25)



The background of the slide features a light gray, semi-transparent image of several virus-like particles. These particles are roughly spherical with a textured surface and numerous thin, dark spikes protruding from them, resembling coronaviruses. They are scattered across the upper portion of the slide, with some appearing more prominent than others.

Current Clinical Study in Hematologic Malignancies

- Rationale
  - Recognition that voruciclib is primarily a CDK9 inhibitor
  - Evidence of effect in CLL patient samples and synergy with venetoclax in preclinical models
- Goal is to overcome the most common mechanism of resistance to venetoclax
- Focus on diseases where venetoclax is approved and clear medical need identified
  - Acute Myeloid Leukemia (AML)
  - Chronic Lymphocytic Leukemia (CLL)





# Ongoing Phase 1 Study of Voruciclib Alone and in Combination with Venetoclax in AML and B-cell Malignancies

## Study population

- Relapsed/Refractory B-cell malignancies
- Relapsed/Refractory AML

## Dose escalation with standard 3+3 design

- Single agent
- In combination with venetoclax

## Endpoints

- Safety and tolerability
- Pharmacokinetics
- Biologic correlative studies
  - BH3 profiling, MCL-1 expression
  - Molecular mutations analysis
- Preliminary efficacy

### Voruciclib monotherapy dose escalation in AML and B-cell Malignancies

Completed (N = 40)

50 mg → 100 mg → 150 mg → 200 mg

### Voruciclib + Venetoclax dose escalation in AML

Enrolling



50 qod → 50 mg → 100 mg → 150 mg → 200 mg



# Monotherapy Safety Results Do Not Suggest Overlapping Toxicity with Venetoclax in Patients with AML or B-cell Malignancies

Voruciclib at doses up to 200 mg for 14 days in a 28-day cycle was well tolerated, with no DLTs

## Grade 3-4 Treatment-Related Adverse Events

n (%)	Group I* (n=16)		Group II* (n=13)	
	Gr 3	Gr 4	Gr 3	Gr 4
Acute respiratory failure	0	1 (6.3)	0	0
Dyspnea exertional	0	1 (6.3)	0	0
Respiratory failure	0	1 (6.3)	0	0
Hypoxia	1 (6.3)	0	0	0
Interstitial lung disease	1 (6.3)	0	0	0
Pneumonitis	1 (6.3)	0	0	0
AML differentiation syndrome	1 (6.3)	0	0	0
Lymphocyte count decreased	1 (6.3)	0	0	0
Malignant pleural effusion	1 (6.3)	0	0	0
Neutropenia	0	0	0	1 (7.7)
Thrombocytopenia	0	0	0	1 (7.7)
Anemia	0	0	1 (7.7)	0

\* A patient may have ≥1 AE reported

Group 1 = 50 and 100 mg daily continuously | Group 2 = 100, 150, and 200 mg 14 days on/14 days off

- Grade 3-4 treatment-related AEs in Group I were primarily pulmonary and affected 3 patients
- No Grade 3-4 drug-related neutropenia in patients with B-cell malignancies (Group I and II)
- No tumor lysis syndrome
- The 4-week mortality was 17% (4 in Group I and 1 in Group II), all associated with disease progression

Konopleva, ASH 2021



## Safety/Tolerability

- Dose limiting toxicity (DLT) of respiratory failure at 100 mg *daily* in 2 pts with AML
  - Confounded by prior allogeneic transplant and AML differentiation syndrome
- No DLTs on *intermittent* dosing at 100, 150 and 200 mg
- Dose escalation stopped without reaching maximum tolerated dose (MTD)
  - 150 - 200 mg expected to inhibit CDK9 based on preclinical studies

## Clinical Activity

Evidence of single agent antitumor activity

- 1 patient with follicular lymphoma achieved a near partial response (46% reduction in tumor size) lasting 6 months
- 1 patient with diffuse large B-cell lymphoma had stable disease lasting 4 months
- 1 patient with AML achieved a Morphology Leukemia Free State
- Disease Control Rate = 50% in 24 patients administered voruciclib on 14 days on/14 days off schedule



## Ongoing Evaluation of Voruciclib + Venetoclax in Relapsed/Refractor (R/R) AML Demonstrates Encouraging Signs of Clinical Activity at Low Dose

Dose escalation began from a very low dose of 50 mg every-other-day

- Requested by FDA due to the introduction of a new formulation

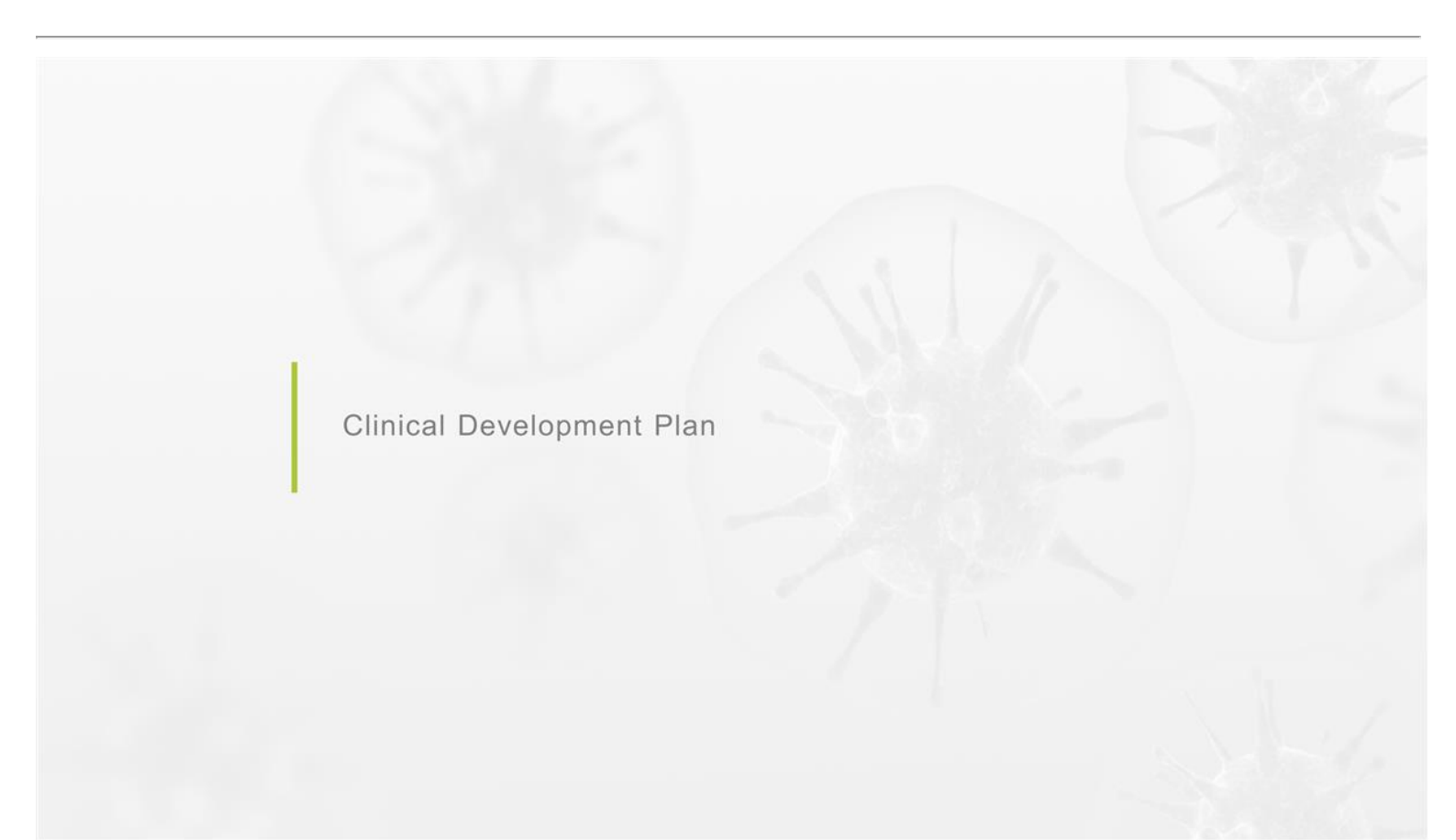
Encouraging results in 2 patients in 6 patient cohort at 50 mg every-other-day

- Partial remission after 1 cycle in a patient who had received 4 prior therapies including standard induction chemotherapy, stem cell transplant and venetoclax-azacitidine
- Decreased transfusion requirement in 1 patient

No new safety findings compared to single-agent results

Enrollment ongoing at higher dose levels



A background image showing several spherical virus particles with prominent surface spikes, resembling coronaviruses, against a light grey, slightly blurred background. The particles are scattered across the upper half of the page.

Clinical Development Plan

### Acute Myeloid Leukemia

- Venetoclax in combination with a hypomethylating agent (e.g. azacitidine) or low-dose cytarabine is standard of care in unfit patients with previously untreated AML
  - Median overall survival of 15 months with venetoclax-azacitidine<sup>1</sup> indicates further improvement is needed
- Voruciclib in combination with venetoclax-azacitidine may improve response rate and overall survival and represents a significant medical need
- An additional medical need is in patients with AML after failure of standard therapies
  - Median overall survival of <6 months with current approaches indicates further improvement needed

1. DiNardo, NEJM 2020

### Chronic Lymphocytic Leukemia

- Venetoclax-rituximab is an approved combination for the treatment of relapsed CLL
- Voruciclib in combination with venetoclax-rituximab may improve response rate and Progression Free Survival (PFS) and represents a medical need in this disease



## Voruciclib Summary

- Oral CDK9 inhibitor: Pre-clinical data demonstrate down regulation of Mcl-1 and synergy with venetoclax in multiple hematologic malignancy models
- Increased Mcl-1 is clinically established as a venetoclax resistance mechanism
- Early clinical data demonstrates encouraging initial tolerability and activity
  - No overlapping toxicity with venetoclax predicted and no significant myelosuppression observed as monotherapy
- The ongoing Phase 1b trial is expected to report initial results from the combination regimen around the end of 2023
- Proof of principle of combination will support voruciclib value in combination where venetoclax is standard of care





ME-344: Mitochondrial Inhibitor

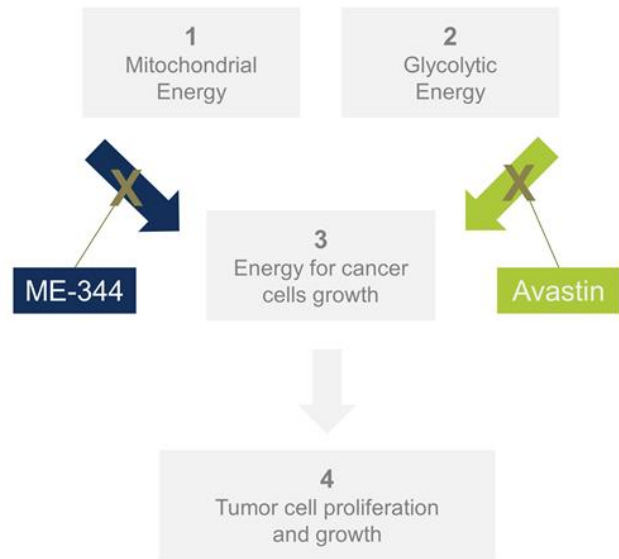




Scientific Rationale & Mechanism of Action

## ME-344: A Potential Novel Mechanism of Action to Address Multiple Cancers in Combination with Anti-angiogenic Therapies Like Avastin®

1. ME-344 blocks the production of adenosine triphosphate (ATP), a source of cellular energy, by inhibiting the OXPHOS pathway.
2. Anti-angiogenic therapies, like Avastin, result in reducing glycolysis, another source of energy for cells
3. Cancer cells need significant amounts of energy to grow, and can switch between mitochondria and glycolytic metabolic pathways to escape the blocking of either energy source
4. The potential to inhibit both mitochondrial energy production via ME-344 and glycolytic energy production via VEGF inhibition (e.g., Avastin) is intended to result in synthetic lethality of cancer cells





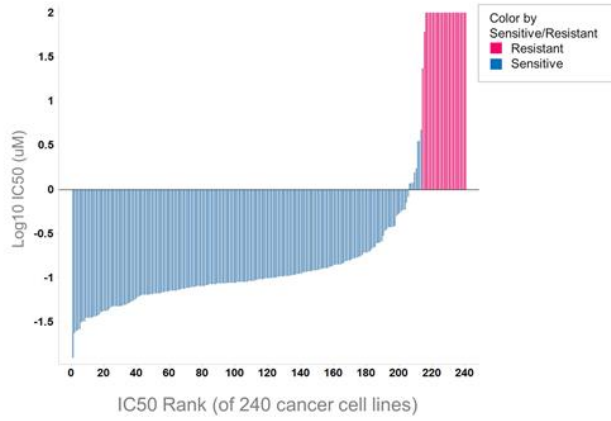
Non-Clinical Studies

# ME-344 as a Single Agent is an Inhibitor of Cancer Cell Proliferation in Pre-Clinical Models

ME-344 displays nM potency against cell lines from multiple solid tumors and AML

ME-344 shows minimal effects on normal cells

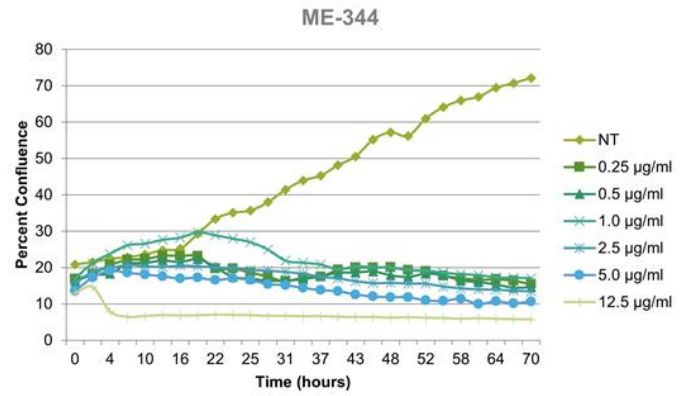
## Inhibits cancer cell lines proliferation



Data on file

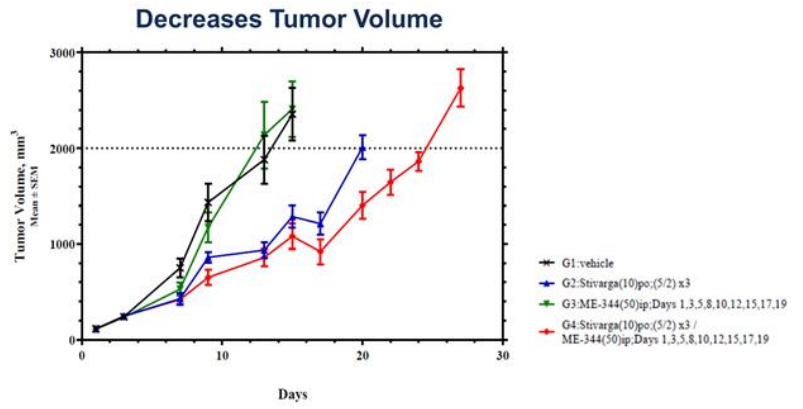
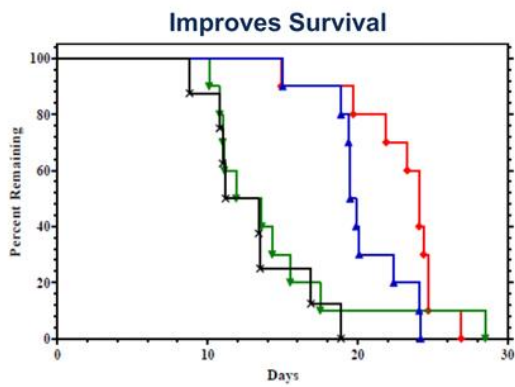


## Inhibits ovarian cancer stem cell proliferation



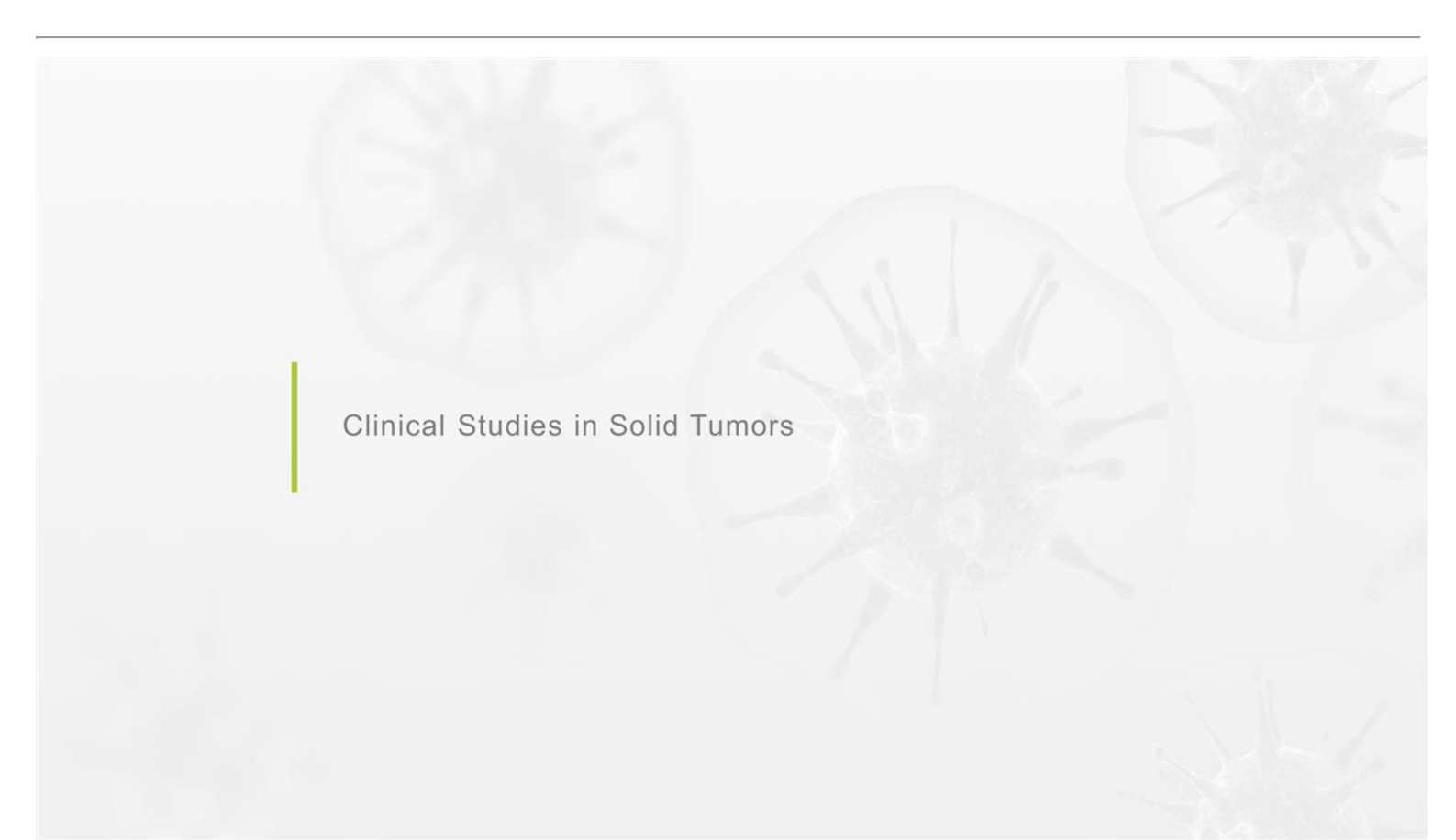
# ME-344 Synergizes with Anti-angiogenic TKI to Enhance Antitumor Effect in Colorectal Cancer Xenograft Model

## ME-344 + REGORAFENIB DECREASES MEAN TUMOR VOLUMES AND EXTENDS SURVIVAL



Data on file



A microscopic image showing several cells with prominent, spiky protrusions on their surfaces, characteristic of cancer cells. The cells are arranged in a cluster, with one cell in the center being more sharply focused than the others. The background is a light, hazy grey.

Clinical Studies in Solid Tumors

### Ph 1 Study Single Agent

Bendel, Cancer 2015

- 1.25 to 20 mg/kg weekly in 28-day cycles
- Refractory solid tumors
- 30 pts
- Maximum Tolerated Dose (MTD) = 10 mg/kg
- Dose Limiting Toxicity (DLT) = Gr 3 neuropathy at 15-20 mg/kg
- 1 Partial Response (PR) in small cell lung cancer and 10 stable disease (SD)
- Disease control rate = 37%

### Ph 1-2 Study with Topotecan

Diamond, Invest New Drugs 2017

- 10 mg/kg + topotecan 4 mg/m<sup>2</sup> Days 1, 8, 15
- R/R small cell lung cancer and ovarian cancer
- 46 pts
- Substantial myelosuppression
- 1 PR in ovarian cancer and 21 SD
- Disease control rate = 49%



**Treatment-Related Adverse Events in  $\geq 10\%$  of Patients (N= 30)**

Toxicity <sup>a</sup>	Grade 1	Grade 2	Grade 3	Total
Neuropathy <sup>b</sup>	1 (3%)	1 (3%)	4 (14%)	6 (20%)
Nausea	4 (13%)	2 (7%)	0	6 (20%)
Dizziness	3 (10%)	1 (3%)	2 (7%)	6 (20%)
Fatigue	2 (7%)	3 (10%)	0	5 (17%)
Vomiting	2 (7%)	2 (7%)	0	4 (13%)
Diarrhea	1 (3%)	2 (7%)	0	3 (10%)
Asthenia	1 (3%)	1 (3%)	1 (3%)	3 (10%)

<sup>a</sup> No grade 4 treatment-related adverse events reported.

<sup>b</sup> Includes peripheral neuropathy, peripheral motor neuropathy, and peripheral sensory neuropathy





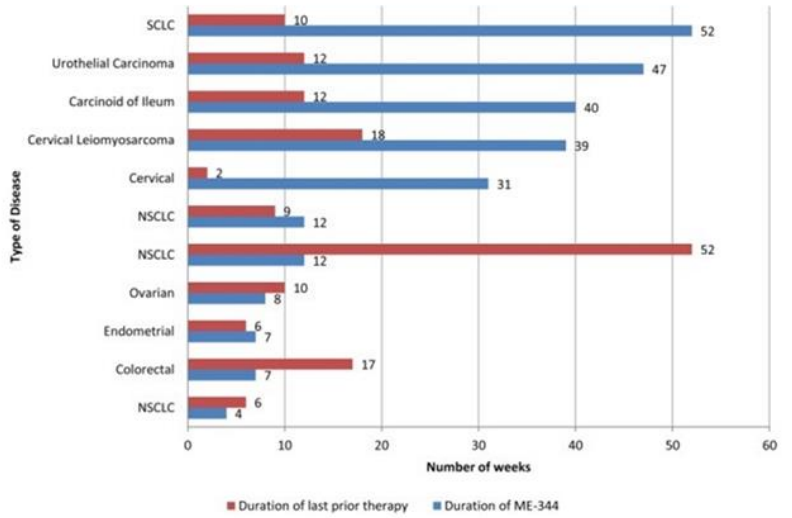
# ME-344 Monotherapy Ph 1 Dose Escalation Study – Key Efficacy Findings

1 PR in SCLC lasting 52 weeks

10 SD

DCR = 37% (11/30 pts)

## Duration of ME-344 therapy vs immediate prior therapy in patients achieving a partial response or stable disease



Bendel et al. Cancer 2015



## Clinical Study Objectives:

- Assess ability of bevacizumab to shift tumor reliance from glycolysis to mitochondrial metabolism
- Assess ability of ME-344 + Avastin to inhibit tumor proliferation compared to Avastin + placebo

Treatment-naïve  
HER2-negative  
breast cancer

**Arm A** Bevacizumab 15 mg/kg day 1  
ME-344 10mg/kg days 8, 15, 21

**Arm B** Bevacizumab 15 mg/kg day 1  
Saline 500cc days 8, 15, 21

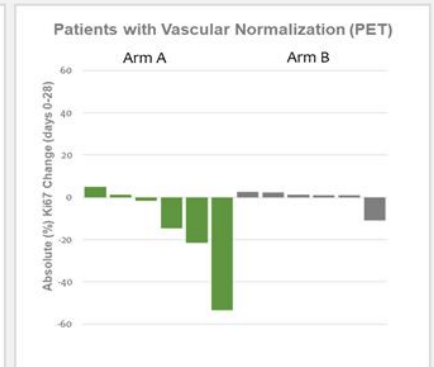
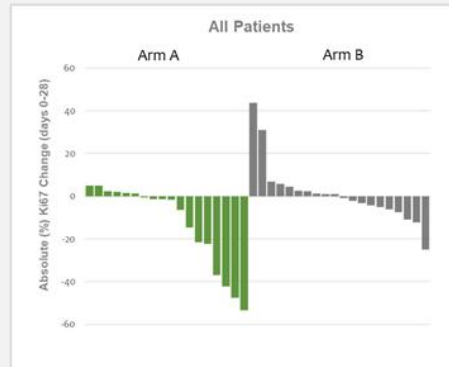
**Analysis:**  
FDG-PET: days 1 and 28  
Biopsy: days 1 and 28

Sponsored by Spanish National Cancer Research Centre



ME-344 in combination with bevacizumab in Her2-negative breast cancer patients demonstrated anti-tumor activity as evidenced by decreased Ki67

Qunitela-Fandino, *Clin Cancer Res* (2020) 26 (1): 35–45.





Current Clinical Study in Colorectal Cancer

Phase 1b Study Intended to Show Clinical Proof-of-Concept of ME-344 in Combination with VEGF Inhibition in Recurrent Metastatic Colorectal cancer

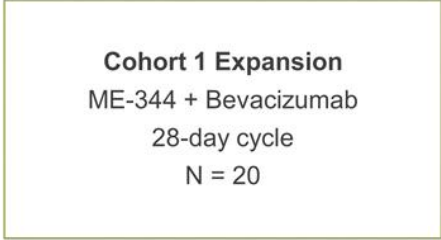
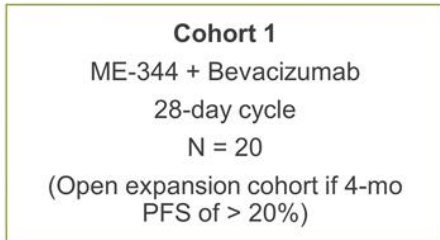
**RELAPSED/REFRACTORY COLORECTAL CANCER**

- Patients with progressive disease after failed prior therapy and no available approved option

**PRIMARY OBJECTIVE: PFS**

**SECONDARY OBJECTIVES: OS, safety**

FPI 1H  
2023



**TREATMENT UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY**



A background image showing several spherical virus particles with prominent surface spikes, resembling coronaviruses, against a light, hazy background. The particles are rendered in a semi-transparent, light grey color.

Clinical Development Plan

### Colorectal Cancer

- Oral TKI VEGF inhibitors and trifluridine-tipiracilare ± bevacizumab are standard treatment options for patients with colorectal cancer after failures of standard therapies
- Median overall survival of 6-12 months indicates a significant medical need
- ME-344 in combination with bevacizumab may improve response rate and overall survival and represents an attractive registration strategy

### Other Cancers

- VEGF inhibitors like Avastin and regorafenib are approved in multiple solid tumor indications, providing opportunities to expand combinatorial use of ME-344 beyond colorectal cancer patients.
- Examples include gastrointestinal stromal tumors, hepatocellular carcinoma, ovarian cancer and renal cell carcinoma



## ME-344 Summary

- ME-344 demonstrated potential to prevent anti-angiogenic escape with Avastin in patients and with VEGF TKIs in multiple pre-clinical models

- ME-344 demonstrated Ki67 decrease in combination with Avastin compared to placebo in HER2-negative breast cancer study, indicative of antitumor activity
  - Pharmacodynamics supports on-target effect
  - Normalized tumor vasculature and hypoxia correction correlate with enhanced antitumor activity

- Phase 1b trial evaluating ME-344 + bevacizumab in patients with relapsed metastatic colorectal cancer intended to show proof of principle:
  - Data to support ME-344 value in combination with bevacizumab/VEGF inhibition
  - Data from the Phase 1b study to support opening enrollment in an expansion cohort are expected around the end of 2023





## Q&A Participants



**Nick Abbott, PhD**

Principal, Abbott Biotech Consultancy  
Most recently, Senior Analyst Equity Research,  
Wells Fargo Corporate and Investment Banking



**Richard Ghalie, MD**

Chief Medical Officer, MEI Pharma  
Formerly Ligand, Favrilite and others, and practicing oncologist





# Q & A

## A Combined Company with Significant Opportunities for Value Creation



Three differentiated, promising, clinical candidates based on solid science and data\*

Pipeline led by planned eganelisib Phase 2 Study in Squamous cell carcinoma of the head & neck (SCCHN)

Voruciclib + Venclexta® P1 Study: Initial Results ~YE 2023

ME-344 + Avastin® P1 Study: Initial Results ~YE 2023

Eganelisib + Keytruda® P2 Study: Initial Safety/Efficacy 2H 2024



Utilize understandings of biology to overcome resistance mechanisms of standard of care therapies

Advance potential first-in-class programs to value creating transactions or commercialization



Anticipated Cash at closing of ~\$100M expected to fund operations to mid-2025 and clinical data over the next ~6-24 months



Experienced Leadership Team

\*Dates refer to expected timelines.



&

