Pfizer Logo

Pfizer Presents Scientific Advancements from its Leading Oncology Portfolio at ASCO 2023 Annual Meeting

Thursday, May 25, 2023 - 05:00pm

- *Data spans 15+ therapies across 10+ types of cancer, including six early pipeline medicines*
- *New data will be presented for three potential therapies with regulatory decisions anticipated this year in certain types of multiple myeloma, prostate cancer, and non-small cell lung cancer*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) will present data across its Oncology portfolio and growing pipeline, covering multiple tumor types and novel mechanisms of action at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago from June 2 through June 6. Abstracts include new data from pivotal trials supporting ongoing regulatory reviews for three potential therapies, if approved, and new clinical data for six early pipeline assets. In addition, Pfizer will highlight its ongoing scientific leadership in breast cancer with additional real-world evidence (RWE) for IBRANCE® (palbociclib) and initial first-in-human results for its novel CDK4- and CDK2-selective inhibitors, respectively, and novel epigenetic modulator KAT6 inhibitor.

“At ASCO, Pfizer will present new data across the four key areas of our industry-leading portfolio – breast cancer, genitourinary cancer, hematology, and precision medicine – and for the first time, first-in-human data for some of our most exciting pipeline medicines,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. “With four anticipated regulatory decisions this year and a growing portfolio of multiple mechanisms of action, Pfizer Oncology is poised to take our scientific innovation to the next level and bring new hope to people with cancer.”

Today, Pfizer Oncology has a comprehensive portfolio of 24 approved innovative cancer medicines and biosimilars to treat more than 30 cancer types and an extensive pipeline of more than 30 programs in clinical development. With the recently announced proposed acquisition of Seagen*, a leader in antibody-drug conjugate technology, Pfizer is further accelerating its fight against cancer to deliver the next generation of Oncology breakthroughs.

“Placing patients at the center of everything we do is a critical component of advancing cutting-edge science and improving outcomes for patients,” said Dany Habr, M.D., Oncology Chief Medical Affairs Officer, Pfizer. “At ASCO, we look forward to connecting with the entire Oncology community to continue our efforts and shared approaches in making scientific breakthroughs accessible to all people living with cancer, everywhere.”

Pfizer’s commitment to advancing scientific innovation will be on display at ASCO 2023 with more than 40 company-sponsored abstracts. Highlights include:

- 13 abstracts across the comprehensive MagnetisMM clinical trial program reinforcing the efficacy and safety of elranatamab, an investigational subcutaneous B-cell maturation antigen (BCMA)-CD3-targeted bispecific antibody, in relapsed or refractory multiple myeloma (RRMM), including an oral presentation

on the first data from patients treated with prior BCMA-targeted therapy. Elranatamab is under Priority Review with the U.S. Food and Drug Administration (FDA) and under review with the European Medicines Agency (EMA) for the treatment of RRMM.
- Four abstracts, including an oral presentation on new additional data from the Phase 3 TALAPRO-2 study, supporting the potential of TALZENNA® (talazoparib), an oral poly ADP-ribose polymerase (PARP) inhibitor that plays a role in DNA damage repair, in combination with XTANDI® (enzalutamide), an androgen receptor signaling inhibitor, in men with metastatic castration-resistant prostate cancer. The FDA has granted Priority Review for the Supplemental New Drug Application (sNDA) for TALZENNA in combination with XTANDI and an application is also under review with the EMA.
- For the first time, the primary efficacy and safety results from the Phase 2 PHAROS trial exploring BRAFTOVI® (encorafenib), an oral BRAF kinase inhibitor, given in combination with MEKTOVI® (binimetinib), an oral MEK inhibitor, in patients with metastatic non-small cell lung cancer harboring a *BRAF* V600E mutation.** Results from the PHAROS study support the sNDAs for BRAFTOVI and MEKTOVI in this setting that are currently under review by the FDA.
- Advancements across Pfizer's leading breast cancer portfolio and pipeline, including a new analysis of real-world evidence for IBRANCE, an oral first-in-class inhibitor of cyclin-dependent kinases (CDKs) 4 and 6, as a first-line treatment of metastatic breast cancer. In addition, the first Phase 1 data for the CDK4-selective inhibitor PF-07220060, the CDK2-selective inhibitor PF-07104091 and the KAT6 inhibitor PF-07248144, all investigational agents for advanced or metastatic hormone-receptor positive breast cancer, will be presented.

A complete list of Pfizer-sponsored accepted abstracts is available at https://cdn.pfizer.com/pfizercom/ASCO-Abstract-Chart-5.19.23-Pfizer-Sponsored-Abstracts.pdf.

Pfizer is also continuing its commitment to help non-scientists understand the latest findings with the development of abstract plain language summaries (APLS) for company-sponsored research being presented at ASCO, which are written in non-technical language. Those interested in learning more can visit www.Pfizer.com/apls to access the summaries starting May 25.

Key Pfizer-sponsored oral and poster discussion presentations at ASCO 2023 include:

BREAST CANCER
Poster Discussion (Abstract 3009) Saturday, June 3, 1:15-2:45 PM CDT First-in-human first-in-class Phase 1/2a study of the next generation CDK4-selective inhibitor PF-07220060 in patients (pts) with advanced solid tumors, enriched for HR+ HER2- mBC pts who progressed on prior CDK4/6 inhibitors and endocrine therapy. Yap TA
Poster Discussion (Abstract 3010) Saturday, June 3, 1:15-2:45 PM CDT First-in-human Phase 1/2a study of a potent and novel CDK2-selective inhibitor PF-07104091 in patients (pts) with advanced solid tumors, enriched for CDK4/6 inhibitor resistant HR+/HER2- breast cancer pts. Yap TA

Poster Discussion (Abstract 1018)
Sunday, June 4, 11:30 AM-1:00 PM CDT

First-line systemic treatment with palbociclib in women aged ?70 years presenting with hormone receptors-positive advanced breast cancer: Results from the PALOMAGE program.

Carola E

GENITOURINARY CANCERS

Oral Presentation (Abstract 5004)
Sunday, June 4, 8:00-11:00 AM CDT

TALAPRO-2: Phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) versus placebo (PBO) + ENZA as first-line (1L) treatment for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) harboring homologous recombination repair (HRR) gene alterations.

Agarwal N

Poster Discussion (Abstract 5013)
Saturday, June 3, 1:15-2:45 PM CDT

Patient-reported outcomes (PROs) among men receiving talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA as first-line (1L) treatment for metastatic castration-resistant prostate cancer (mCRPC): Results from a phase 3 study (TALAPRO-2).

Agarwal N

Poster Discussion (Abstract 4515)
Saturday, June 3, 3:00-4:30 PM CDT

Estimated net benefit of avelumab (AVE) + best supportive care (BSC) vs BSC alone for patients (pts) with advanced urothelial carcinoma (aUC) using a quality-adjusted time without cancer symptoms or toxicity (Q-TWiST) analysis.

Powles T

Poster Discussion (Abstract 4516)
Saturday, June 3, 3:00-4:30 PM CDT

Long-term safety of avelumab first-line (1L) maintenance for advanced urothelial carcinoma (aUC) in the JAVELIN Bladder 100 trial.

Bellmunt J

HEMATOLOGY

Oral Presentation (Abstract 8008)
Saturday, June 3, 1:15-4:15 PM CDT

Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma (RRMM) and prior B-cell maturation antigen (BCMA)-directed therapies: A pooled analysis from MagnetisMM studies.

Nooka AK

PRECISION MEDICINE
Poster Discussion (Abstract 9018) Sunday, June 4, 4:30-6:00 PM CDT Efficacy and safety of encorafenib (enco) plus binimetinib (bini) in patients with *BRAF* V600E-mutant (*BRAF* ^{V600E}) metastatic non-small cell lung cancer (NSCLC) from the phase 2 PHAROS study. Riely G
Other/Advanced Cancers
Oral Presentation (Abstract 11508) Monday, June 5, 11:30 AM-2:30 PM CDT Safety and clinical activity of TTI-621 in combination with doxorubicin in patients with unresectable or metastatic high-grade leiomyosarcoma: Results from the low-dose expansion cohort. Movva S
Poster Discussion (Abstract 3020) Saturday, June 3, 1:15-2:45 PM CDT A first-in-human, phase 1 study of the SHP2 inhibitor PF-07284892 as monotherapy and in combination with different targeted therapies in oncogene-driven treatment-resistant solid tumors. Drilon A

**Pfizer and Seagen remain two separate, independent companies prior to closing. Closing of the transaction is subject to fulfillment of customary closing conditions, including approval of Seagen's stockholders and receipt of necessary regulatory clearances.*

***Pfizer has exclusive rights to BRAFTOVI and MEKTOVI in the U.S., Canada, and all countries in the Latin American, African, and Middle Eastern regions. Ono Pharmaceutical Co., Ltd. has exclusive rights to commercialize both products in Japan and South Korea, Medison has exclusive rights in Israel, and Pierre Fabre has exclusive rights in all other countries, including Europe and Asia-Pacific (excluding Japan and South Korea).*

Prescribing Information for Pfizer Medicines

Please see full Prescribing Information for BRAFTOVI® (encorafenib) and full Prescribing Information for MEKTOVI® (binimetinib) or visit https://braftovimektovi.pfizerpro.com.

Please see full Prescribing Information for IBRANCE® (palbociclib) tablets and full Prescribing Information for IBRANCE® (palbociclib) capsules or visit https://ibrance.pfizerpro.com.

Please see full Prescribing Information for TALZENNA® (talazoparib) or visit https://talzenna.pfizerpro.com.

Please see full Prescribing Information for XTANDI® (enzalutamide) or visit https://www.xtandihcp.com.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of May 25, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's oncology portfolio of marketed and investigational therapies, including BRAFTOVI® (encorafenib), MEKTOVI® (binimetinib) , IBRANCE® (palbociclib), TALZENNA® (talazoparib), XTANDI® (enzalutamide), and elranatamab, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody, and Pfizer's proposed acquisition of Seagen, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of Pfizer's oncology portfolio; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indication for Pfizer's oncology products and product candidates; whether and when any such applications that may be pending or filed may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such products will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer's oncology products and product candidates; risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition of Seagen (including the failure to obtain necessary regulatory approvals and failure to obtain the requisite vote by Seagen stockholders) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the possibility that competing offers for Seagen may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition of Seagen, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the Seagen transaction

making it more difficult to maintain business and operational relationships; negative effects of the consummation of the proposed acquisition of Seagen on the market price of Pfizer's common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Seagen's business; risks related to the financing of the Seagen transaction; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

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