Pfizer Logo

Pfizer Advances Bold Vision for Future of Cancer Care at the ASCO 2025 Annual Meeting

Wednesday, April 23, 2025 - 03:46pm

- *More than 60 abstracts, including 15 oral and rapid oral presentations, highlight advancements across Pfizer's industry-leading Oncology portfolio*
- *ASCO press program to feature overall survival and progression-free survival data for BRAFTOVI® (encorafenib) combination regimen in first-line* BRAF V600E*-mutant metastatic colorectal cancer and progression-free survival data from VERITAC-2 study of vepdegestrant in metastatic breast cancer*
- *Multiple studies show the combination potential of vedotin antibody-drug conjugates (ADCs) with pembrolizumab, including the first Phase 1 data in thoracic cancers for two first-in-class ADCs*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) will showcase data across its portfolio of potential breakthrough cancer medicines at the 2025 American Society of Clinical Oncology (ASCO®) Annual Meeting, taking place May 30 to June 3 in Chicago. Data from more than 60 company-sponsored, investigator-sponsored, and collaborative research abstracts, including 9 oral presentations and 6 rapid oral presentations, will be presented across Pfizer's key tumor areas, including breast, genitourinary, hematologic, and thoracic cancers, as well as colorectal cancer.

"This has already been a significant year for Pfizer's Oncology pipeline, with multiple Phase 3 data readouts and regulatory approvals, and the initiation of pivotal registrational programs across our major tumor areas of focus," said Chris Boshoff, MD, PhD, Chief Scientific Officer and President, Research & Development, Pfizer. "The depth and diversity of our data presentations at ASCO are building on that momentum to bring us closer to our goal of delivering eight breakthrough cancer medicines by 2030."

Pfizer will have two late-breaking oral presentations featured in ASCO's embargoed pre-meeting press briefing on May 27. These include the primary analysis of the pivotal overall survival (OS) and progression-free survival (PFS) results from the Phase 3 BREAKWATER study investigating BRAFTOVI® (encorafenib) in combination with cetuximab (marketed as ERBITUX®) and mFOLFOX6 in patients with *BRAF V600E*-mutant metastatic colorectal cancer,* as well as the first presentation of the PFS results from the Phase 3 VERITAC-2 study of vepdegestrant in adults with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer (a/mBC) in partnership with Arvinas.**

Pfizer will share additional updates from key late-stage programs, including five-year survival data from the Phase 3 ARCHES study of XTANDI® (enzalutamide) in combination with androgen deprivation therapy in metastatic hormone-sensitive prostate cancer (mHPSC),*** and the first combination data for ELREXFIO® (elranatamab) + daratumumab + lenalidomide from the ongoing MagnetisMM-6 study in patients with transplant-ineligible (TI) newly diagnosed multiple myeloma (NDMM).

Pfizer will also share new findings highlighting the company's strategy to explore novel vedotin antibody-drug conjugates (ADCs) in combination with immune checkpoint inhibitors to potentially enhance anti-tumor activity.

For the first time, Pfizer will present encouraging Phase 1 data on two novel investigational ADCs in combination with pembrolizumab in thoracic cancers: sigvotatug vedotin (SV), an integrin beta-6 (IB6)-directed ADC, in lung cancer and head and neck cancers, and PDL1V (PF-08046054), a PD-L1 directed ADC, in head and neck cancers. Additionally, new exploratory analyses will be presented from the pivotal EV-302 trial with PADCEV® (enfortumab vedotin) in combination with KEYTRUDA® (pembrolizumab) in patients with previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC).****

Several presentations will highlight updated results from ongoing Phase 1 studies that inform the dosing strategy in registrational programs for two molecules targeting epigenetic regulators: mevrometostat, an investigational EZH2 inhibitor being evaluated in combination with XTANDI for metastatic castration-resistant prostate cancer (mCRPC); and PF-07248144, a potential first-in-class KAT6 inhibitor for ER+/HER2- metastatic breast cancer (mBC).

“Our data at ASCO this year reflect how we are strategically progressing our deep pipeline of next generation cancer medicines while simultaneously extending the impact of our foundational therapies to reach more people living with cancer,” said Megan O’Meara, Head of Early-Stage Development and Interim Head of Late-Stage Development, Pfizer Oncology. “Important early-stage updates highlight our extensive pipeline and depth within our core cancer types, as we advance up to nine new pivotal Phase 3 trials this year.”

Key ASCO Presentations

Colorectal Cancers

- **BRAFTOVI**: A late-breaking session will detail PFS and OS results from the Phase 3 BREAKWATER study of BRAFTOVI in combination with cetuximab and mFOLFOX6 chemotherapy in*BRAF V600E*-mutant metastatic colorectal cancer, further establishing the benefit of the BRAFTOVI combination regimen following its FDA accelerated approval in late 2024. These pivotal study results follow the topline results announcement for PFS and OS and the objective response rate (ORR) results presented at ASCO GI. These new data will also be featured in the ASCO press program.

Breast Cancer

- **Vepdegestrant**: In a late-breaking session, PFS data will be presented for the first time from the Phase 3 VERITAC-2 study of vepdegestrant, a PROTAC ER degrader, in ER+/HER2? a/mBC. These detailed data follow the topline results from VERITAC-2 announced earlier this year and will also be featured in the ASCO press program.
- **PF-07248144 (KAT6 inhibitor)**: A rapid oral presentation will highlight dose optimization data from an ongoing Phase 1 study for PF-07248144, a potential first-in-class KAT6 inhibitor, in patients with ER+/HER2? mBC. These results support the recommended dosing for PF-07248144 ahead of the Phase 3 trial initiation in second-line mBC planned for 2H 2025.
- **IBRANCE® (palbociclib)**: Roche will present detailed results from the OS analysis of the Phase 3 INAVO120 study investigating ITOVEBI™ (inavolisib) in combination with IBRANCE and fulvestrant in patients with*PIK3CA*-mutated, HR+/HER2-, endocrine-resistant, locally a/mBC. This presentation will be featured in ASCO’s embargoed pre-meeting press briefing on May 21.

Genitourinary Cancers

- **XTANDI**: Five-year follow-up overall survival data from the ARCHES study of XTANDI in combination with androgen deprivation therapy in patients with mHSPC will be featured in an oral presentation. In addition, updates from the Astellas-supported, investigator-sponsored ENZAMET Phase 3 research study,

led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and sponsored by the University of Sydney, will also be presented, including 8 year-outcomes in men with mHSPC. These presentations further underscore the value of XTANDI across approved indications.

- **Mevrometostat**: A poster presentation will highlight pharmacokinetic and safety data from the ongoing Phase 1 study for mevrometostat, an investigational EZH2 inhibitor, in combination with XTANDI. These updated data further inform the dosing strategy for mevrometostat in a robust registrational program that includes two Phase 3 trials in mCRPC, and a third trial in metastatic castration-sensitive prostate cancer (mCSPC) that is planned to start in 1H 2025.
- **PADCEV**: Additional updates from the Phase 3 EV-302 study of PADCEV in combination with KEYTRUDA in previously untreated la/mUC will be presented, including an oral presentation with exploratory analysis of responders.

Hematologic Cancers

- **ELREXFIO**: Initial safety and efficacy results from Part 1 of the ongoing MagnetisMM-6 study of ELREXFIO in combination with daratumumab and lenalidomide in patients with newly diagnosed MM that are not eligible for transplant will be presented as an oral presentation. Part 1 of the ongoing MagnetisMM-6 study evaluates the optimal dose of the ELREXFIO combination regimen in patients with RRMM or NDMM to determine the recommended phase 3 dose for part 2.

Thoracic Cancers

- **Sigvotatug vedotin (SV):** Phase 1 results for SV, an IB6-directed vedotin ADC, in combination with pembrolizumab in non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) will be featured in a rapid oral presentation. This initial combination data for SV with pembrolizumab support a Phase 3 study in first line PD-L1-High NSCLC, initiated this year. The data also support the overall SV trial program that includes an ongoing Phase 3 monotherapy trial in second line+ NSCLC.
- **PDL1V (PF-08046054)**: Two poster presentations will highlight interim Phase 1 results for PDL1V, a PD-L1 directed vedotin ADC, as monotherapy in NSCLC and initial safety and efficacy data in combination with pembrolizumab in patients with first-line recurrent or metastatic (r/m) HNSCC. These data provide additional support for the initiation of the two pivotal Phase 3 trials planned for PDL1V in 2025 in second line+ NSCLC and first line r/mHNSCC.

Additional information on key Pfizer-sponsored abstracts, including date and time of presentation, follows in the chart below. A complete list of Pfizer-sponsored accepted abstracts is available here.

Pfizer is 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 22, 2025.

COLORECTAL CANCERS

Oral Presentation (Abstract LBA3500)
Friday, May 30, 2:45-5:45 PM CDT

First-line encorafenib + cetuximab + mFOLFOX6 in *BRAF V600E*-mutant metastatic colorectal cancer (BREAKWATER): progression-free survival and updated overall survival analyses

Elez et al

BREAST CANCER

Rapid Oral Presentation (Abstract 1020)
Friday, May 30, 2:45-4:15 PM CDT

Dose optimization of PF-07248144, a first-in-class KAT6 inhibitor, in patients (pts) with ER+/HER2? metastatic breast cancer (mBC): Results from phase 1 study to support the recommended phase 3 dose (RP3D)

LoRusso et al

Oral Presentation (Abstract LBA1000)
Saturday, May 31, 1:15-4:15 PM CDT

Vepdegestrant, a PROTAC estrogen receptor (ER) degrader, vs fulvestrant in ER-positive/human epidermal growth factor receptor 2 (HER2)–negative advanced breast cancer: Results of the global, randomized, phase 3 VERITAC-2 study

Hamilton et al

GENITOURINARY CANCERS

Oral Presentation (Abstract 4502)
Sunday, June 1, 9:45 AM-12:45 PM CDT

Exploratory analysis of responders from the phase 3 EV-302 trial of enfortumab vedotin plus pembrolizumab (EV+P) vs chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC)

Gupta et al

Oral Presentation (Abstract 5005)
Tuesday, June 3, 9:45 AM-12:45 PM CDT

ARCHES 5-year follow-up overall survival (OS) analysis of enzalutamide (ENZA) plus androgen deprivation therapy (ADT) in patients (pts) with metastatic hormone-sensitive prostate cancer (mHSPC)

Armstrong et al

Poster Presentation (Abstract 4571)
Monday, June 2, 9:00 AM-12:00 PM CDT

EV-302: Long-term subgroup analysis from the phase 3 global study of enfortumab vedotin in combination with pembrolizumab (EV+P) vs chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC)

Bedke et al

Poster Presentation (Abstract 5046) Monday, June 2, 9:00 AM-12:00 PM CDT Safety and pharmacokinetics of mevrometostat (M) in combination with enzalutamide (E) in patients with metastatic castration-resistant prostate cancer (mCRPC) Matsubara et al
HEMATOLOGIC CANCERS
Oral Presentation (Abstract 7504) Tuesday, June 3, 9:45 AM-12:45 PM CDT Elranatamab in combination with daratumumab and lenalidomide (EDR) in patients with newly diagnosed multiple myeloma (NDMM) not eligible for transplant: Initial results from MagnetisMM-6 part 1 Quach et al
THORACIC CANCERS
Rapid Oral Presentation (Abstract 3010) Monday, June 2, 8:00-9:30 AM CDT Sigvotatug vedotin (SV), an investigational integrin beta-6 (IB6)–directed antibody?drug conjugate (ADC), and pembrolizumab combination therapy: Initial results from an ongoing phase 1 study (SGNB6A-001) Sehgal et al
Poster Presentation (Abstract 6033) Monday, June 2, 9:00 AM-12:00 PM CDT Initial safety and efficacy of PDL1V (PF-08046054), a vedotin-based ADC targeting PD-L1, in combination with pembrolizumab in patients with recurrent or metastatic (R/M) HNSCC Gillison et al
Poster Presentation (Abstract 8611) Saturday, May 31, 1:30-4:30 PM CDT Interim results of PDL1V (PF-08046054), a vedotin-based ADC targeting PD-L1, in patients with NSCLC in a phase 1 trial Fontana et al

**The BREAKWATER trial was conducted with support from ONO Pharmaceutical, Merck KGaA, Darmstadt, Germany and Eli Lilly and Company.*
***Pfizer and Arvinas have a global collaboration for the co-development and co-commercialization of vepdegestrant.*
****XTANDI® is jointly developed and commercialized by Pfizer and Astellas in the United States.*
*****Pfizer and Astellas have a clinical collaboration agreement with Merck to evaluate the combination of PADCEV® and KEYTRUDA® in patients with previously untreated metastatic urothelial cancer.*

Prescribing Information for Pfizer Medicines

Please see full Prescribing Information for BRAFTOVI®.

Please see full Prescribing Information, including BOXED WARNING, for ELREXFIO™ (elranatamab-bcmm).

Please see full Prescribing Information for IBRANCE® (palbociclib) tablets and IBRANCE® (palbociclib) capsules.

Please see full Prescribing Information, including BOXED WARNING, for PADCEV® (enfortumab vedotin).

Please see full Prescribing Information for XTANDI® (enzalutamide).

About Pfizer Oncology
At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including small molecules, antibody-drug conjugates (ADCs), and bispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer live better and longer lives.

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 175 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 X 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 April 23, 2025. 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 Oncology and Pfizer's oncology portfolio of marketed and investigational therapies, including their potential benefits; expectations for our product pipeline, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, launches, clinical trial results and other developing data; the development or commercial potential of our product pipeline, in-line products, product candidates and additional indications or combinations, including expected clinical trial protocols, the potential and timing for the initiation and progress of clinical trials and data read-outs from trials; the timing and potential for the submission of applications for and receipt of regulatory approvals; the timing and potential for product launches and commercialization; expected breakthrough, best- or first-in-class or blockbuster status or expected market entry of our medicines; potential patients reached; the regulatory landscape; the competitive landscape; and other statements about our business, operations and financial results that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risk 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; risks associated with interim and preliminary 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 any drug applications, biologics license applications and/or emergency use authorization applications may be filed in any jurisdictions for any potential indication for Pfizer's product candidates; whether and when any such applications that may be filed for any of Pfizer's product candidates 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 product candidates 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 products or product candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the impact of COVID-19 on Pfizer's 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, 2024 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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