Pfizer Logo

Pfizer to Showcase Advancements Across Genitourinary Cancers at ASCO GU Cancers Symposium

Tuesday, January 28, 2025 - 06:45am

- *More than 20 abstracts span Pfizer's leading genitourinary cancer portfolio of approved standards of care and growing pipeline across prostate and bladder cancers*
- *Detailed overall survival (OS) results from the pivotal Phase 3 TALAPRO-2 trial of TALZENNA® in combination with XTANDI® in patients with metastatic castration-resistant prostate cancer (mCRPC)*
- *Updated analysis from the Phase 3 EV-302 trial highlights sustained OS benefit of PADCEV® in combination with pembrolizumab in locally advanced or metastatic urothelial cancer*
- *First randomized progression-free survival (PFS) data for mevrometostat in combination with XTANDI in mCRPC*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) will present the latest results from its leading genitourinary (GU) portfolio at the American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium taking place February 13-15 in San Francisco, California. Data from more than 20 company-sponsored, investigator-sponsored, and collaborative research abstracts, including five oral presentations, highlight advancements in developing new standards of care within prostate and bladder cancer across the company's core scientific modalities, including small molecules and antibody-drug conjugates.

"Our long-standing commitment to the genitourinary cancer community has been foundational in our mission to transform the treatment landscapes for patients with bladder and prostate cancers," said Karin Tollefson, Chief Oncology Medical Officer, Pfizer. "Our strong presence at this year's ASCO GU highlights the longer-term impacts of our approved leading medicines for patients in their respective indications. We are also looking forward to sharing updates from our rapidly growing pipeline of novel targets and combination approaches, which have the potential to help address the diverse needs of patients across various stages of disease."

Pfizer's GU portfolio includes seven approved medicines across bladder, prostate, and kidney cancers, as well as a growing late-stage pipeline of scientific modalities and combination approaches. Key Pfizer presentations at ASCO GU include the detailed overall survival (OS) results from the Phase 3 TALAPRO-2 trial with TALZENNA® (talazoparib) plus XTANDI® (enzalutamide) in patients with metastatic castration-resistant prostate cancer (mCRPC), which will be featured in ASCO GU's official Press Program. In addition, updated analysis from the Phase 3 global EV-302 study of PADCEV® (enfortumab vedotin-ejfv) in combination with pembrolizumab in locally advanced or metastatic urothelial cancer (la/mUC) will be presented, highlighting the long-term efficacy benefits of the combination.

From the pipeline, the first randomized progression-free survival (PFS) data from the ongoing Phase 1 dose-escalation study for mevrometostat plus XTANDI reinforce the potential of this investigational combination for patients with mCRPC. Additional pipeline presentations include updated data and real-world evidence for different types of bladder cancer, supporting the development of two potential transformative treatments,

disitamab vedotin, an investigational antibody-drug conjugate (ADC), and sasanlimab, an investigational subcutaneous PD-1 blocker.

Key ASCO GU Presentations

Prostate Cancer

- **TALZENNA plus XTANDI:**Oral and poster presentations from the pivotal Phase 3 TALAPRO-2 trial of TALZENNA in combination with XTANDI will provide detailed results on the statistically significant and clinically meaningful improvement in OS in all-comers (cohort 1) as well as in those patients with homologous recombination repair (HRR) gene-mutated mCRPC (cohort 2), compared to XTANDI alone. TALZENNA in combination with XTANDI has been approved for use in over 35 countries globally for patients with certain types of mCRPC*. The OS results will be shared with global health authorities to potentially update the TALZENNA label.
- **XTANDI:** Six abstracts continue to underscore the benefit of XTANDI across its approved indications, including two posters highlighting follow-up analysis from the EMBARK trial of XTANDI in combination with leuprolide in patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high-risk for metastasis.
- **Mevrometostat:** The first randomized PFS results from the ongoing Phase 1 dose-expansion study examine the potential of mevrometostat (PF-06821497), an investigational selective inhibitor of enhancer of zeste homolog 2 (EZH2), in combination with XTANDI in patients with mCRPC, compared to XTANDI alone. Pfizer initiated two pivotal Phase 3 trials for mevrometostat plus XTANDI in 2024 and expects to start a Phase 3 study of mevrometostat plus XTANDI in first-line mCSPC during the first half of 2025.

Bladder Cancer

- **PADCEV:** Long-term follow-up data from the groundbreaking Phase 3 EV-302 study of PADCEV in combination with pembrolizumab, including OS and safety data, continue to demonstrate consistent efficacy versus chemotherapy in a broad population, reinforcing the combination as standard of care in first-line treatment of la/muC.
- **Disitamab vedotin:** Updated efficacy and safety data from an ongoing Phase 2 study (sponsored by Remegen) evaluating the HER2-targeting ADC disitamab vedotin plus toripalimab show encouraging results as a perioperative regimen in HER2-expressing muscle-invasive bladder cancer (MIBC). These data add to the growing body of evidence supporting the continued development of disitamab vedotin across stages of bladder cancer.
- **Sasanlimab:** Three real-world evidence poster presentations highlight the need for advanced treatment options for patients with non-muscle invasive bladder cancer (NMIBC), including presentations on Bacillus Calmette-Guérin (BCG) treatment patterns, impact of BCG shortages, and outcomes and treatment patterns in patients with high-risk NMIBC. Pfizer recently reported positive topline results for sasanlimab in combination with BCG as induction therapy with or without maintenance in patients with BCG- naïve, high-risk NMIBC. Detailed results from the Phase 3 CREST trial will be presented at an upcoming congress.

Additional information on key Pfizer-sponsored abstracts at ASCO GU 2025, including date and time of presentation, follow in the chart below. A complete list of Pfizer-sponsored accepted abstracts is available here.

*TALZENNA in combination with XTANDI was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with HRR gene-mutated mCRPC in June 2023.

Prostate Cancer
Final overall survival (OS) with talazoparib (TALA) + enzalutamide (ENZA) as first-line treatment in unselected patients with metastatic castration-resistant prostate cancer (mCRPC) in the Phase 3 TALAPRO-2 trial (Abstract #LBA18) Agarwal, N Oral Abstract Session Thursday, February 13, 11:42 AM – 11:52 AM EST Presentation Time: 8:42 AM – 8:52 AM PST
Final overall survival (OS) with talazoparib (TALA) + enzalutamide (ENZA) as first-line (1L) treatment in patients (pts) with homologous recombination repair (HRR)-deficient metastatic castration-resistant prostate cancer (mCRPC) in the Phase 3 TALAPRO-2 trial (Abstract #LBA141) Fizazi, K Poster Session Thursday, February 13, 2:25 PM – 3:45 PM EST Presentation Time: 11:25 AM – 12:45 PM PST
Mevrometostat (PF-06821497), an enhancer of zeste homolog 2 (EZH2) inhibitor, in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC): A randomized dose-expansion study (Abstract #LBA138) Schweizer, MT Rapid Oral Abstract Session Thursday, February 13, 8:25 PM – 8:30 PM EST Presentation Time: 5:25 PM – 5:30 PM PST
Bladder Cancer
EV-302: Updated 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) (Abstract #664) Powles, TB Rapid Oral Abstract Session Friday, February 14, 7:10 PM – 7:15 PM EST Presentation Time: 4:10 PM – 4:15 PM PST
Neoadjuvant treatment with disitamab vedotin plus perioperative toripalimab in patients with muscle-invasive bladder cancer (MIBC) with HER2 expression: Updated efficacy and safety results from the phase II RC48-C017 trial (Abstract #665) Sheng, X Oral Abstract Session Friday, February 14, 11:57 AM – 12:07 PM EST Presentation Time: 8:57 AM – 9:07 AM PST

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.

Prescribing Information for Pfizer Medicines

Please read full Prescribing Information for TALZENNA® (talazoparib)

Please read full Prescribing Information for XTANDI® (enzalutamide)

Please read full Prescribing Information, including BOXED WARNING, for PADCEV® (enfortumab vedotin-ejfv)

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 healthcare 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 healthcare providers, governments, and local communities to support and expand access to reliable, affordable healthcare 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 www.facebook.com/Pfizer/.

Disclosure notice

The information contained in this release is as of January 28, 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 pipeline, in-line products and product candidates, including XTANDI® (enzalutamide), TALZENNA® (talazoparib), PADCEV® (enfortumab vedotin-ejfv), mevrometostat, disitamab vedotin and sasanlimab, 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. Risk and uncertainties include, among other things, uncertainties regarding the commercial success of Pfizer's oncology products and product candidates; 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 applications may be filed with any regulatory authorities in any jurisdictions for any potential indication for Pfizer's product candidates; whether and when any such applications that may be pending or 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; 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, 2023, 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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