Pfizer Highlights Progress in Accelerating Breakthrough Cancer Medicines at ASCO 2024 Annual Meeting

Monday, April 29, 2024 - 06:45am

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More than 50 abstracts, including 11 oral presentations, span Pfizer’s robust portfolio of approved and pipeline therapies across its key tumor areas and core scientific modalities

New five-year progression-free survival data for LORBRENA® (lorlatinib) in first-line ALK-positive advanced lung cancer

Results from ECHELON-3, third Phase 3 study to demonstrate overall survival benefit for ADCETRIS® (brentuximab vedotin) in a type of lymphoma

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) highlights its progress in advancing new potential standards of care in Oncology at the 2024 American Society of Clinical Oncology (ASCO®) Annual Meeting, taking place May 31 to June 4 in Chicago. More than 50 abstracts, including 11 oral presentations, will be presented from Pfizer’s broadened portfolio of approved and pipeline therapies across the company’s key tumor areas and core scientific modalities, including small molecules, antibody-drug conjugates (ADCs)

and bispecific antibodies.

“We are excited to participate in our first ASCO Annual Meeting following the creation of Pfizer’s new Oncology organization, where we will highlight our efforts to accelerate breakthrough medicines that help people with cancer live better and longer lives,” said Chris Boshoff, Chief Oncology Officer and Executive Vice President, Pfizer. “We are looking forward to key data presentations across our newly expanded portfolio, including additional evidence reinforcing the benefit of several approved medicines and promising new data from our deep and diverse pipeline.”

Key research includes an oral presentation of new five-year progression-free survival (PFS) results from the Phase 3 CROWN study of LORBRENA® (lorlatinib) in previously untreated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC), which will also be featured in ASCO’s embargoed pre-meeting press briefing on Wednesday, May 29. Additionally, results from the Phase 3 ECHELON-3 study of ADCETRIS® (brentuximab vedotin) in combination with lenalidomide and rituximab in relapsed/refractory diffuse large B-cell lymphoma (DLBCL) will be presented for the first time in an oral late-breaking session.

Pfizer will also present Phase 1 data for several priority pipeline therapies, including oral presentations with updated results for sigvotatug vedotin (B6A; integrin beta-6 [IB6]-directed ADC) in NSCLC and data for PF-07248144, a potential first-in-class KAT6 inhibitor, in hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (mBC).

“At ASCO, Pfizer will share important data highlighting the long-term impact of our medicines for patients, including five-year follow-up from the LORBRENA CROWN study, as well as the third Phase 3 study to demonstrate overall survival benefit for ADCETRIS in a type of lymphoma – in this case, relapsed/refractory diffuse large B-cell lymphoma,” said Karin Tollefson, Chief Oncology Medical Officer, Pfizer. “We are also looking forward to sharing updated results from our pipeline, where we now have over 50 programs in development and are rapidly advancing 20 ongoing pivotal trials across our key tumor types.”

Key ASCO Presentations

Pfizer will present data across its four tumor areas of focus at ASCO: breast cancer, genitourinary cancer, hematology-oncology and thoracic cancers, which includes lung cancer.

Breast Cancer

In breast cancer, Pfizer will present data for two next-generation pipeline medicines for HR+/HER2- mBC: updated Phase 1/2a safety data for atirmociclib, a potential best-in-class, highly selective cyclin-dependent kinase 4 (CDK4) inhibitor currently in Phase 3 development, and an oral presentation featuring Phase 1 data for PF-07248144, a potential first-in-class KAT6 inhibitor. Additionally, data for TUKYSA® (tucatinib) demonstrate its activity in previously treated HER2-mutated mBC, and new real-world evidence continues to support the value of IBRANCE® (palbociclib) in HR+/HER2- mBC, including from HENRI-3, a SEER-Medicare analysis evaluating overall survival (OS) with IBRANCE plus an aromatase inhibitor (AI) versus AI alone.

Genitourinary Cancer

Highlights from Pfizer’s genitourinary cancer portfolio will include updated data that continue to reinforce the potential of several recent priority launches, including PADCEV® (enfortumab vedotin-ejfv) in combination with KEYTRUDA® (pembrolizumab) in locally advanced/metastatic urothelial cancer,* XTANDI® (enzalutamide) in non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high-risk for metastasis,** and TALZENNA® (talazoparib) in combination with XTANDI in metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) mutations. Additionally, updated Phase 1 data will be presented for the investigational enhancer of zeste homolog 2 (EZH2) inhibitor mevrometostat in combination with XTANDI in mCRPC; Pfizer anticipates initiating Phase 3 studies for this combination later this year.

Hematology-Oncology

In addition to the ECHELON-3 OS results for ADCETRIS in relapsed/refractory DLBCL, Pfizer will present seven-year OS results for ADCETRIS in advanced classical Hodgkin lymphoma,*** as well as new clinical and pharmacokinetic data with alternative dosing regimens for ELREXFIO™ (elranatamab-bcmm) in relapsed/refractory multiple myeloma from the MagnetisMM-9 trial.

Thoracic Cancer

In its thoracic portfolio, in addition to the LORBRENA CROWN results, Pfizer will present updated Phase 1 data for sigvotatug vedotin in advanced NSCLC, a promising investigational ADC that recently initiated a Phase 3 study.

Additional Tumor Types

An oral presentation on extended duration of response from the Phase 3 MOUNTAINEER trial adds to the positive profile of TUKYSA in colorectal cancer. In addition, data will be presented from the innovaTV 301 trial of TIVDAK® (tisotumab vedotin-tftv), for which a supplemental Biologics License Application for the treatment of previously treated recurrent or metastatic cervical cancer was granted priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act date of May 9, 2024.****

Additional information on key Pfizer-sponsored abstracts, including date and time of presentation, follow 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 Friday, May 24.

BREAST CANCER

Oral Presentation (Abstract 3006)

Saturday, June 1, 3:00-6:00 PM CDT

A phase 1 dose expansion study of a first-in-class KAT6 inhibitor — (PF-07248144) in patients with advanced or metastatic ER+ HER2− breast cancer

Mukohara et al

Poster Presentation (Abstract 3108)

Saturday, June 1, 9:00 AM-12:00 PM CDT

First-in-human phase 1/2a study of the first-in-class, next-generation CDK4-selective inhibitor PF-07220060 + endocrine therapy (ET): Updated safety data in patients with

HR+/HER2− mBC

Giordano et al

Poster Presentation (Abstract 1111)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Overall survival with palbociclib (PAL) plus an aromatase inhibitor (AI) versus AI alone in older patients (pts) with de novo, HR+/HER2− metastatic breast cancer: A SEER-Medicare analysis

Brufsky et al

Poster Presentation (Abstract 1105)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Tucatinib and trastuzumab for previously treated HER2-mutated metastatic breast cancer (SGNTUC-019): A phase 2 basket study

Okines et al

GENITOURINARY CANCER

Oral Presentation (Abstract 4502)

Monday, June 3, 8:00-11:00 AM CDT

Patient-reported outcomes (PROs) from a randomized, phase 3 trial of enfortumab vedotin plus pembrolizumab (EV+P) versus platinum-based chemotherapy (PBC) in previously untreated locally advanced or metastatic urothelial cancer (la/mUC)

Gupta et al

Oral Presentation (Abstract 4503)

Monday, June 3, 8:00-11:00 AM CDT

Impact of exposure on outcomes with enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer

Petrylak et al

Oral Presentation (Abstract 5005)

Saturday, June 1, 3:00-6:00 PM CDT

EMBARK post-hoc analysis of impact of treatment suspension (TxS) on health-related quality of life (HRQoL)

Freedland et al

Poster Presentation (Abstract 5021)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Discovery of a novel non-negative matrix factorization (NMF)-based homologous recombination deficiency (HRD) score and subsequent exploration in TALAPRO-2 (TP-2), a phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA as first-line treatment in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC)

Fizazi et al

Poster Presentation (Abstract 5061)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Phase 1 trial of mevrometostat (PF-06821497), a potent and selective inhibitor of enhancer of zeste homolog 2 (EZH2), in castration-resistant prostate cancer (CRPC)

Schweizer et al

Poster Presentation (Abstract 5063)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Matching-adjusted indirect comparisons (MAICs) of talazoparib plus enzalutamide (TALA+ENZA) versus olaparib plus abiraterone and prednisone/prednisolone (OLAP+AAP) for first-line (1L) therapy in patients with metastatic castration-resistant prostate cancer (mCRPC) and homologous recombination repair mutations (HRRm)/BRCAm

Castro et al

Poster Presentation (Abstract 4562)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Enfortumab vedotin (EV) with pembrolizumab (P) versus chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC): Analysis of cisplatin (cis)-eligible population from EV-302/KEYNOTE-A39

Bedke et al

Poster Presentation (Abstract 4563)

Sunday, June 2, 9:00 AM-12:00 PM CDT

Enfortumab vedotin (EV) with pembrolizumab (P) versus chemotherapy (chemo) in previously untreated locally advanced or metastatic urothelial carcinoma (la/mUC): Analysis of the cisplatin (cis)-ineligible population from EV-302/KEYNOTE-A39

Van Der Heijden et al

HEMATOLOGY-ONCOLOGY

Oral Presentation (Abstract LBA7005)

Saturday, June 1, 3:00-6:00 PM CDT

Brentuximab vedotin in combination with lenalidomide and rituximab in patients with relapsed/refractory diffuse large B-cell lymphoma: Results from the phase 3 ECHELON-3 study

Kim et al

Poster Presentation (Abstract 7053)

Monday, June 3, 9:00 AM-12:00 PM CDT

Seven-year overall survival analysis from ECHELON-1 study of A+AVD versus ABVD in patients with previously untreated stage III/IV classical Hodgkin lymphoma

Ansell et al

Poster Presentation (Abstract 7522)

Monday, June 3, 9:00 AM-12:00 PM CDT

Evaluation of cytokine release syndrome (CRS) in patients with relapsed or refractory multiple myeloma (RRMM) receiving step-up priming doses and longer dosing intervals of elranatamab: MagnetisMM-9

Sborov D

THORACIC CANCER

Oral Presentation (Abstract LBA8503)

Friday, May 31, 2:45-5:45 PM CDT

Lorlatinib vs crizotinib in treatment-naïve patients with advanced ALK+ non-small cell lung cancer: 5-year progression-free survival and safety from the CROWN study

Solomon et al

Rapid Oral Presentation (Abstract 8521)

Saturday, June 1, 4:30-6:00 PM CDT

Efficacy and safety of sigvotatug vedotin, an investigational ADC, in NSCLC: Updated phase 1 results (SGNB6A-001)

Peters et al

GYNECOLOGICAL CANCER

Poster Presentation (Abstract 5531)

Monday, June 3, 9:00 AM-12:00 PM CDT

Tisotumab vedotin in 2L/3L recurrent or metastatic cervical cancer: subsequent therapy data from ENGOT-cx12/GOG-3057/innovaTV 301

Manso Sánchez et al

GASTROINTESTINAL CANCER

Oral Presentation (Abstract 3509)

Monday, June 3, 1:15-2:45 PM CDT

Final results of a phase 2 study of tucatinib and trastuzumab for HER2-positive mCRC (MOUNTAINEER)

Strickler et al

**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.*

***XTANDI® is jointly developed and commercialized by Pfizer and Astellas in the United States.*

****Pfizer and Takeda jointly develop ADCETRIS® on a 50:50 basis, except in Japan where Takeda is solely responsible for development costs. Pfizer has U.S. and Canadian commercialization rights, and Takeda has rights to commercialize ADCETRIS® in the rest of the world.*

*****TIVDAK® is co-owned by Genmab and Pfizer, under an agreement in which the companies share costs and profits for the product on a 50:50 basis.*

Prescribing Information for Pfizer Medicines

Please see full Prescribing Information, including BOXED WARNING, for ADCETRIS® (brentuximab vedotin).

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

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

Please see full Prescribing Information for LORBRENA® (lorlatinib).

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

Please see full Prescribing Information for TUKYSA® (tucatinib).

Please see full Prescribing Information for TALZENNA® (talazoparib).

Please see full Prescribing Information, including BOXED WARNING, for TIVDAK® (tisotumab vedotin-tftv).

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 more than 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 29, 2024. The Company 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; 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; anticipated operating and financial performance; 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 ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; 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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