



Pfizer Showcases Scientific Leadership in Breast Cancer and Blood Disorders Across More than 100 Presentations at ASH and SABCS

Thursday, December 05, 2024 - 05:06pm

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) will highlight the latest advancements from its growing hematology and breast cancer portfolios at the American Society of Hematology (ASH) Annual Meeting & Exposition (December 7-10) and the San Antonio Breast Cancer Symposium (SABCS, December 10-13). Data from more than 100 company-sponsored, investigator-sponsored, and collaborative research abstracts, including 13 oral presentations and four poster spotlights, will be shared across the company's approved medicines and expanding portfolio of potential breakthroughs for patients with blood and breast cancers, as well as rare blood disorders.

"Our robust presence at ASH and SABCS reinforces Pfizer's legacy of scientific innovation for people living with blood disorders and breast cancer," said Chris Boshoff, Chief Oncology Officer and Executive Vice President, Pfizer. "We are pleased to share the latest updates for some of our key approved medicines, including ADCETRIS, ELREXFIO, and IBRANCE, which continue to generate compelling data as foundations of care in their

respective indications. We are also excited to present new results in hemophilia and from our expanding pipeline of innovative, next-generation therapy candidates for both blood and breast cancers, including new data on combination approaches across our core scientific modalities.”

Key ASH Presentations

Data from more than 75 company-sponsored, investigator-sponsored, and collaborative research abstracts will be presented at ASH, including updated analyses from the pivotal ECHELON-3 trial supporting the clinical benefit of ADCETRIS® (brentuximab vedotin) in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). New data for ELREXFIO® (elranatamab-bcmm) in relapsed/refractory multiple myeloma (RRMM) will also be presented from the pivotal MagnetisMM-3 trial, as well as Phase 1 combination data from the MagnetisMM-20 trial. Pfizer will also present updates from its growing Hematology-Oncology pipeline, which includes next-generation CD30 antibody-drug conjugates and other novel and differentiated molecules, including the first presentation of combination data for SEA-CD70 in high-risk myelodysplastic syndromes.

Additionally, Pfizer will present results across its portfolio of investigational and approved medicines in benign hematology.

ADCETRIS: Additional analyses from the Phase 3 ECHELON-3 trial will be presented, highlighting the durability of complete responses and consistent benefit of ADCETRIS in combination with lenalidomide and rituximab in patients with relapsed/refractory DLBCL, including enrollment of elderly patients, those who are refractory to most recent treatment, and those who have received prior CAR-T therapy. These findings also underscore the overall survival (OS) advantage over lenalidomide and rituximab plus placebo in patients who have received at least two prior lines of therapy. In addition, updated two-year follow-up data from a Phase 2 study investigating the combination of ADCETRIS, nivolumab, doxorubicin, and dacarbazine in newly diagnosed early-stage classical Hodgkin lymphoma (cHL) will be presented highlighting promising efficacy and safety of this investigational novel combination.**ELREXFIO:** A post hoc analysis of the Phase 2 MagnetisMM-3 trial continues to show deep and durable responses after longer-term follow-up of nearly three years, and these responses were also maintained with a reduction to once-monthly dosing in RRMM. Data will also be shared from the ongoing Phase 1b MagnetisMM-20 trial that indicate encouraging clinical efficacy and predictable safety signals with ELREXFIO in combination with carfilzomib and dexamethasone after a median of two prior lines of therapy (range: one to three).**SEA-CD70 (PF-08046040):** Encouraging preliminary data from the ongoing Phase 1 study with PF-08046040, also known as SEA-CD70, a nonfucosylated monoclonal antibody targeting CD70 that is

designed to enhance effector function, will be shared for the first time from the combination dose-optimization cohort with azacitidine in patients with higher-risk myelodysplastic syndromes (MDS). SEA-CD70 is being developed with the goal of being a best-in-class foundational medicine either alone or as combination treatment in myeloid malignancies.

Key SABCS Presentations

Data from 30 company-sponsored, investigator-sponsored, and collaborative research abstracts will be presented at SABCS, including nine real-world analyses affirming IBRANCE[®] (palbociclib) as a first-line standard-of-care treatment for hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC). The company will also present new data from its expanding pipeline of innovative, next-generation therapy candidates that have the potential to address critical unmet patient needs across all subtypes and stages of breast cancer, including new and updated Phase 1 data for atirmociclib, vepdegestrant, and the novel KAT6 inhibitor, PF-07248144.

IBRANCE : In P-VERIFY, the largest-ever real-world comparative overall survival analysis of first-line CDK4/6 inhibitors plus aromatase inhibitor (AI) therapy in HR+/HER2- MBC, numerically similar overall survival rates were observed across CDK4/6 inhibitor groups at 12, 24, and 30 months.**Atirmociclib (PF-07220060)**: Updated data will be presented from a Phase 1/2a study of atirmociclib, a next-generation, highly selective CDK4 inhibitor, in combination with letrozole as a potential first-line treatment for patients with HR+/HER2- MBC. Atirmociclib is being developed as a potential future CDK inhibitor backbone therapy in HR+ MBC, and a Phase 3 study in the first-line setting is anticipated to start by early 2025.**Vepdegestrant**: For the first time, initial Phase 1b data will be shared from the Phase 1b/2 TACTIVE-U trial evaluating the combination of vepdegestrant, a potential first-in-class PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, in combination with abemaciclib in patients with ER+/HER2- locally advanced or MBC. These data reinforce the potential of vepdegestrant as a new backbone endocrine therapy, and Pfizer and Arvinas anticipate topline Phase 3 data evaluating vepdegestrant as a monotherapy in the first quarter of 2025.**KAT6 (PF-07248144)** : Updated efficacy and safety data will be presented from a Phase 1 dose-expansion study of PF-07248144, a novel KAT6 inhibitor, in heavily pretreated ER+/HER2- MBC. These early data continue to provide strong clinical proof of concept for this novel target as a potential new treatment approach for ER+/HER2- MBC, and Pfizer anticipates initiating a Phase 3 study for PF-07248144 in the post-CDK4/6 inhibitor setting in mid-2025.

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

https://www.pfizer.com/ASH_and_SABCS_2024_Sponsored_Abstacts.

Blood Cancers

Updated Analysis of Brentuximab Vedotin, Nivolumab, Doxorubicin, and Dacarbazine for Nonbulky, Early-Stage Classical Hodgkin Lymphoma (Abstract #460)

Abramson J

Oral Presentation

Sunday, December 8, 9:30-11:00 AM PST

Presentation Time: 10:15 AM PST

Efficacy of Elranatamab (ELRA) in Combination with Carfilzomib (CFZ) and Dexamethasone (DEX) in the Phase 1b MagnetisMM-20 Trial in Relapsed or Refractory Multiple Myeloma (RRMM) (Abstract #1024)

Tomasson MH

Oral Presentation

Monday, December 9, 4:30-5:30 PM PST

Presentation Time: 5:15 PM PST

PF-08046040 (SEA-CD70), a Nonfucosylated CD70-Directed Antibody, in Combination with Azacitidine for Patients with Myelodysplastic Syndromes (MDS): A Phase 1 Dose-Finding and Dose Expansion Study (Abstract #1840)

Poster Presentation

Saturday, December 7, 5:30-7:30 PM PST

Durability of Complete Responses in Patients from the ECHELON-3 Study (Abstract #3101)

Yasenchak C

Poster Presentation

Sunday, December 8, 6:00-8:00 PM PST

MagnetisMM-3: Long-Term Update and Efficacy and Safety of Less Frequent Dosing of Elranatamab in Patients with Relapsed or Refractory Multiple Myeloma (Abstract #4738)

Prince M

Poster Presentation

Monday, December 9, 6:00-8:00 PM PST

Outcomes in Older Patients with Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) from the ECHELON-3 Study (Abstract #4483)

Bartlett N

Poster Presentation

Monday, December 9, 6:00-8:00 PM PST

Outcomes by Refractory Status and Prior Therapies Received in Patients with Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) from the ECHELON-3 Study (Abstract #4489)

Hahn U

Poster Presentation

Monday, December 9, 6:00-8:00 PM PST

Hemophilia

Efficacy and Safety of Giroctocogene Fitelparvovec in Adults with Moderately Severe to Severe Hemophilia A: Primary Analysis Results from the Phase 3 AFFINE Gene Therapy Trial (Abstract #1053)

Leavitt AD

Oral Presentation

Monday, December 9, 4:30-6:00 PM PST

Presentation Time: 5:00 PM PST

Descriptive Characterization of Bleeding Events in Participants with Severe Hemophilia A or B without Inhibitors, Receiving Prophylactic Marstacimab Treatment (Abstract #716)

Matino D

Oral Presentation

Monday, December 9, 10:30 AM-12:00 PM PST

Presentation Time: 10:45 AM PST

Sickle Cell Disease

Qualitative Interview Study to Characterize the Treatment Experiences of Participants with Sickle Cell Disease and Assess Perceptions of Red Blood Cell Transfusions (Abstract #3691)

Kosa K

Poster Presentation

Sunday, December 8, 6:00-8:00 PM PST

Breast Cancer

Comparative overall survival of CDK4/6is plus an aromatase inhibitor (AI) in HR+/HER2-MBC in the US real-world setting

Rugo et al

Poster Spotlight Presentation (PS2-03)

Thursday, December 12, 7:00-8:30 AM CST

PF-07248144, a first-in-class KAT6 inhibitor, in patients with HR+ HER2– metastatic breast cancer: Updated results from phase 1 dose expansion study

Mukohara et al

Poster Presentation (P4-10-28)

Thursday, December 12, 5:30-7:00 PM CST

Vepdegestrant, a PROteolysis TARgeting Chimera (PROTAC) Estrogen Receptor (ER) Degradar, Plus Abemaciclib in ER-Positive/Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Advanced or Metastatic Breast Cancer: TACTIVE-U Preliminary Phase 1b Results

Hilton et al

Poster Presentation (P4-12-03)

Thursday, December 12, 5:30-7:00 PM CST

The next-generation CDK4-selective inhibitor atirmociclib (PF-07220060) in combination with letrozole as first-line treatment in patients with HR+/HER2+ metastatic breast cancer

Giordana et al

Poster Presentation (P5-07-28)

Friday, December 13, 12:30-2:00 PM CST

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 Rare Disease

There are over 10,000 known rare diseases that affect approximately 400 million people worldwide. 80% of these diseases have genetic origins and 50% affect children. Collectively, people living with a rare disease represent one of the largest underserved patient communities in the world, with less than 10% of known rare diseases having one or more approved treatments.

At Pfizer, we believe that people living with a rare disease, along with the untold number of family members and caregivers who support them, deserve more. For more than 40 years, we have provided critical treatment options for patients with rare diseases including 11 Pfizer Rare Disease medicines that have received regulatory approval.

Prescribing Information for Pfizer Medicines

Please read full Prescribing Information, including BOXED WARNING, for ADCETRIS.

Please read full Prescribing Information, including BOXED WARNING, for ELREXFIO.

Please read full Prescribing Information for HYMPAVZI.

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

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 December 5, 2024. 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 hematology and breast cancer portfolio and pipeline, ADCETRIS (brentuximab vedotin), ELREXFIO (elranatamab-bcmm), SEA-CD70 (PF-08046040), IBRANCE (palbociclib), atirmociclib (PF-07220060), vepdegestrant, and the novel KAT6 inhibitor, PF-07248144, 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 breast cancer and hematology 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; 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 for any potential indications for brentuximab vedotin, elranatamab-bcmm, PF-08046040, palbociclib, PF-07220060, vepdegestrant, and PF-07248144, or any other product candidates; whether and when any applications that may be pending or filed for brentuximab vedotin, elranatamab-bcmm, PF-08046040 or any such other 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 brentuximab vedotin, elranatamab-bcmm, PF-08046040, palbociclib, PF-07220060, vepdegestrant, and PF-07248144, or any such other 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 brentuximab vedotin, elranatamab-bcmm, PF-08046040, palbociclib, PF-07220060, vepdegestrant, and PF-07248144, or any such other product candidates; uncertainties regarding 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, 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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Source: Pfizer Inc.