Pfizer Oncology to Present Data Across 13 Different Types of Cancer at ASCO 2017 Annual Meeting

Wednesday, May 17, 2017 - 04:00pm

Data to be Presented on More Than 15 Clinical-Stage Assets in Both Solid and Hematologic Tumors

Pfizer Inc. (NYSE:PFE) today announced it will present more than 50 abstracts, involving more than 15 clinical-stage assets across solid and hematologic tumors and 12 mechanisms of action, at the 53rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago from June 2-6, 2017.

New data will be featured in nine oral presentations from company-sponsored clinical trials, including a late-breaker on the investigational compound dacomitinib in locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutation, which will be featured in the official ASCO press program. Other abstracts provide insights into treating lung, breast, kidney and prostate cancers and hematologic malignancies across marketed and investigational Pfizer therapies, including immuno-oncology (IO) and IO combinations.

“While tremendous strides in cancer are made every day, it’s clear there is so much more to achieve on behalf of patients,” said Liz Barrett, Global President and General Manager, Pfizer Oncology. “Through our cutting-edge science and a desire to work collaboratively, Pfizer Oncology continues to break boundaries in cancer care and is helping to redefine life with cancer.”

“Our presentations at this year’s ASCO cover a broad range of drug development: from Phase 1 to Phase 3; from immunotherapy to targeted agents and antibody-drug conjugates; from disease areas in which we have extensive experience to disease areas that we are entering for the first time,” said Mace Rothenberg, MD, Chief Development Officer, Oncology, Pfizer Global Product Development. “We are very excited about sharing these results with the oncology community and working with them to realize the full potential of our medicines.”

Hematology Highlights

New clinical data from a broad range of therapies will be presented, providing insights into potential treatments for several blood cancers, including acute and chronic leukemias.

Key abstracts in investigational settings include:

Bosutinib versus imatinib for newly diagnosed chronic myeloid leukemia (CML): initial results from the phase 3 BFORE trial Factors associated with allogeneic hematopoietic stem cell transplantation outcomes in patients with relapsed/refractory acute lymphoblastic leukemia treated with inotuzumab ozogamicin versus conventional chemotherapy

Lung Cancer Highlights

New data will be highlighted for two investigational NSCLC therapies that target EGFR and anaplastic lymphoma kinase (ALK) genetic alterations and reinforce the increasingly important role that biomarker-driven treatments are playing across lung cancers.

Key abstracts include:

Dacomitinib versus gefitinib for the first-line treatment of advanced EGFR mutation positive non-small cell lung cancer (ARCHER 1050): A randomized, open-label phase 3 trial Efficacy and safety of lorlatinib in ALK+ non-small-cell lung cancer patients with ≥1 prior ALK tyrosine kinase inhibitor: A phase I/II study

Breast Cancer Highlights

Pfizer is also working to expand treatment options for patients with a certain type of metastatic breast cancer with talazoparib, an investigational, dual-mechanism PARP inhibitor. Results from a Phase 2 study of talazoparib will be presented. In addition, updated overall survival data from the PALOMA-1 study of IBRANCE® (palbociclib) will be shared.

Key abstracts include:

Results of a phase 2 study of talazoparib following platinum or multiple cytotoxic regimens in advanced breast cancer patients with germline BRCA1/2 mutations (ABRAZO)
Overall survival results from the randomized phase 2 study of palbociclib in combination with letrozole vs letrozole alone for first-line treatment of ER+/HER2– advanced breast cancer (PALOMA-1; TRIO-18)

Renal Cell Carcinoma Highlights

For the past 10 years, Pfizer has been a leader in developing new treatments for patients with advanced kidney cancer. Building on this experience, Pfizer is sharing early data from a novel immuno-therapy combination with INLYTA® (axitinib) and PD-L1 inhibitor avelumab in advanced renal cell carcinoma (RCC), being developed in collaboration with Merck KGaA, Darmstadt, Germany. Further, a sub-analysis from the use of SUTENT® (sunitinib) in the adjuvant RCC setting will also be presented.

Key abstracts in investigational settings include:

First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma (aRCC): results from a phase 1b trial
A phase 3 trial of adjuvant sunitinib in patients with high-risk renal cell carcinoma (RCC): validation of the 16-gene Recurrence Score in stage III patients

Prostate Cancer Highlights

New clinical data provide insights into combination of agents most likely to benefit patients with metastatic castration-resistant prostate cancer (CRPC) following PSA progression with enzalutamide, adding to the robust and rigorous clinical trial program of XTANDI® (enzalutamide) in metastatic CRPC and other prostate cancer populations.

Key abstracts include:

A phase 4, randomized, double-blind, placebo-controlled study of continued enzalutamide post prostate-specific antigen progression in men with chemotherapy-naïve metastatic castration-resistant prostate cancer

Pfizer-Sponsored Studies Oral Presentation Planner

Title/Abstract Number Date/Time (CDT) Location

(Abstract 1001) Overall survival results from the randomized phase 2 study of palbociclib in combination with letrozole (L) vs letrozole alone for first-line treatment of ER+/HER2– advanced breast cancer (PALOMA-1; TRIO-18) Finn R

Saturday, June 3 1:27 - 1:39 p.m.

Hall D1

(Abstract 5004) A phase 4, randomized, double-blind, placebo-controlled study of continued enzalutamide post prostate-specific antigen progression in men with chemotherapy-naïve metastatic castration-resistant prostate cancer Attard G

Saturday, June 3 2:27 - 2:39 p.m.

Hall B1

(Abstract 1007) Final results of a phase 2 study of talazoparib following platinum or multiple cytotoxic regimens in advanced breast cancer patients with germline BRCA1/2 Mutations (ABRAZO) Turner NC

Saturday, June 3 3:27 - 3:39 p.m.

Hall D1

(Abstract 4504) First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma: results from a phase 1b trial Choueiri TK

Monday, June 5 9:12 - 9:24 a.m.

Arie Crown Theater

(Abstract 4508) Phase 3 trial of adjuvant sunitinib in patients with high-risk renal cell carcinoma (RCC): Validation of the 16-gene Recurrence Score in stage III patients Escudier B

Monday, June 5 10:24 - 10:36 a.m.

Arie Crown Theater

(Abstract 7002) Bosutinib vs imatinib for newly diagnosed chronic myeloid leukemia (CML): initial results from the BFORE trial Cortes JE

Tuesday, June 6 10:09 - 10:21 a.m.

E450ab
(Abstract 9006) Efficacy and safety of lorlatinib in ALK+ non-small-cell lung cancer patients with ≥1 prior ALK tyrosine kinase inhibitor: A phase I/II study Shaw A

Tuesday, June 6 11:45 - 11:57 a.m.

Hall D1
(Abstract 7007) Factors associated with allogeneic hematopoietic stem cell transplantation outcomes in patients with relapsed/refractory acute lymphoblastic leukemia treated with inotuzumab ozogamicin versus conventional chemotherapy Kebriaei P

Tuesday, June 6 11:57 a.m. - 12:09 p.m.

E450ab
(Abstract LBA9007) Dacomitinib versus gefitinib for the first-line treatment of advanced EGFR mutation positive non-small cell lung cancer (ARCHER 1050): A randomized, open-label phase 3 trial Mok T

Tuesday, June 6 11:57 a.m. - 12:09 p.m.
Hall D1

For a complete list of Pfizer-sponsored abstracts featuring data on our broad pipeline of biologics and small molecules, please visit:
http://www.pfizer.com/files/news/2017_ASCO_Pfizer_Data_Presentation_Fact_Sheet_FINAL_4.20.

Learn more about how Pfizer Oncology is applying innovative approaches to improve the outlook for people living with cancer
at http://www.pfizer.com/research/therapeutic_areas/oncology.

Additionally, Pfizer and Astellas announced the discontinuation of the planned ENDEAR trial (A Phase III, Randomized, International Study Comparing the Efficacy and Safety of

Enzalutamide in Combination With Paclitaxel Chemotherapy or as Monotherapy Versus Placebo With Paclitaxel in Patients With Advanced, Diagnostic-Positive, Triple-Negative Breast Cancer); no patients were ever enrolled in the trial. Furthermore, the companies have decided that based on the data from the enzalutamide Phase 2 HER2+ and ER/PR+ breast cancer studies, there will not be follow-on Phase 3 studies at this time.

*Enzalutamide is developed through a collaboration between Pfizer and Astellas and commercialized under the brand name XTANDI®.

Dacomitinib, lorlatinib, inotuzumab ozogamicin and talazoparib are investigational agents and have not been approved by any regulatory agencies.

Please see full Prescribing Information for BOSULIF® (bosutinib) at http://labeling.pfizer.com/ShowLabeling.aspx?id=884.

Please see full Prescribing Information for IBRANCE® (palbociclib) at http://labeling.pfizer.com/ShowLabeling.aspx?id=2191.

Please see full Prescribing Information for INLYTA® (axitinib) at http://labeling.pfizer.com/ShowLabeling.aspx?id=759.

Please see full Prescribing Information for SUTENT® (sunitinib malate), Including Boxed Warning, at http://labeling.pfizer.com/showlabeling.aspx?id=607.

Please see full Prescribing Information for XTANDI® (enzalutamide) at https://www.astellas.us/docs/us/12A005-ENZ-WPI.pdf?v=1.

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on those living with cancer. As a leader in oncology speeding cures and accessible breakthrough medicines to patients, Pfizer Oncology is helping to redefine life with cancer. Our strong pipeline of biologics, small molecules and immunotherapies, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments and licensing partners, Pfizer Oncology strives to cure or control cancer with its breakthrough medicines. Because Pfizer Oncology knows that success in oncology is not measured solely by the medicines you manufacture, but rather by the meaningful partnerships you make to have a more positive impact on people’s lives.

Pfizer Inc.: Working together for a healthier worldTM

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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. 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 150 years, Pfizer has 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 @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE:

The information contained in this release is as of May 17, 2017. 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 marketed and investigational oncology portfolio, including its 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 products; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with initial data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; 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

indications for Pfizer’s oncology products and product candidates; whether and when any drug applications that are pending or that may be filed may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Pfizer’s oncology products and product candidates; 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, 2016 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.

Media Contact: Sally Beatty (212) 733-6566 Investor Contact: Chuck Triano (212) 733-3901