U.S. FDA and European Medicines Agency Accept Regulatory Submissions for Review of Talazoparib for Metastatic Breast Cancer Patients with an Inherited BRCA Mutation

Thursday, June 07, 2018 - 04:00am

U.S. New Drug Application Granted FDA Priority Review Submissions Based on Data from EMBRACA, the Largest Phase 3 Trial Performed to Date of a PARP Inhibitor in BRCA-mutated MBC

Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration accepted for filing and granted Priority Review designation to the company's New Drug Application for talazoparib. The submission is based on results from the EMBRACA trial, which evaluated talazoparib versus chemotherapy in patients with germline (inherited) BRCA-mutated (gBRCAm), HER2-negative locally advanced or metastatic breast cancer (MBC). Talazoparib is an investigational, once-daily, oral poly ADP ribose polymerase (PARP) inhibitor. The European Medicines Agency has also accepted the Marketing Authorization Application for talazoparib in this patient population.

"Women with a hereditary BRCA mutation are typically diagnosed with breast cancer at a younger age than the overall breast cancer population and have limited treatment options when they develop advanced disease," said Mace Rothenberg, M.D., chief development officer, Oncology, Pfizer Global Product Development. "Today's filing acceptances are just the latest example of the success of Pfizer's precision medicine approach to drug development, in this case targeting the faulty DNA damage repair process associated with BRCA mutations. We are now one step closer to offering a

potential alternative to chemotherapy for these patients.”

The FDA grants Priority Review designation to medicines that may offer significant advances in treatment or may provide a treatment where no adequate therapy exists. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in December 2018.

The pivotal, randomized EMBRACA trial evaluated once-daily talazoparib compared to physician’s choice chemotherapy (capecitibine, eribulin, gemcitabine or vinorelbine) in 431 patients with an inherited BRCA1/2 mutation and locally advanced or metastatic triple negative (TNBC) or hormone receptor-positive (HR+)/HER2- breast cancer. The study met its primary endpoint, demonstrating superior progression-free survival (PFS) with talazoparib versus chemotherapy. The PFS benefit was consistent across prespecified subgroups, including those who had a history of brain metastases, patients previously treated with chemotherapy, TNBC patients and those with HR+ disease. Grade ≥3 adverse reactions with talazoparib that occurred with a frequency of at least 10% were anemia (35%), neutropenia (17%) and thrombocytopenia (17%). The primary results were presented at the 2017 San Antonio Breast Cancer Symposium. For more information on the EMBRACA trial, go to www.clinicaltrials.gov.

About Talazoparib

Talazoparib is an investigational anti-cancer medicine called a PARP (poly ADP ribose polymerase) inhibitor. Preclinical studies suggest that talazoparib is highly potent and has a dual mechanism of action, with the potential to induce tumor cell death by blocking PARP enzyme activity and trapping PARP on the sites of DNA damage. Talazoparib is currently being evaluated in advanced gBRCAm breast cancer and early triple negative breast cancer as well as DNA damage repair (DDR)-deficient prostate cancer and in combination with immunotherapy in various solid tumor types. Talazoparib has not been approved by any regulatory authorities for the treatment of any disease.

About Germline (Inherited) BRCA-Mutated Breast Cancer

BRCA1 and BRCA2 are human genes that produce proteins involved in DNA repair. When either of these genes is altered or mutated, DNA repair may not progress correctly. This can lead to the development of certain types of cancer such as breast cancer.1,2,3 BRCA mutations can be hereditary (germline) or occur spontaneously (somatic).1 Together, BRCA1 and BRCA2 mutations account for about 25 to 30 percent of hereditary breast cancers and about 5 to 10 percent of all breast cancers.4,5 It is estimated that about 72 percent of people who inherit a BRCA1 mutation and about 69 percent who inherit a

BRCA2 mutation will develop breast cancer by age 80.1 Epidemiologic studies indicate that individuals with gBRCAm breast cancer are diagnosed at a median age of 40-45, which is approximately 20 years younger than the overall breast cancer population.6

BRCA-mutated breast cancer is considered metastatic if it has spread beyond the breast to other parts of the body, including the bones, liver, lung or brain. There is currently no cure for metastatic breast cancer, the most advanced stage (stage IV) of the disease. The goal of treatment is to delay or slow disease progression while maintaining quality of life.7

About Pfizer Oncology

Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on people living with cancer. Our growing pipeline of biologics, small molecules and immunotherapies is focused on identifying and translating the best scientific breakthroughs into clinical application for patients across a diverse array of solid tumors and hematologic cancers. Today, we have 10 approved oncology medicines and 14 assets currently in clinical development. By maximizing our internal scientific resources and collaborating with other companies, government and academic institutions, as well as patients and non-profit and professional organizations, we are bringing together the brightest and most enterprising minds to take on the toughest cancers. Together we can accelerate breakthrough treatments to patients around the world and work to redefine life with cancer.

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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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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, 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 Twitter at

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DISCLOSURE NOTICE: The information contained in this release is as of June 7, 2018. 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 a product candidate, talazoparib, and Pfizer's oncology portfolio, 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, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical 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 new drug applications may be filed in any other jurisdictions for talazoparib or any other oncology products; whether and when the applications for talazoparib pending with the FDA and the European Medicines Agency or any such other applications that may be pending or 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, and, if approved, whether talazoparib or any such other oncology products will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of talazoparib or other oncology products; 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, 2017 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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