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Pfizer Provides Update on IBRANCE® (palbociclib)

Thursday, January 08, 2015 - 03:30am

The U.S. Food and Drug Administration (FDA) has informed Pfizer Inc. that at this time there is no plan for an Oncologic Drugs Advisory Committee meeting for IBRANCE® (palbociclib). Pfizer continues to have an open and productive dialogue with the FDA as the application for IBRANCE advances. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is April 13, 2015. The Company reports that it has entered label discussions with the FDA and hopes to be able to bring IBRANCE to patients who need it as soon as possible.

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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, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE*: The information contained in this release is as of January 8, 2015. 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 IBRANCE (palbociclib), an investigational therapy, 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, 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; whether the PALOMA-2 Phase 3 trial of palbociclib for the potential indication for the treatment of postmenopausal women with ER+, HER2- advanced breast cancer who have not received previous systemic treatment for their advanced disease (the "Potential Indication") will demonstrate a statistically significant improvement in progression-free survival and whether the other Phase 3 trials of palbociclib will meet their primary endpoints; 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 other jurisdictions for the Potential Indication or in any jurisdictions for any other potential indications for palbociclib; whether and when the new drug application for the Potential Indication or any such other applications may be approved by the FDA or other 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 the FDA and

other regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of the Potential Indication or any other such indications; 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, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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