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# EMA Adopts Opinion On Taliglucerase Alfa Marketing Authorization Application

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) and Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX) today announced that the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has adopted an Opinion recommending against the Marketing Authorization of taliglucerase alfa, an enzyme replacement therapy (ERT) for the treatment of Gaucher disease. As part of its Opinion, the CHMP gave a positive risk-benefit assessment for taliglucerase alfa concluding that the benefits of the medicine outweighed its risks in the treatment of Type 1 Gaucher disease.

Despite the positive risk-benefit assessment, the Committee could not recommend Marketing Authorization due to Shire's velaglucerase alfa, which received prior Marketing Authorization with orphan drug designation for the same condition. Therefore, Shire's treatment has orphan market exclusivity in the European Union (EU) for ten years from the time of its authorization in August 2010. Pfizer pursued a request for derogation from Shire's orphan market exclusivity based on a number of factors. This request, however, was denied.

"While we are disappointed by the CHMP's recommendation, we are encouraged that the Committee gave a positive risk-benefit assessment. The recommendation was based solely on orphan market exclusivity and not the safety and efficacy profile of taliglucerase alfa," said Diem Nguyen, General Manager Biosimilars. "Pfizer will continue to work with relevant stakeholders to determine appropriate next steps."

Pfizer and Protalix are dedicated to the treatment of Gaucher disease worldwide and continue to move forward with other global regulatory filings for taliglucerase alfa. Taliglucerase alfa (ELELYSO™) was approved by the U.S. Food and Drug Administration on May 1, 2012 for the long term enzyme replacement therapy (ERT) of adults with a confirmed diagnosis of Type 1 Gaucher disease.

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa. Under the terms of the agreement, Pfizer received exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix retained the exclusive commercialization rights in Israel.

**Pfizer Inc.: Working together for a healthier world™**

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's

best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments visit www.pfizer.com.

**Protalix BioTherapeutics Inc.**

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell based expression system, ProCellEx(R). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first approved product manufactured by ProCellEx, ELELYSO™ (taliglucerase alfa), an enzyme replacement therapy for the treatment of Gaucher disease, was approved for marketing by the U.S. Food and Drug Administration on May 1, 2012. Additional marketing applications for taliglucerase alfa have been filed in other countries.

This release contains forward-looking statements about ELELYSO that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties related to the timing of a commercial launch and market acceptance in the United States; decisions by regulatory authorities in other countries regarding whether and when to approve drug applications that have been or may be filed for ELELYSO as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of June 22, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or 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, 2011 and in its reports on Form 10-Q and Form 8-K.

Protalix Forward Looking Statement Disclaimer

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The statements in this release are valid only as of the date hereof and Protalix disclaims any obligation to update this information. These and other risks and uncertainties are detailed under the heading "Risk Factors" in Protalix's Annual Report on Form 10-K for the year ended December 31, 2011 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

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