Pfizer and Protalix BioTherapeutics Announce Submission of taliglucerase alfa for European Marketing Authorization for the Treatment of Gaucher Disease

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NEW YORK and CARMIEL, Israel--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX, TASE: PLX) today announced the submission of a Marketing Authorization Application to the European Medicines Agency for taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD)for the treatment of Gaucher disease. Taliglucerase alfa was granted Orphan Designation by the European Commission for the treatment of Gaucher disease on March 23, 2010.

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.

Taliglucerase alfa was granted orphan drug designation by the U.S. Food and Drug Administration. A New Drug Application (NDA) for taliglucerase alfa has been accepted by the FDA and assigned a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011. Taliglucerase alfa is available to patients with Gaucher disease in the United States under an Expanded Access protocol as well as to patients in several member states of the European Union, Israel and other countries under Named Patient provisions.

DISCLOSURE NOTICE: The information contained in this release is as of November 29, 2010. Neither Pfizer nor Protalix BioTherapeutics assumes any obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

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. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others, risks relating to: the review process of the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMEA), other foreign regulatory bodies and other governmental regulatory bodies, including the risk that regulatory authorities may find that the data from Protalix BioTherapeutics' clinical trials and other studies is insufficient for regulatory approval; delays in the FDA's, the EMEA's or other health regulatory authorities' approval of any applications Protalix BioTherapeutics and/or Pfizer file or refusals to approve such filings, including the New Drug Application (NDA) filed with the FDA and the Marketing Authorization Application (MAA) submitted to the EMEA for taliglucerase alfa for the treatment of Gaucher disease; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application filed for any such drug product; risks relating to the decisions of the FDA, EMEA and other foreign regulatory authorities regarding labeling and other matters that could affect the commercial availability or potential of taliglucerase alfa; risks relating to competitive developments regarding taliglucerase alfa; and other factors described in Pfizer's and Protalix BioTherapeutics' filings with the Securities and Exchange Commission. Even if favorable testing data is generated from clinical trials of drug products, the FDA, EMEA or any other foreign regulatory authority may not accept or approve an NDA or MAA, as applicable, filed by a pharmaceutical or biotechnology company for such drug product.

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