# European Medicines Agency's COMP Adopts Positive Opinion for the Orphan Drug Designation for Protalix's taliglucerase alfa

January 13, 2010

Jan. 13, 2010 (PR Newswire) --

CARMIEL, Israel, Jan. 13 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX), announced today that the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMEA), after reviewing all relevant clinical data, has recommended that the European Commission grant orphan drug designation to taliglucerase alfa, the Company's proprietary plant cell expressed recombinant form of glucocerebrosidase for the treatment of Gaucher disease. The U.S. Food and Drug Administration (FDA) granted orphan drug designation and fast track designation to taliglucerase alfa in 2009.

Orphan drug designation in Europe is granted to medicinal products intended for the diagnosis, prevention and treatment of life-threatening diseases and very serious conditions that affect not more than five in 10,000 people in the European Union. Orphan drug designation is generally given to medicinal products that treat conditions for which no current therapy exists or are expected to bring a significant benefit to patients over existing therapies. If granted by the European Commission, orphan drug designation will provide the Company with a centralized procedure for obtaining marketing authorization for taliglucerase alfa, with a single marketing authorization valid throughout all EU Member States. The Company may also be eligible for a number of additional incentives including protocol assistance, reduction in registration fees and eligibility for grants and initiatives supporting research and development related to the orphan drug designation.

"This is an important step in our global commercialization strategy for taliglucerase alfa," said Dr. Einat Brill Almon, the Company's Senior Vice President, Product Development. "We plan to file a marketing authorization application with the European Medicines Agency for taliglucerase alfa in the upcoming months."

The Company reported positive top-line results from its pivotal phase III clinical trial of taliglucerase alfa in October 2009. Full results from this study will be presented at the Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2010, February 10-12, in Miami, Florida. In addition, the Company completed the filing of a New Drug Application for taliglucerase alfa with the FDA in December 2009.

In November 2009, the Company entered into a license and supply agreement with Pfizer Inc. (NYSE: PFE) pursuant to which the Company granted Pfizer the exclusive worldwide rights to develop and commercialize taliglucerase alfa for the treatment of Gaucher disease, except for Israel. The Company retained the right to develop and commercialize taliglucerase alfa in Israel.

About Gaucher disease

Gaucher disease, an inherited condition, is the most prevalent lysosomal storage disorder, with an incidence of about 1 in 20,000 live births. People with Gaucher disease do not have enough of an enzyme, beta-glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins expressed through its proprietary plant cell based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease.

Safe Harbor Statement:

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. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others, risks relating to: the successful preclinical development of our product candidates; the completion of clinical trials; the review process of the FDA, the EMEA, other foreign regulatory bodies and other governmental regulatory bodies, including the FDA's and the EMEA's review of any filings we make in connection with the treatment protocol; delays in the FDA's, the EMEA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; the identification of lead compounds; the risk that we may fail to satisfy certain conditions relating to grants we have received from the Office of the Chief Scientist of Israel's Ministry of Industry and Trade which may lead to our being required to refund grants previously received together with interest and penalties; the risk that the Office of the Chief Scientist may not deliver to us all of the funds awarded to us; uncertainties related to the ability to attract and retain partners for our technologies and products under development; and other factors described in our filings with the Securities and Exchange Commission. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical

trials of drug products, the FDA, EMEA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA, EMEA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.


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SOURCE Protalix BioTherapeutics, Inc.


Source: PR Newswire (January 13, 2010 - 7:30 AM EST)