Protalix BioTherapeutics Receives PDUFA Date for taliglucerase alfa

July 12, 2010

CARMIEL, Israel, July 12, 2010 /PRNewswire via COMTEX/ --

Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX), announced today that the Company's New Drug Application (NDA) for taliglucerase alfa has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA granted taliglucerase alfa a standard review time of ten months, assigning a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011. Taliglucerase alfa is the Company's proprietary plant cell expressed recombinant form of human Glucocerebrosidase (GCD) which is being developed for the treatment of Gaucher disease under a Special Protocol Assessment (SPA) with the FDA. Following the completion of a phase III clinical trial of taliglucerase alfa, the Company completed the submission of a rolling NDA with the FDA in April 2010.

"If approved, taliglucerase alfa will be an attractive and important therapeutic option for Gaucher patients," said Dr. David Aviezer, President and Chief Executive Officer of Protalix. "We look forward to working closely with the agency through this final stage of the review process."

Taliglucerase alfa has been granted orphan drug designation from the FDA in the United States. The Company continues to make taliglucerase alfa available to Gaucher patients in the United States under an Expanded Access protocol, as well as to patients in the European Union, Israel and other countries under Named Patient provisions.

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. Protalix filed a rolling NDA submission with the FDA in December 2009. In November 2009, Protalix granted Pfizer Inc. exclusive, worldwide rights to develop and commercialize taliglucerase alfa for the treatment of Gaucher disease, except in Israel. Protalix retained the right to commercialize taliglucerase alfa in Israel.

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 completion of our 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 for taliglucerase alfa, including the risk that regulatory authorities may find that the data from our 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 we file or refusals to approve such filings, including the NDA we filed with the FDA or 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 we file for any such drug product; 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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