Protalix BioTherapeutics Announces FDA Accepts for Review Complete Response Resubmission for Taliglucerase Alfa and Assigns PDUFA Date

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Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX, TASE:PLX), announced today that the U.S. Food & Drug Administration (FDA) has accepted for review the resubmission of the taliglucerase alfa New Drug Application (NDA) following the Company's receipt of a Complete Response Letter (CRL) in February 2011. The FDA deemed the resubmission a class 2, or 6-month, response and established February 1, 2012 as the Prescription Drug User Fee Act (PDUFA) date. 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.

"We look forward to working with the FDA in moving taliglucerase alfa through the regulatory review process over the next few months," stated Dr. David Aviezer, President and CEO of Protalix.

The Company's submission addresses the questions posed by the FDA in the CRL, including the request for clinical data from the Company's switchover trial and long-term extension trial, and additional information relating to chemistry, manufacturing and controls (CMC).

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa.

"Pfizer has worked closely with Protalix to achieve this important milestone," said Diem Nguyen, General Manager, Biosimilars. "Pfizer is ready to make taliglucerase alfa commercially available to Gaucher patients in the United States, if approved by the FDA."

About Protalix

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(TM). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner in an environment free of mammalian components and viruses. Protalix's lead compound, taliglucerase alfa, an enzyme replacement therapy for the treatment of Gaucher disease, completed Phase III development. To date, marketing applications have been submitted for taliglucerase alfa in the United States, the European Union, Brazil, Israel and Australia. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel(TM)) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; and others.

Forward Looking Statements

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 terms "anticipate," "believe," "estimate," "expect" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. 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: the FDA may find that the information we provided in our reply to the Complete Response Letter is insufficient for regulatory approval; risks relating to the review process of the FDA, the European Medicines Agency (EMA), other foreign regulatory bodies and other governmental regulatory bodies, including the risk that regulatory authorities may find that the data from our clinical trials and other studies is insufficient for regulatory approval; risks relating to delays in the FDA's, the EMA's or other foreign regulatory authorities' approval of any applications we file or refusals to approve such filings, including the NDA we filed with the FDA for taliglucerase alfa for the treatment of Gaucher disease; our facilities may fail to remain complaint with GMP (Good Manufacturing Practices); applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application we file for the drug product; risks relating to the completion of our clinical trials; 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 from clinical trials of drug products, the FDA, EMA 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, EMA 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 operations 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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