Protalix Announces Successful European GMP Audit

December 1, 2011

CARMIEL, Israel, Dec. 1, 2011 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE-AMEX:PLX, TASE:PLX), announced today that the Irish Medicines Board (IMB) has completed a successful GMP (Good Manufacturing Practice) audit of the Company's manufacturing facility in Carmiel, Israel, and has issued a Certificate of GMP Compliance of a Manufacturer for the facility. The IMB Certificate is accepted by all health authorities in the European Union (EU) under the EU's centralized marketing authorization procedure, and by authorities of several other countries that recognize EU Certification. The audit was performed as part of the European Medicines Agency's (EMA) evaluation of the Marketing Authorization Application for taliglucerase alfa for the treatment of Gaucher disease.

In addition to the EMA, the U.S. Food and Drug Administration (FDA), Israeli Ministry of Health and Brazilian National Health Surveillance Agency have completed audits of the Company's manufacturing facility and deemed the facility acceptable.

"We are pleased to accomplish this major regulatory milestone," said Dr. Michal Kahana, Protalix's Vice President of Quality Affairs. "This important achievement helps demonstrate the viability of our proprietary plant-cell based technology platform, which is the engine behind all our pipeline candidates."

To date, marketing applications for taliglucerase alfa have been submitted in the United States, European Union, Brazil, Israel and Australia. The Prescription Drug User Fee Act (PDUFA) target date for taliglucerase alfa in the United States is February 1, 2012.

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: risks related to any failure by our company to comply with GMP with respect to any product candidate in any jurisdiction; risks relating to the review process of the FDA, the EMA and other foreign 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; the risk that 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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