Protalix Announces Successful GMP Manufacturing Audit by Brazil's National Health Surveillance Agency

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Protalix BioTherapeutics, Inc. (NYSE-AMEX: PLX, TASE: PLX), announced today that Brazil's National Health Surveillance Agency ("Agencia Nacional de Vigilancia Sanitaria" or "ANVISA") has completed a successful GMP (Good Manufacturing Practice) audit of the Company's manufacturing facility in Carmiel, Israel, and determined that the facility is acceptable. The audit was performed as part of the Brazilian Ministry of Health's evaluation of the New Drug Application filed with ANVISA for taliglucerase alfa for the treatment of Gaucher disease.

"The successful audit of our manufacturing facility by Brazil's ANVISA is an important milestone," said Dr. David Aviezer, Protalix's President and Chief Executive Officer. "This important achievement helps demonstrate the viability, quality and commercial potential of our proprietary, plant-cell based technology platform."

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

To date, marketing applications for taliglucerase alfa have been submitted in the United States, European Union, Brazil, Israel and Australia.

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, European Union, Brazil, Israel and Australia. With respect to the NDA filed in the United States, the Company received a complete response letter (CRL) from the FDA in February 2011. In May 2011, the Company's management held a productive meeting with the agency to clarify the FDA's requests and the Company plans to submit its response to the CRL within the next few months. 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. 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 our clinical trials; the review process of the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMEA, other foreign regulatory bodies and other governmental regulatory bodies; 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; the risk that our facilities may fail to remain complaint with GMP (Good Manufacturing Practices); the risk that the FDA may find that the information we provide in a resubmission of the NDA for taliglucerase alfa in response to our receipt of a complete response letter from the FDA in February 2011 is insufficient for regulatory approval; 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. 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 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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