



Protalix Announces Successful GMP Manufacturing Audit by Israel's Ministry of Health

March 3, 2010

Israel, Mar. 3, 2010 (PRNewswire-FirstCall) -- Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX), announced today that the Israeli Ministry of Health has completed a successful GMP (Good Manufacturing Practice) audit of the Company's manufacturing facility in Carmiel, Israel. The audit was performed as part of the Ministry of Health's evaluation of the company's manufacturing process of taliglucerase alfa for the treatment of Gaucher disease.

"The successful audit of our manufacturing facility by the Israeli Health Ministry is another important milestone toward our plans to commercialize taliglucerase alfa in Israel and throughout the world," said Dr. David Aviezer, President and CEO of Protalix. "This important achievement helps to demonstrate the viability, quality and commercial potential of our proprietary plant-cell based technology platform."

In February 2010, the company announced Phase III data at the Lysosomal Disease Network's WORLD symposium. The study, which reached its primary endpoint, demonstrated a mean reduction in spleen volume in both treatment arms studied (60 U/kg, 30 U/kg taliglucerase alfa) in patients with Gaucher disease in a highly significant statistical manner. In this study, taliglucerase alfa was well tolerated, no serious or severe adverse events were reported, a low (6%) level of antibody formation was found and there was no neutralizing antibody formation.

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, α -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 the Company believes will allow for the 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. In August 2009, the FDA granted orphan drug status and fast track designation to taliglucerase alfa for the treatment of Gaucher disease and 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 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.

SOURCE Protalix BioTherapeutics, Inc.

Source: PR Newswire (March 3, 2010 - 8:32 AM EST)

