

# Protalix BioTherapeutics Announces Presentation of PRX-105 Data at the BARDA Industry Day

## January 4, 2011

CARMIEL, Israel, Jan. 4, 2011 / PRNewswire via COMTEX/ --

Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX, TASE:PLX), announced today that it has been invited to deliver an oral presentation on PRX-105, the Company's plant cell expressed pegylated recombinant human acetylcholinesterase in development for use in several therapeutic and prophylactic indications, as well as in a biodefense program and an organophosphate-based pesticide treatment program, at the Biomedical Advanced Research and Development Authority (BARDA) Industry Day. BARDA resides within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services (HHS). The BARDA Industry Day is being held in conjunction with the HHS 5th Annual Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Stakeholders Workshop being held on January 10 through 12, 2011, in Washington, D.C.

The Company's presentation, entitled "PRX-105:A Novel Biological Countermeasure for Nerve Agents," includes preclinical and Phase I data and will be presented on January 12, 2011. In pre-clinical studies, PRX-105 successfully protected animals exposed to organophosphate nerve gas agent analogs in both the prophylactic and post-exposure settings. The Phase I clinical trial of PRX-105 established the pharmacokinetics of the protein and demonstrated that single dose, intravenous administration of PRX-105 is safe and well tolerated.

### About the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

PHEMCE is a coordinated interagency effort that is responsible for defining and prioritizing requirements for public health emergency medical countermeasures; focusing research, development, and procurement activities on the identified requirements; and establishing deployment and use strategies for medical countermeasures in the strategic national stockpile. The Stakeholders Workshop includes plenary talks from the U.S. federal government, the American Medical Association, and state and local speakers, as well as seven breakout sessions on various topics related to the PHEMCE mission. The BARDA Industry Day will include a poster session, exhibitor hall and over 40 oral presentations highlighting cutting edge medical countermeasure research.

### About PRX-105

We are developing PRX-105, our proprietary plant cell-based acetylcholinesterase (AChE) and its molecular variants, for use in several therapeutic and prophylactic indications, as well as in a biodefense program and an organophosphate-based pesticide treatment program. We have received from the Yissum Research and Development Company and the Boyce Thompson Institute, Inc. an exclusive, worldwide right and license to certain technology, including patents and certain patent applications relating to AChE for the therapeutic and prophylactic indications as well as an exclusive license not limited to such indications with respect to certain of those patents and patent applications.

### **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. 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, including its PRX-105 development program. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease. Protalix's new drug application (NDA) for taliglucerase alfa has been accepted by the U.S. Food and Drug Administration (FDA) and granted a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011.

### 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 our clinical trials; the review process of the FDA, the 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; 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 from 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 operations by reducing our potential marketable products and our ability to generate corresponding produc

Investor Contact Marcy Nanus The Trout Group, LLC Telephone: 646-378-2927 Email: <u>mnanus@troutgroup.com</u>

SOURCE Protalix BioTherapeutics, Inc.