Subject: Protalix - press release: U.S. Food and Drug Administration Approves Protalix's Treatment Protocol for prGCD

CARMIEL, Israel--(BUSINESS WIRE)--Protalix BioTherapeutics, Inc. (NYSE-Amex:PLX), announced today that the U.S. Food and Drug Administration (FDA) has approved the Company's treatment protocol for prGCD, the Company's proprietary plant-cell expressed recombinant form of glucocerebrosidase (GCD) for the treatment of Gaucher disease. The treatment protocol allows physicians and other care-providers to treat patients of Gaucher disease with prGCD in the United States and additional countries world-wide while studies of prGCD continue as part of the Company's ongoing pivotal Phase III clinical trial. Prior to accepting the protocol, the FDA reviewed available data from the Company's on-going Phase III clinical development programs.

The treatment protocol is a multicenter, open-label trial designed to allow physicians and other care-providers to treat patients of Gaucher disease with prGCD during the expected shortage of Cerezyme® and thereafter. Cerezyme® is a mammalian cell expressed version of glucocerebrosidase and the only enzyme replacement therapy currently approved for Gaucher disease. The treatment protocol allows patients enrolled in the protocol to continue being treated with prGCD until its anticipated marketing approval from the FDA. The Company will provide the drug free of charge to patients enrolled in the protocol.

"We appreciate the guidance and vote of confidence provided by the FDA in establishing a treatment protocol for prGCD and are working closely with physicians and patient advocacy groups to allow Gaucher disease patients to gain access to our drug," commented Dr. David Aviezer, the Company's President and Chief Executive Officer. "We expect to conclude our phase III pivotal study next month and are looking forward to announcing top-line results from this study in October. We anticipate filing an NDA with the FDA by the end of this year."

About Protalix BioTherapeutics

Protalix is a biopharmaceutical company. Its goal is to become a fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins to be 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 conducting a Phase III pivotal study for its lead product candidate, prGCD, to be used in enzyme replacement therapy for Gaucher disease, a rare and serious lysosomal storage disorder in humans with severe and debilitating symptoms. Protalix and the U.S. Food and Drug Administration agreed on the final design of the pivotal Phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. Protalix has completed enrollment for this study and is treating patients in the study in North America, South America, Israel, Europe and South Africa. The study is monitored by an independent Data Monitoring Committee, including experts in the field, who monitor the on-going safety data, which has recently held their last scheduled meeting before the end of the trial. No serious adverse events have been reported in the study. Protalix is also advancing additional recombinant biopharmaceutical drug development programs