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Protalex Doses First Patient in Third Cohort of European Phase 1b Study of PRTX-100 in ITP

New Trial Sites in the U.K. Open and Enrolling Patients

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- Protalex, Inc. (OTCQB: PRTX), a clinical-stage biopharmaceutical company, today announced that following a planned interim analysis of data from the second dose cohort of its European Phase 1b study of PRTX-100 in adults with persistent/chronic Immune Thrombocytopenia (ITP) (PRTX-100-203 Study), the Company has initiated enrollment in the third cohort of this dose-escalating study. The first patient in the third cohort was recently dosed at 12.0 µg/kg, double that of the second dose cohort of 6.0 µg/kg. PRTX-100 has been granted Orphan Drug Designation in the U.S. and in Europe for the treatment of ITP.

The 203 Study is a European open-label, dose escalating study that can enroll up to 30 patients in as many as five cohorts. Patients only needed to have received one prior ITP treatment to potentially be eligible for the 203 study. Each patient will receive four weekly intravenous doses of PRTX-100 and will be monitored for up to 48 weeks thereafter. The primary study endpoint of the 203 Study is to evaluate the safety of PRTX-100. Secondary endpoints include efficacy, immunogenicity, and pharmacokinetics.

As previously noted, Protalex has opened seven new clinical trial sites in the U.K. for the 203 Study to accelerate recruitment. Nicola Cooper, M.D., Hammersmith Hospital, London, is the National Coordinating Investigator for the trial in the U.K. Dr. Cooper enrolled the final patient into the second cohort of the 203 study, which marked the first patient enrolled in the U.K.

“I am pleased to serve as the U.K. National Coordinating Investigator for the Protalex ITP trial and to assist Protalex with the development of their investigational agent, PRTX-100. I look forward to the results of the study as the dose of PRTX-100 is escalated in the trial,” stated Dr. Cooper.

Richard J. Francovitch, Ph.D., Vice President, ITP Programs at Protalex, added, “Initiating the third dose cohort of the PRTX-100-203 Study is an important milestone as Protalex evaluates the activity of PRTX-100 across a broad range of doses. Protalex is thrilled to have Dr. Cooper and other U.K. investigators join the study to contribute to the growing knowledge base and development of PRTX-100 in ITP.”

About Immune Thrombocytopenia (ITP)
ITP is an autoimmune-mediated condition characterized by bruising and increased

bleeding due to immune-mediated accelerated destruction of platelets and impaired production of platelets. The diagnosis of ITP is based upon a low platelet count, usually less than 100,000 per microliter of blood, in the absence of other possible causes of reduced platelet numbers such as an underlying illness or medication.

About PRTX-100
PRTX-100, a new generation immunomodulatory therapy, is a highly purified form of SpA, an immunomodulatory protein known to modify aspects of the human immune system. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to modulate immune processes. Pre-clinical data indicate that PRTX-100 may have the potential to treat ITP by reducing the immune-mediated destruction of the platelets. The two most recently approved drugs used to treat ITP, Nplate® (romiplostin) and Promacta®/Revolade™ (eltrombopag) both increase the production of platelets but do not appear to affect the underlying platelet destruction process. The safety, tolerability, and pharmacokinetics of PRTX-100 have been characterized in six clinical studies and was recently granted Orphan Drug Designation in the U.S. and Europe for the treatment of ITP. In two Phase 1b clinical trials in adult patients with active Rheumatoid Arthritis (RA), PRTX-100 was generally safe and well tolerated at all dose levels, and at certain higher doses, more patients showed improvement in measures of RA disease activity than did patients at the lower dose or placebo cohorts. PRTX-100 is given as a short intravenous infusion.

About Protalex, Inc.
Protalex, Inc. is a clinical-stage biopharmaceutical company focused on the development of a class of drugs for treating autoimmune and inflammatory diseases including RA and Immune Thrombocytopenia (ITP). In the U.S., Protalex has open INDs for the treatment of RA and ITP and in Europe, an open IMPD for ITP. Please visit the Protalex website at www.protalex.com to learn more about Protalex and its lead drug candidate, PRTX-100.

Forward-Looking Statements
Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other unknown factors that could cause the Company's actual operating or clinical results to be materially different from any historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements that explicitly describe these risks and uncertainties, readers are urged to consider statements that contain terms such as "believes," "belief," "expects," "expect," "intends," "intend," "anticipate," "anticipates," "plans," "plan," to be uncertain and forward-looking. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in the Company's filings with Securities and Exchange Commission.

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