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Protalex Doses First Patient in Final and Highest Dose Cohort of European Phase 1b Study of PRTX-100 in Immune Thrombocytopenia

U.S. 202 ITP Study to Expand Enrollment with Opening of Sites in U.K.

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 fourth dose cohort of its European Phase 1b study of PRTX-100 (PRTX-100-203 Study) in adults with persistent/chronic Immune Thrombocytopenia (ITP), the Company has initiated enrollment in the fifth and highest dose cohort of this dose-escalating study. The first patient in this final cohort was recently dosed in the United Kingdom at 24 micrograms/kg, the highest dose of PRTX-100 used in any clinical trial to date. One of the three patients treated in the fourth dose cohort (18 micrograms/kg) achieved a protocol defined platelet response. 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 with chronic, persistent ITP are eligible for the 203 Study if they have received one prior ITP treatment and their platelet counts remain low. Each patient receives four weekly intravenous doses of PRTX-100 and is 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.

“We are very pleased to be treating patients in the final and highest dose cohort of the 203 Study in Europe, particularly as one patient from the fourth cohort demonstrated a platelet response to treatment with PRTX-100. Platelet responses have been observed in patients treated with lower doses of PRTX-100, so we look forward to the treatment results in the fifth and highest dose cohort,” stated Richard J. Francovitch, Ph.D., Protalex’s Vice President, ITP Programs. “We have been satisfied with the safety data obtained from patients treated in lower dose cohorts and expect the results from this final dose cohort will provide important safety data relating to the highest dose of PRTX-100 yet studied in clinical trials. Importantly, the collective data from the 203 Study will inform the future development plans for the ITP program.”

Arnold P. Kling, President, of Protalex, commented, “Protalex is encouraged by the increased rate of enrollment into the 203 Study since opening the trial at multiple sites in the U.K. We were able to initiate enrollment in the final dose cohort within 2 months of

opening the last cohort. With that in mind, we have received regulatory approval in the U.K. to open enrollment in our Phase 1/2 study of PRTX-100 in adults with persistent/chronic ITP (PRTX-100-202 Study) that previously was only open at sites in the U.S. Several new clinical sites in the U.K. will begin recruiting patients in the coming weeks for the fourth cohort of the 202 Study at a dose of 12.0 micrograms/kg.

The 202 Study is an open-label, dose escalating study that can enroll up to 36 patients in as many as six cohorts. Each patient receives four weekly intravenous doses of PRTX-100 and is monitored for up to 48 weeks thereafter. The primary study endpoint of the 202 Study is a platelet response to PRTX 100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. Enrollment is continuing at several study sites in the U.S.

About Immune Thrombocytopenia (ITP)

ITP is an autoimmune 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 PRTX-100 has been 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.

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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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