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Protalex Announces Data from Phase 1b Trial of PRTX-100 in Patients with Immune Thrombocytopenia Presented at the European Hematology Association 23rd Annual Meeting

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- Protalex, Inc. (OTCQB: PRTX), a clinical-stage biopharmaceutical company, today announced that data highlighting results from its European Phase 1b open-label, dose-escalation study of PRTX-100 in adult patients with persistent/chronic immune thrombocytopenia (ITP) (the PRTX-100-203 Study) were presented in a poster today at the European Hematology Association 23rd Annual Meeting underway in Stockholm. Protalex's lead drug candidate PRTX-100, is a highly purified form of staphylococcal protein A. The poster is now available on the Company's website at www.protalex.com.

The poster, entitled "*A Phase 1B Open-Label Dose-Escalation Study of PRTX-100, a Highly Purified Form of Staphylococcal Protein A (SpA), in Adult Patients with Persistent/Chronic Immune Thrombocytopenia,*" was presented by a principal investigator for the 203 Study, Dr. Nicola Cooper, Hammersmith Hospital, London.

The poster highlights findings from fifteen patients enrolled in all five dose escalating cohorts and included seven women and eight men ages 22 to 82. The primary objective of this study was to evaluate the safety of five different doses of PRTX-100. The data demonstrated that PRTX-100 had an acceptable safety profile across the dose range studied. The data also showed that platelet counts were elevated in most patients that received four weeks of treatment, with six patients having a peak platelet count that was at least double their baseline count. Two patients achieved a per protocol platelet response. Enrollment in the 203 Study was completed in May and final data will be presented at a future scientific conference following completion of analysis in the next few months.

"We are pleased to present data demonstrating the safety and tolerability of PRTX-100 in the target ITP patient population. The increase in platelets observed in many patients is similarly positive and this data will contribute to developing an advanced clinical trial strategy," stated Richard J. Francovitch, Ph.D., Protalex's Vice President, ITP Programs. "ITP is a debilitating illness that affects patient quality of life and contributes to mortality if left untreated. We believe that PRTX-100 may prove to be a safe and effective therapy in the treatment of this disease."

About the PRTX-100-203 Study

The 203 Study is a Phase 1b, open-label, dose-escalating study conducted in Europe that enrolled fifteen patients in five separate dose cohorts. Patients with chronic, persistent ITP were eligible for the 203 Study if they had received one prior ITP treatment and their platelet counts remained low. Each patient who completed the study received four weekly intravenous doses of PRTX-100 and was 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.

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 eight human clinical studies (seven completed, one ongoing), 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 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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