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Protalex Announces First Patient Dosed in European Phase Ib Study of PRTX-100 for Immune Thrombocytopenia

Therapeutic approach supported by pre-clinical studies presented at ASH 2015

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today announced dosing of the first patient in its European Phase Ib study of PRTX-100 in adults with persistent/chronic Immune Thrombocytopenia (ITP) (the PRTX-100-203 Study). PRTX-100, Protalex's lead drug candidate, is a highly purified form of Staphylococcal protein A (SpA), which was granted Orphan Drug Designation in Europe and the U.S. for the treatment of ITP. A similar Phase I/II clinical study of PRTX-100 is underway in the U.S. (the PRTX-100-202 Study). PRTX-100 is also the subject of ongoing clinical development in Rheumatoid Arthritis (RA).

The 203 Study is an open-label, dose-escalation study that will enroll up to 30 patients in as many as five cohorts at five to six clinical centers in France. 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 safety. Secondary endpoints include platelet response, immunogenicity and pharmacokinetics.

"The 203 Study is designed to evaluate the safety and efficacy of PRTX-100 in a range of doses. Combined with the recently initiated U.S-based 202 Study, the 203 Study will provide important data to support our continued development plans for PRTX-100 in ITP. We look forward to continuing enrollment in these Phase I/II clinical trials in 2016," stated Richard J. Francovitch, Ph.D., Protalex's Vice President-ITP Programs. "Our enthusiasm for the ITP clinical development program is further supported by data from preclinical studies of PRTX-100 in a sophisticated animal model of ITP that were presented at the American Society of Hematology (ASH) meeting last month. We believe PRTX-100 may offer a promising new approach to treat patients with ITP."

About Immune Thrombocytopenia (ITP)

ITP is an autoimmune-mediated condition characterized by bruising and increased bleeding as a result of 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. Preclinical 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 five clinical studies. PRTX-100 was recently granted Orphan Drug Designation in the U.S. and Europe for the treatment of ITP. In two Phase Ib 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.

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 in RA and ITP. Please visit Protalex's 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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