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Protalex Announces Regulatory Approval to Initiate Phase Ib Trial of PRTX-100 to Treat Immune Thrombocytopenia in France

Also Receives Positive Opinion for Orphan Drug Designation in EU for PRTX-100 to Treat ITP

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announced today that the French National Agency for Medicines and Health Products (ANSM) has approved the company's clinical trial application to begin a Phase Ib study of PRTX-100 in adult patients with persistent/chronic immune thrombocytopenia (ITP). This approval authorizes Protalex to initiate the study (PRTX-100-203 Study) at several sites in France. The company expects to commence enrollment before year end.

In addition, Protalex announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP.

Approval of the 203 Study and the positive COMP opinion follow Protalex's previously announced initiation of a U.S. Phase I/II clinical trial of PRTX-100 in adult ITP patients (PRTX-100-202 Study) and receipt of Orphan Drug Designation (ODD) for PRTX-100 to treat ITP from the U.S. Food and Drug Administration's Office of Orphan Products Development.

PRTX-100, Protalex's lead drug candidate, is a new generation immunomodulatory therapy that is under investigation for the treatment of autoimmune diseases such as rheumatoid arthritis (RA) and ITP. PRTX-100 is a highly purified form of Staphylococcal protein A (SpA), a bacterial protein demonstrated by Protalex and others to affect immune function in various preclinical studies.

The 203 Study is an open-label, dose-escalating study that will enroll up to 30 patients in as many as five cohorts. 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 to PRTX-100, immunogenicity and pharmacokinetics.

"The 203 Study is designed to evaluate the safety and efficacy of PRTX-100 in a range of doses and, along with the recently initiated U.S.-based 202 Study, will provide important data to support further development plans in ITP," stated Richard J. Francovitch, Ph.D.,

Protalex's Vice President-ITP Programs. "Protalex is also very pleased to have received a positive opinion from the EMA COMP on the PRTX-100 application for ODD. Based on preclinical observations and data generated in prior clinical trials in patients with RA, we believe PRTX-100 represents a promising new approach for the treatment of 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.

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. Historically ITP has been treated with therapies designed to diminish the increased platelet destruction by immunosuppression. In contrast, pre-clinical data indicate that PRTX-100 may have the potential to treat ITP by reducing the immune-mediated destruction of the platelets through immunomodulatory processes that don't lead to immunosuppression.

Nplate® is a registered trademark of Amgen, Inc. and Promacta®/Revolade™ are registered trademarks of Novartis A G.

About PRTX-100

PRTX-100, a new generation immunomodulatory therapy, is a highly purified form of SpA, a protein found in the cell wall of the bacterium *Staphylococcus aureus*. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to modulate immune processes. The safety, tolerability and pharmacokinetics of PRTX-100 have been characterized in five clinical studies and was recently granted Orphan Drug Designation in the U.S. for ITP. In two Phase Ib clinical trials in adult patients with active 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 Rheumatoid Arthritis (RA) and Immune Thrombocytopenia (ITP). In the U.S., Protalex has open IND's in RA and ITP. Please visit Protalex's website at www.protalex.com to learn more about Protalex and its lead product, 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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