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Protalex to Initiate Enrollment of U.S. Phase I/II Trial of PRTX-100 to Treat Immune Thrombocytopenia

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announced today that it will initiate enrollment for a Phase I/II study of PRTX-100 in adult patients with persistent/chronic immune thrombocytopenia (ITP) at several sites in the United States (the PRTX-100-202 Study) in the coming weeks. Protalex previously announced U.S. FDA acceptance of an Investigational New Drug application (IND) for this study. PRTX-100, Protalex's lead drug, is a new generation immunomodulatory therapy that is under investigation for autoimmune diseases such as rheumatoid arthritis (RA) and ITP. PRTX-100 is a highly purified form of Staphylococcal protein A (SpA), a bacterial protein known to modify aspects of the human immune system.

The 202 Study is an open-label, dose escalating study that will enroll up to 36 patients in as many as six 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 202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics.

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.

"Our decision to initiate clinical trials in ITP is supported by illuminating findings in a sophisticated animal model of ITP that demonstrated the ability of PRTX-100 to raise platelet counts by mechanisms that impede the platelet destruction process," stated Richard J. Francovitch, Ph.D., Protalex's Vice President ITP Programs. "We look forward to sharing these encouraging data at a scientific meeting in the coming months. Furthermore, PRTX-100 has established an acceptable safety profile in five clinical studies, three of which included patients with RA, another autoimmune disease. In addition, we are also preparing to evaluate PRTX-100 as a treatment for ITP in a European Phase Ib clinical trial to produce data to corroborate our pre-clinical results."

In June, PRTX-100 was granted Orphan Drug Designation (ODD) by the FDA's Office of Orphan Products Development to treat ITP. An application for ODD in Europe for PRTX-100 is pending before the European Medicines Agency.

Orphan drug designation provides certain exclusivity benefits, tax credits for certain research and a waiver of the New Drug Application user fee.

About Immune Thrombocytopenia (ITP)

ITP is an autoimmune bleeding disorder characterized by a low amount of platelets (thrombocytes) in the blood that are necessary for normal blood clotting. Individuals with ITP have platelets that are mistakenly attacked and prematurely destroyed by antibodies and cells in their own immune system (B and T cells), which, in turn, can lead to the abnormal bleeding. Other blood components such as red and white blood cells usually remain normal.

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, an immunomodulatory protein produced by bacteria. 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 1b 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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