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Protalex Receives Positive Interim Review from Independent Safety Monitoring Committee in Its European Phase 1b Study of PRTX-100 to Treat Immune Thrombocytopenia

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today announced that following a planned interim data review by its independent Safety Monitoring Committee (SMC), the Company is continuing enrollment and increasing the dose for subjects in its European Phase 1b study of PRTX-100 in adults with persistent/chronic Immune Thrombocytopenia (ITP) (PRTX-100-203 Study). The dose of PRTX-100 for subjects in the next treatment group (6.0 micrograms/kg) will be twice that of the initial starting dosage (3.0 micrograms/kg).

PRTX-100, Protalex's lead drug candidate, is a highly purified form of Staphylococcal protein A (SpA) and has been the subject of ongoing clinical development in both ITP and rheumatoid arthritis (RA). PRTX-100 was recently granted Orphan Drug Designation in the U.S. and in Europe for the treatment of ITP and is currently the subject of clinical studies in both the U.S. and Europe.

The 203 Study is an open-label, dose escalating study that can 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 safety, platelet response, immunogenicity, and pharmacokinetics. Enrollment in the 203 Study is currently taking place at several study sites in France.

"We continue to be encouraged by the ongoing progress both in the 203 trial in Europe and in the parallel 202 trial in the U.S., which support the development of a new treatment for ITP. We are pleased to continue patient enrollment and dose escalation in the 203 Study and look forward to advancing to the next cohort of the study," stated Richard J. Francovitch, Ph.D., Protalex's Vice President ITP Programs.

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. 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. In three 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 administered as a short intravenous infusion.

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

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 IND's for the treatment of RA and ITP and in Europe, an open IMPD for 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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