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Protalex Awarded Grant from FDA Office of Orphan Products Development to Foster Clinical Development of PRTX-100 for the Treatment of Immune Thrombocytopenia

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- **Protalex, Inc. (OTCQB:PRTX)**, a clinical-stage biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) has awarded the Company a $403,000 grant to support future clinical development activity of PRTX-100 as a treatment for Immune Thrombocytopenia (ITP). The goal of FDA's OOPD Orphan Products Clinical Trials Grants Program is to encourage the clinical development of new drugs for use in rare diseases or conditions where no current therapy exists, or where the candidate drug will be superior to the existing therapy.

PRTX-100 is a highly purified form of Staphylococcal protein A (SpA), which is an immunomodulatory protein known to modify aspects of the human immune system. PRTX-100 is a new generation immunomodulatory therapy and has been granted Orphan Drug Designation as a potential treatment for ITP in both the U.S. and Europe.

Protalex is currently enrolling patients into two Phase 1/2 dose-escalating studies of PRTX-100 as a potential new treatment for ITP at several sites in the U.S. (the 202 Study) and in Europe (the 203 Study) and has so far seen patients in each completed lower dose cohort achieve a protocol-defined platelet response.

“We are delighted to have been granted this funding from the FDA’s OOPD as it underscores the great need for innovative, effective treatments for this rare autoimmune disease, and recognizes the potential benefits that PRTX-100 may provide for patients with ITP,” stated Richard J. Francovitch, Ph.D., Protalex’s Vice President, ITP Programs. “We recently opened new dose cohorts in both the 202 and 203 studies and look forward to the results as the studies move forward evaluating higher doses of PRTX-100.”

Arnold P. Kling, President of Protalex, also noted, “The FDA provides grants for clinical studies on safety and/or effectiveness that will hopefully result in or substantially contribute to market approval of these candidate drugs. Given that this FDA program has been used in the past to bring more than 60 drugs to market, we are encouraged by their support and the promise that PRTX-100 holds in treating ITP as well as other autoimmune diseases.”

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® (romiplostim) and Promacta®/Revolade™ (eltrombopag), both increase the production of platelets but do not appear to affect the underlying platelet destruction process.

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 safety, tolerability and pharmacokinetics of PRTX-100 have been characterized in six clinical studies and was recently 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.

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 Immune Thrombocytopenia (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 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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