PROTALEX ANNOUNCES PUBLICATION IN THE BRITISH JOURNAL OF HAEMATOLOGY SUPPORTING THE POTENTIAL OF PRTX-100 TO TREAT IMMUNE THROMBOCYTOPENIA

FLORHAM PARK, N.J. (October 26, 2017) – Protalex, Inc. (OTCQB: PRTX), a clinical-stage biopharmaceutical company, announces that preclinical data showing its lead drug candidate PRTX-100 increases blood platelet counts in a murine model of immune thrombocytopenia (ITP) were published in the recent issue of the peer-reviewed journal, British Journal of Haematology, in an article titled, “A highly purified form of Staphylococcal protein A alleviates murine immune thrombocytopenia.” The complete article can be accessed here.

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 achieve a protocol-defined platelet response in the lower dose cohorts.

The study conducted by John W. Semple, Ph.D., Division of Haematology and Transfusion Medicine, Lund University, Lund, Sweden and the Keenan Research Center for Biomedical Science, St. Michael’s Hospital, Toronto, Canada, evaluated the efficacy of PRTX-100 in vivo using a well-established murine model of ITP. The study compared PRTX-100 to a placebo control and to intravenous immunoglobulin (IVIg), which is an effective first-line treatment for ITP. Study results demonstrated the ability of PRTX-100 to limit the destruction of platelets thereby raising platelet counts in mice with severe thrombocytopenia.

“Treatment with PRTX-100 provided a benefit by rescuing platelet counts in severely thrombocytopenic mice and produced results comparable to IVIg, a standard ITP therapy,” stated Richard J. Francovitch, Ph.D., Protalex’ s Vice President, ITP Programs and a co-author of the study. “We are pleased to have these favorable data published in this prestigious peer-reviewed journal. These observations corroborate earlier preclinical investigations that have identified a number of immunomodulatory activities for PRTX-100 and provide supporting evidence for its potential role in the management of ITP. The results of these preclinical investigations are particularly encouraging as we advance treatment with PRTX-100 in higher-dose cohorts in our ongoing 202 and 203 studies. We look forward to the results of those cohorts in the coming months,” Dr. Francovitch added.

PRTX-100 exhibits multiple immunomodulatory effects, and its previously reported ability to prevent the premature destruction of platelets provides a rationale for its use in the treatment of ITP which is further confirmed by the results provided in this publication.

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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