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Protalex Provides Update on US and EU Studies of PRTX-100 to Treat Immune Thrombocytopenia

Expanding Number of Clinical Sites in US and EU; Underscoring Growing Interest in PRTX-100 among Clinical Investigators

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today provides an update on its U.S. Phase 1/2 and European Phase 1b studies of PRTX-100 in adults with persistent, chronic Immune Thrombocytopenia (ITP). PRTX-100, Protalex's lead drug candidate, is a highly-purified form of Staphylococcal protein A (SpA) and is the subject of ongoing clinical development in ITP and rheumatoid arthritis (RA). PRTX-100 has been granted Orphan Drug Designation in the U.S. and in Europe for the treatment of ITP.

The 202 Study in U.S.

The 202 Study is an open-label, Phase 1/2 dose escalating study in patients who have previously received treatment with a thrombopoietin receptor agonist and at least one additional ITP therapy. This study can enroll up to 36 patients in as many as six cohorts. Each patient receives four weekly intravenous doses of PRTX-100 and is monitored for up to 48 weeks thereafter. The 202 study is enrolling its second cohort of patients at the dose of 3.0 micrograms/kg, three times the 1.0 micrograms/kg dose of the first cohort. The primary study endpoint of the 202 Study is a platelet response to PRTX-100. Secondary endpoints include safety, immunogenicity, and pharmacokinetics. All patients to date have been enrolled at two study sites in the U.S., and the enrollment has recently expanded to seven sites, including several noted U.S. medical centers:

- Weill Cornell Medical Center (New York, NY)
- Massachusetts General Hospital (Boston, MA)
- Norris Cancer Hospital, University of Southern California (Los Angeles, CA)
- Cleveland Clinic Foundation (Cleveland, OH)
- Gabrail Cancer Center (Canton, OH)
- National Institute of Medical Research (Pasadena, TX)
- Michigan Center of Medical Research (Farmington Hills, MI)

The 203 Study in Europe

The 203 Study is an open-label, Phase 1b dose escalating study in Europe involving patients who have received at least one prior ITP treatment. This study can enroll up to 30 patients in as many as five cohorts. Subjects receive four weekly intravenous doses of PRTX-100 and are monitored for up to 48 weeks thereafter. The 203 study is now enrolling patients in the second cohort at a dose of 6.0 micrograms/kg, twice the dose of the first cohort. The primary study endpoint of the 203 Study is safety. Secondary endpoints include safety, platelet response, immunogenicity, and pharmacokinetics. Enrollment in the 203 Study to date has taken place at five study sites in France. The 203 study was recently expanded to nine sites, including the following clinical sites:

- Mondor Hospital (Paris)
- Claude Huriez Hospital (Lille)
- Haut-Levêque Hospital (Pessac)
- Côte de Nacre Hospital (Caen)
- Centre Hospitalier Universitaire François Mitterand (Dijon)
- Canceropole (Toulouse)
- Centre Hospitalier La Timône (Marseille)
- Centre Hospitalier Universitaire de Nantes (Nantes)
- Centre Hospitalier Lyon Sud (Lyon)

In addition, the Company has signed an agreement with a leading contract research organization to manage the addition of initially six new clinical sites in the United Kingdom. Protalex anticipates these sites will commence patient screening in mid-April.

Initial Results

Data from initial cohorts in the two dose escalation trials of ITP patients treated with PRTX-100 have demonstrated an acceptable safety profile to support continued enrollment into higher-dose cohorts in both trials. Two platelet responses, as defined per protocol, at the lowest dose cohorts in the trials have been observed, as described in part in an abstract published in connection with the American Society of Hematology conference in December 2016. The complete abstract can be accessed here.

Management Commentary

“We are particularly pleased to be expanding the number of clinical sites for our 202 and 203 studies of PRTX-100 as a potentially new treatment for ITP. The number and quality of new institutions joining our studies underscores the growing interest in our novel immunomodulatory approach for the treatment of ITP,” stated Richard J. Francovitch, Ph.D., Protalex’s Vice President ITP Programs. “To meet the challenge of patient enrollment associated with a rare disease like ITP, especially in a population that has not responded adequately to current therapies, we have expanded the number of clinical sites markedly. With this expansion, we will soon have more than 20 sites worldwide for patient enrollment. We look forward to completing the second cohorts in the 202 and 203 studies

and to advancing to the next cohort in each study."

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 A G.

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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