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Protalex Announces Lead Drug Candidate PRTX-100 Reduces Disease Activity in a Mouse Model of Myasthenia Gravis

Findings Support Advancement of PRTX-100 into its Third Clinical Indication

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- **Protalex, Inc. (OTCQB:PRTX)**, a clinical-stage biopharmaceutical company, today announced preliminary findings that its lead drug candidate PRTX-100 reduced disease activity in a second, confirmatory mouse study of myasthenia gravis (MG), an autoimmune disorder mediated by anti-self antibodies that react with the neuromuscular junction. The study was conducted by the Laboratory for Myasthenia Gravis Research at George Washington University.

The study demonstrated potential clinical benefits of PRTX-100 in mice with established MG symptoms. Treatment with PRTX-100 preserved grip strength and decreased disease activity scores relative to control animals.

“We are encouraged by the data readout on our second confirmatory preclinical study for PRTX-100 in MG and hope to use it to advance our path to clinical development in this indication,” said Michelle D. Catalina, Ph.D., Preclinical Director of Protalex. “Autoimmune disorders typically have great impact on quality of life for patients, and often have few effective and tolerable treatment options. It is our hope to advance PRTX-100 in MG, with the goal of offering a new treatment option. We expect a detailed analysis of the final study results will be presented for scientific presentation later this summer and subsequently for publication.”

About Myasthenia Gravis

MG is an autoimmune disorder caused by anti-self antibodies that react with the neuromuscular junction, causing muscle weakness and fatigability. MG remains underdiagnosed in the U.S. and has an estimated incidence of 14 to 20 per 100,000 population, meaning there are approximately 36,000 to 60,000 cases in the U.S.[1] Current treatments, which include corticosteroids and immunosuppressant agents, are not optimal as they can cause severe adverse events. Neurological autoimmune disorders in general lack efficacious treatments without adverse side effects.

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. The safety, tolerability and pharmacokinetics of PRTX-100 have been characterized in eight human clinical studies (seven completed, one ongoing), and PRTX-100 has been granted Orphan Drug Designation in the U.S. and Europe for the treatment of Immune Thrombocytopenia (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.

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 INDs 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.

[1] http://www.myasthenia.org/HealthProfessionals/ClinicalOverviewofMG.aspx

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