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Protalex Initiates Enrollment of Phase I/II Continuation Trial of PRTX-100 in Active Rheumatoid Arthritis Patients

Open Label Study Will Evaluate Former Patients Over 6-Month Period

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announced today that following completion of its U.S.-based, multicenter Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 (the 104 Study) in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (RA), the Company has initiated enrollment of a Phase I/II open-label, multiple, fixed-dose study (the 105 Study) that is open only to 104 Study patients who indicated their desire for additional treatment. Protalex's lead drug PRTX-100 is a highly purified form of Staphylococcal Protein A.

The PRTX-100-105 Study is an open-label, single group study with up to 12 former participants from the 104 Study who will receive a fixed dose of PRTX-100 over a 6-month period at a single site in the U.S. The primary study endpoint of the 105 Study is the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints include immunogenicity, effects on measures of RA disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of joint evaluations with ultrasound and biomarkers as disease markers.

William E. Gannon, Jr., M.D., Protalex's Chief Medical Officer, explained the 105 Study's rationale, "Although the majority of RA patients achieve an improvement of their RA with older disease modifying agents such as methotrexate and leflunomide, all of these agents provoke adverse events. Commonly used biological agents, including TNF inhibitors like Humira, Enbrel and/or Remicade, increase the risk of serious infections. Our ongoing development program is focused on determining whether PRTX-100 modifies the disease course of RA with an improved safety profile and a dosing regimen comparable to current therapies."

"In addition, on average the patients in the 104 Study had RA for 13 years. Many of these patients had discontinued treatment with one or more of the TNF inhibitors. In the 104 Study, some patients experienced relief using PRTX-100 and asked their physician if they could continue to be treated with PRTX-100. Based on their request, as conveyed by the Principal Investigator of the 104 Study, the Company agreed to conduct the 105 Study in the belief that continued treatment may benefit these patients and provide longer term safety information about PRTX-100," added Dr. Gannon.

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 rheumatoid arthritis (RA). Protalex's lead product, PRTX-100, is a formulation of a proprietary, highly purified form of Staphylococcal Protein A, which is an immunomodulatory protein produced by bacteria. 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 five clinical studies. In two 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.

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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