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# Protalex Announces Interim Findings from U.S. Phase 1(b) Trial of PRTX-100 in Active Rheumatoid Arthritis Patients

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today announced preliminary findings from a limited interim analysis of its U.S.-based multicenter Phase 1(b) randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (PRTX-100-104 Study). PRTX-100 is an investigational drug incorporating a highly purified form of Staphylococcal Protein A. The interim analysis included patients in the first four dosing cohorts of the five-cohort study through day 85 of the study protocol.

Five U.S. clinical centers enrolled 41 patients in Cohorts 1 through 4 of the 104 Study; five patients discontinued from the study prior to their day 85 visit. A preliminary interim analysis of Cohorts 1 through 4 indicated that PRTX-100 was generally safe and well tolerated. The rate of adverse events (AEs) among patients receiving PRTX-100 was comparable to that of those receiving placebo and similar to that seen in prior clinical studies of PRTX-100; two patients discontinued the study because of treatment-related AEs. Pharmacokinetic analyses indicated a roughly linear increase in plasma maximum concentrations with increasing doses of 1.5, 3.0, 6.0, and 12 mcg/kg. Effects on measures of disease activity showed that patients who received PRTX-100 had average DAS28-CRP and CDAI scores lower than the average scores of those who received placebo, which is consistent with a therapeutic effect in patients with this disease. A detailed analysis of the final 104 Study results of Cohorts 1 through 4 will be prepared for scientific presentation and publication this spring.

Additionally, Protalex has completed randomization of all 20 patients into Cohort 5 of the 104 Study which is the final cohort. These patients are receiving 5 weekly doses of PRTX-100 or placebo, followed by 4 monthly “maintenance” doses thereafter, with total drug exposure over the six month study visit period not to exceed that of Cohort 4 (60 mcg).

Commenting on the findings, Edward Bernton, M.D., Protalex’s Chief Scientific Officer noted, "We are pleased that these preliminary findings extend our knowledge of the safety and pharmacologic profile of PRTX-100 at higher doses than used in prior studies, and have included them in a recent submission to the U.S. Food and Drug Administration. Moreover, we are encouraged by the promising effects on certain key measures of disease activity, and we are excited by the potential of PRTX-100 as a novel immunomodulatory therapy for RA and possibly other autoimmune diseases."

**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. Protalex completed a Phase 1b clinical trial in adult patients with active RA in South Africa that demonstrated that PRTX-100 was generally safe and well tolerated at all dose levels, and at the higher doses, more patients showed improvement in their CDAI (Clinical Disease Activity Index) for RA than did patients at the lower dose or placebo cohorts. The safety, tolerability, and pharmacokinetics of PRTX-100 have now been characterized in four clinical studies, with the final cohort in a fifth clinical study nearing completion.

**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 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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