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Protalex Announces Preliminary Unblinded Findings from Cohorts 1-4 of U.S. Phase 1b Trial of PRTX-100 in Active Rheumatoid Arthritis Patients

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today announced it has completed analysis of certain key parameters from its U.S.-based multicenter Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate or leflunomide in adults with active rheumatoid arthritis (RA) (PRTX-100-104 Study). The primary endpoint of the study is to assess safety and tolerability, with secondary objectives to examine the effects of PRTX-100 on measures of disease activity, assessing the immunogenicity and evaluating the pharmacokinetic (PK) parameters after repeated doses, and determining possible relationships between the immunogenicity of PRTX-100 and safety, PK and efficacy parameters.

PRTX-100 is an investigational drug incorporating a highly purified form of Staphylococcal Protein A. The unblinded analysis included 41 patients recruited at five U.S. clinical sites in the first four dosing cohorts of the five-cohort study through completion of the 25-week study protocol.

The preliminary results indicated that PRTX-100 was generally safe and well tolerated and the Adverse Event (AE) profile was consistent with prior trials results. There were no immediate hypersensitivity reactions, nor any treatment-related Serious Adverse Events (SAEs) evident and no expedited reports to the U.S. Food and Drug Administration (FDA) were required. Pharmacokinetic analyses indicated a roughly linear increase in plasma maximum concentrations with increasing doses of 1.5, 3.0, 6.0, and 12mcg/kg.

Moreover, the study revealed positive effects of PRTX-100 treatment on certain measures of disease activity, although these effects were not statistically significant. At the higher doses, PRTX-100 showed activity comparable to existing well known biologics with apparent onset of action occurring subsequent to the fifth and final dose. For example, four weeks following the last PRTX-100 dose (Day 57), 32% of active-treated and 13% of placebo-treated patients had attained an ACR50 response. At day 113, 29% of the active-treated patients who received 6 or 12 mcg/kg PRTX-100 plus methotrexate achieved DAS28-CRP scores less than 2.6 (remission), while the placebo-treated patients showed no remission. Notably, among all patients treated with PRTX-100, 43% had DAS28-CRP < 3.2 (low disease activity) on both Day 57 and Day 85, while only 14% of placebo-treated patients showed such a reduction in RA disease activity on these days.

The Company expects to submit an interim clinical study report to the FDA in the thirdquarter of 2014.

Additionally, 16 out of 20 patients in the final cohort of the 104 Study (Cohort 5) have completed dosing though Day 85, and per protocol, all patients will receive their last doses in July 2014. Similar to subjects in Cohorts 1 through 4, patients in Cohort 5 are receiving five weekly doses of PRTX-100 or placebo, but additionally will receive four monthly “maintenance” doses thereafter.

Commenting on the findings, William E. Gannon Jr., M.D., Protalex’s Chief Medical Officer stated, "We are very encouraged by both the safety and the positive efficacy trends of PRTX-100 in this Phase 1b study. As previously noted, these findings extend our knowledge of the safety and pharmacologic profile of PRTX-100 at higher doses than used in prior studies and again suggest promising effects on RA disease activity. We believe the findings clearly indicate that PRTX-100 warrants further study both in RA and possibly in other autoimmune disorders and these important data will help guide our clinical development program for PRTX-100."

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 five clinical studies.

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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