October 31, 2013

Protalex Initiates Enrollment of Final Cohort in Phase 1b Trial of PRTX-100 in Active Rheumatoid Arthritis Patients

SUMMIT, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, today announced that following completion of Cohort 4 which expanded the 3.0 mcg, 6.0 mcg, and 12.0 mcg/kg dose cohorts by an additional 9 patients, the Company has initiated enrollment of its fifth and final cohort (Cohort 5) in its 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 is an investigational drug incorporating a highly purified form of Staphylococcal Protein A.

The Cohort 5 sub-study will enroll up to 16 patients and will include additional monthly maintenance doses of PRTX-100 in the 3.0 mcg/kg to 6.0 mcg/kg range. Patients may receive up to nine doses of PRTX-100 over the six month study visit period, but the cumulative dose will not exceed that of Cohort 4 (12 mcg/kg).

The primary objective of the first four dose-escalating dose cohorts of the Phase 1b study is to assess the safety and tolerability of four different doses of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate or leflunomide therapy. The primary objective of the Cohort 5 sub-study is to assess safety and tolerability of one of these doses administered on a modified schedule. Secondary objectives include determining 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.

Enrollment is currently taking place at seven study sites in the United States.

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. Protalex's lead product, PRTX-100, is a formulation of a proprietary, highly purified form of Staphylococcal Protein A, which is an immune modulating protein produced by bacteria. Protalex has completed a Phase 1b clinical trial in adult patients with active rheumatoid arthritis in South Africa which 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. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to activate

processes that mediate inflammation in certain autoimmune diseases. Laboratory studies indicate that the mechanism involves interaction with specific immunologic signaling pathways.

Forward-Looking Statements

Statements in this press release, including with respect to the outcome of the Phase 1b study described, 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.

LHA
Anne Marie Fields, 212-838-3777
afields@lhai.com

Source: Protalex, Inc.