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Protalex to Continue Phase 1b Trial of PRTX-100 in Patients with Active Rheumatoid Arthritis Following Data Safety Monitoring Committee Review

SUMMIT, N.J.-- Protalex, Inc. (OTCBB: PRTX), a clinical-stage biopharmaceutical company, today announced that following a planned interim safety review by its Data Safety Monitoring Committee, the Company is continuing enrollment and dosing of patients in its multicenter Phase 1b randomized, multiple-dose, dose-escalation study of PRTX-100 in combination with methotrexate and leflunomide in adults with active rheumatoid arthritis (RA). The dose of PRTX-100 for patients in the current treatment group (6.0 micrograms/kg) is four times that of the initial starting dosage (1.5 micrograms/kg).

PRTX-100 is a new drug formulated from a highly purified form of Staphylococcal Protein A.

The sequential dose-escalation phase is expected to enroll up to 40 patients into four cohorts ranging from 1.5 micrograms/kg up to 18.0 micrograms/kg, or placebo. The dose-escalation phase may be followed by up to 12 additional patients for cohort expansion at the optimal dose. Enrollment is currently taking place at three study sites in the U.S.

The primary objective of this Phase 1b study is to assess the safety and tolerability of intravenous PRTX-100 administered weekly over 5 weeks in patients with active RA on methotrexate therapy. 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.

In addition, the Company announced that it has contracted with a U.S. Food and Drug Administration-approved facility in Europe for the formulation of new drug product at higher concentrations in anticipation of administering higher dosages in this study, as well as for use in future studies.

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 formulated with a proprietary

highly purified form of Staphylococcal Protein A, and has completed a Phase 1b clinical trial in adult patients with active rheumatoid arthritis in South Africa. This trial 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 and to regulate activation of human B-lymphocytes and macrophages, which mediate inflammation in certain autoimmune diseases. Laboratory studies indicate that the mechanism involves interaction with specific intracellular 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.

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