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Protalex Announces Findings from Final Cohort of U.S. Phase 1b Trial of PRTX-100 in Active Rheumatoid Arthritis Patients

Additional monthly maintenance doses suggest increased effect on disease activity

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announced that it has completed analysis from the final cohort (Cohort 5) of 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; the 104 Study). PRTX-100, Protalex's lead drug, is a highly purified form of Staphylococcal Protein A, which is the subject of ongoing clinical development in rheumatoid arthritis RA. Under a separate Investigational New Drug application, the Company will soon commence a clinical trial of PRTX-100 in patients suffering from chronic Immune Thrombocytopenia (ITP), an orphan disease.

The Company previously reported final data from Cohorts 1 through 4 and an interim analysis of pooled data from Cohort 5 of the 104 Study in November 2014. The primary study endpoint of the 104 Study was safety and tolerability with secondary endpoints including immunogenicity, effects on measures of RA disease activity, and evaluating anti-PRTX-100 antibody presence. For patients in all five cohorts of the 104 Study, PRTX-100 was safe and well tolerated in all individuals, including those who develop anti-drug antibodies (ADAs); there were no drug-related Serious Adverse Events (SAEs).

In Cohort 5, the amount of PRTX-100 administered and its dosing frequency were varied from Cohorts 1 through 4 to explore effects on safety, tolerability, and measures of disease activity. Analysis of the Cohort 5 findings suggests that weight-based dosing and monthly maintenance doses were an important aspect of the dosing protocol and should be considered in future trials of PRTX-100.

Additionally, an exploratory analysis of Cohorts 1 through 5 data indicates there may be a relationship between certain biomarkers in a patient's blood before treatment with PRTX-100 and effects on measures of disease activity. In light of this, the Company intends to re-examine the biomarkers from its prior South African RA trial (the 103 Study). Upon the completion of the combined analysis of the 103 Study and 104 Study biomarkers, the Company will determine any next steps to explore the utility of the biomarker in identifying RA patients most likely to benefit from treatment with 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) and Immune Thrombocytopenia (ITP). 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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