November 17, 2014

Protalex Announces Data from Phase 1b Trial of PRTX-100 in Patients with Active Rheumatoid Arthritis Treated for Longer Duration Shows Safety and Reduction in Disease Activity

Data Presented in Poster Presentation at the 2014 American College of Rheumatology Annual Meeting

FLORHAM PARK, N.J.-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announced that data highlighting results from Cohorts 1 through 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 PRTX-100-104 Study) were presented today at the American College of Rheumatology (ACR) and the Association for Rheumatology Health Professionals (ARHP) Annual Meeting 2014, underway in Boston. The poster is now available on the Company's website at www.protalex.com.

The poster, entitled "A Phase 1 Dose-Ranging Repeated-Dose Trial of Parenteral Staphylococcal Protein A (PRTX-100) in Patients with Active Rheumatoid Arthritis on Methotrexate or Leflunomide Therapy," was presented by Craig W. Wiesenhutter, M.D., of the Coeur d'Alene Arthritis Clinic in Coeur d'Alene, Idaho, and a principle investigator of the Phase 1b study.

The Company reported final data from Cohorts 1 through 4 and an interim analysis of pooled data from Cohort 5 of the 104 Study. Cohort 5 included 20 patients with ≥4 swollen joints and ≥5 tender joints despite ongoing treatment with methotrexate or leflunomide. The primary study endpoint of the 104 Study was safety and tolerability. The secondary endpoints included immunogenicity and effects on measures of RA disease activity. For patients in all five cohorts of the 104 Study, PRTX-100 appears safe and well tolerated in all individuals, including those who develop anti-drug antibodies (ADAs).

In Cohort 5, patients were randomized to 420 µg PRTX-100 (12 patients), 240 µg PRTX-100 (3 patients) or placebo (5 patients). Patients received five weekly doses of PRTX-100 followed by four monthly maintenance doses at weeks 8, 12, 16 and 20. The addition of four monthly maintenance doses after the five weekly doses did not increase the rate or type of adverse events (AEs), even in those patients who developed ADAs. Additionally, there was no apparent correlation between the development of ADAs and effects on measures of RA disease activity.

In a post-hoc analysis of Cohorts 1 through 4, patient samples were evaluated using the Vectra® DA (Crescendo Bioscience, Inc.) multi-biomarker test. Comparison of patients with Vectra® DA scores above and below 30 at the time of enrollment showed that patients with Vectra® DA scores > 30 were more likely to have reduced disease activity on Day 57. This suggests that the Vectra® DA biomarker test may enable identification of individuals who could benefit most from the use of PRTX-100 for the treatment of RA. The Vectra® DA is a multi-biomarker test intended to assess RA disease activity by measuring the concentrations of 12 serum proteins, converted into the Vectra® DA score via a proprietary algorithm.

“There were more Cohort 5 patients showing improvement in measures of disease activity, including ACR20 scores, compared to patients in prior Cohorts 1 through 4 who did not receive any monthly maintenance doses, suggesting that the addition of monthly maintenance administration of PRTX-100 may increase its effect on measures of disease activity in RA patients,” noted William E. Gannon, Jr., M.D., Protalex’s Chief Medical Officer.

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. The safety, tolerability and pharmacokinetics of PRTX-100 have been characterized in five clinical studies. In a Phase 1b clinical trial in adult patients with active RA in South Africa 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.

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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Source: Protalex, Inc.