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Protalex Announces PRTX-100 Phase I Data Published in The Journal of Clinical Pharmacology

Highlights pharmacokinetics, safety and pharmacologic activity of PRTX-100 in healthy volunteers

SUMMIT, N.J.-- Protalex, Inc. (OTCBB: PRTX), a clinical-stage biopharmaceutical company, today announced publication of the Company's Phase 1 study with PRTX-100 in healthy volunteers. This article entitled, "Safety, Pharmacokinetic, Immunogenicity, and Pharmacodynamic Responses in Healthy Volunteers Following a Single Intravenous Injection of Purified Staphylococcal Protein A," appears in the *Journal of Clinical Pharmacology,* Volume 53 (9).

The paper describes the first detailed examination of the pharmacokinetics, safety and pharmacologic activity of highly-purified staphylococcal protein A (SPA or PRTX-100) administered as an intravenous injection. A separate publication now in progress will detail the results of the Company's first Phase 1b study of repeated doses in patients with active rheumatoid arthritis (RA) that was presented in November 2012 at the American College of Rheumatology's Annual Meeting.

The Phase 1 study involved 20 healthy adults who received a single intravenous dose of either 0.3 mcg /kg (n=8) or 0.45 mcg/kg (n= 8) of SPA or placebo (n= 4). Changes in C-reactive protein and neopterin were measured as additional markers to detect immune activation or product reactogenicity. Twelve of 16 active-dosed subjects developed detectable anti-protein A antibodies after dosing. These subjects had notably more rapid plasma clearance of PRTX-100 even prior to development of detectable titers. A transient post-dose decrease in circulating lymphocytes was observed as a notable pharmacodynamic effect, but was not correlated with plasma clearance or AUC. All treatment-related adverse events were of mild severity.

In the paper's introduction, the authors also noted that, "We discovered that *in vitro* exposure of human macrophages to SPA at concentrations as low as 10 to 50 ng/mL inhibit both phagocytosis of opsonized platelets, as well as the secretion of tumor necrosis factor-alpha and the up-regulation of CD16 and CD40 after stimulation by bacterial endotoxin. This activity appears to involve inhibitory signaling via Fc receptors. Studies of very low parenteral doses of SPA in the mouse collagen arthritis model showed this treatment to reduce disease activity in a manner comparable to etanercept, a soluble TNF-receptor. Unlike the activity of etanercept, the suppression of disease activity is not abrogated when mice form antibodies to SPA. This suggests that a limited number of intravenous injections of an appropriate dose of SPA might be capable of modulating

deregulated immunity and decreasing disease activity in a variety of autoimmune diseases.”

Edward Bernton, M.D., Protalex’s Chief Scientific Officer and a co-author of the paper stated, “This study first demonstrated the safety and tolerability of small intravenous doses of PRTX-100 and delineated acute and transient pharmacodynamic effects not previously reported. These findings are consistent with the data from our first Phase 1b clinical trial in adult patients with active RA in South Africa completed in January 2012, which showed that PRTX-100 was generally safe and well tolerated at all dose levels. Furthermore, at the higher doses more patients showed improvement in their Clinical Disease Activity Index for RA than did patients at the lower dose or placebo cohorts”.

Protalex is continuing enrollment of its second Phase 1b study of PRTX-100 to assess the safety and tolerability of four different dose ranges of intravenous PRTX-100 administered weekly over five weeks in patients with active RA on methotrexate or leflunomide therapy. Enrollment is currently taking place at five study sites in the U.S. and is expected to expand by an additional two to five U.S. sites.

About Protalex

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 RA 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 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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