

# Protalex Significantly Strengthens Global Intellectual Property Portfolio for Proprietary Immunomodulatory Therapeutic

Granted Six Key International Patents Protecting and Expanding Use for PRTX-100

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announces that the Company has been granted several key patents for PRTX-100, the Company's highly purified form of Staphylococcal protein A (SpA), from governing bodies in the United States, Europe, Canada, and Japan.

PRTX-100 has been the subject of ongoing clinical development in immune thrombocytopenia (ITP) and rheumatoid arthritis (RA). PRTX-100 has been granted Orphan Drug Designation in the U.S. and in Europe for the treatment of ITP.

The following patents were recently granted for PRTX-100:

- U.S. Patent No. 9,370,552 ('552 patent) is a continuation patent to initial U.S. patent No. 7,211,258 ("Protein A compositions and methods of use") filed in 2002 and issued with method of treatment claims for RA, juvenile RA, and systemic lupus erythematosus (SLE). The '552 patent expands the method of treatment of PRTX-100 to include type 1 diabetes.
- European Patents No. 2,570,136 and 2,206,511 (national patents in force in France, Germany, Italy, Spain, Switzerland, and the United Kingdom) includes composition claims relating to numerous autoimmune diseases (RA, ITP, juvenile RA, psoriasis, myasthenia gravis) and dosage expansion.
- Canadian patents No. 2,894,098 and No. 2,481,282 comprise method of treatment claims relating to RA and SLE.
- Japanese patent No. 5,523,796 claims compositions for treating psoriasis, scleroderma, Crohn's Disease, myasthenia gravis, ulcerative colitis, psoriatic arthritis, and pemphigus vulgaris.

In addition, the Company recently received a Notice of Intention to Grant from the European Patent Office for PRTX-100 for an additional patent for composition claims relating to treating inflammation. Additional patents are pending in Europe and Japan. Also, the Company has filed a request for registration for a patent in Hong Kong for PRTX-100 for composition claims for treating inflammation.

"We continue to invest in expanding our global intellectual property portfolio as part of our commitment to broadly protect our proprietary immunomodulatory SpA technology. We are fortifying our patent estate to support our comprehensive strategy for the development and commercialization of PRTX-100 in a variety of autoimmune and inflammatory diseases," stated Arnold P. Kling, President of Protalex.

### **About PRTX-100**

PRTX-100, a new generation immunomodulatory therapy, is a highly purified form of SpA, an immunomodulatory protein known to modify aspects of the human immune system. PRTX-100 has the ability, at very low concentrations, to bind to human B-lymphocytes and macrophages and to modulate immune processes. Pre-clinical data indicate that PRTX-100 may have the potential to treat ITP by reducing the immune-mediated destruction of platelets. The two most recently approved drugs used to treat ITP, Nplate® (romiplostin) and Promacta®/Revolade™ (eltrombopag) increase the production of platelets but do not appear to affect the underlying platelet destruction process.

The safety, tolerability and pharmacokinetics of PRTX-100 have been characterized in six clinical studies. In three 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. PRTX-100 is administered as a short intravenous infusion.

Nplate® is a registered trademark of Amgen, Inc. and Promacta®/Revolade™ are registered trademarks of Novartis A G.

# 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 RA and ITP. In the U.S., Protalex has open INDs for the treatment of RA and ITP, and in Europe, an open IMPD for ITP. Please visit Protalex's website at <a href="https://www.protalex.com">www.protalex.com</a> to learn more about Protalex and its lead drug candidate, PRTX-100.

## **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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