

June 7, 2017



Protalex Issues Letter to Shareholders

FLORHAM PARK, N.J.--(BUSINESS WIRE)-- Protalex, Inc. (OTCQB:PRTX), a clinical-stage biopharmaceutical company, announces that Arnold P. Kling, President, and Chief Executive Officer of Protalex, has issued a Letter to Shareholders providing a business update. The full text of the Letter, which has also been posted to the company's website, follows below.

To My Fellow Shareholders:

Protalex started 2017 with several advances to our global clinical development programs of our lead product, [PRTX-100](#), a highly-purified form of Staphylococcal protein A (SpA), as a potentially safe and effective new treatment for autoimmune diseases, that position us for **continued advancement throughout the balance of the year and beyond.**

We continue to enroll our Phase 1/2 dose escalating studies of PRTX-100 as a potential new treatment for chronic immune thrombocytopenia (ITP) in the U.S. (the 202 Study) and in Europe (the 203 Study). To meet the challenge of patient recruitment associated with an orphan disease like ITP, we markedly expanded the number of clinical sites in both the U.S. and Europe. Last week we began patient screening in the United Kingdom to augment the 203 Study in Europe. With this expansion, we now have **more than 20 sites worldwide open for patient enrollment.**

The 203 study is an ascending dose phase 1/2 focused on adult with ITP who have failed one prior treatment. The 202 study includes adults with chronic ITP who have proven refractory to thrombopoietin agonists. We expect to complete the second cohorts of each of these studies shortly and look forward to advancing both studies to their third cohorts. For additional information on trial design and study sites, please visit www.clinicaltrials.gov.

We are **encouraged by our initial results** in both the 202 and 203 Studies, which thus far show an acceptable safety profile to support continued enrollment into higher-dose cohorts in both trials. We have observed two platelet responses, as defined per protocol, in the trials, as described in part in an abstract published for the American Society of Hematology conference in December 2016.

Regulators have granted PRTX-100 **Orphan Drug Designation as a potential treatment for ITP in both the U.S. and Europe.** This status provides commercial exclusivity benefits, tax credits for certain research, potential research grants and a waiver of the New Drug Application user fee in the U.S. Earlier this year, we **applied for a \$500,000 grant for our ITP trials** with the Office of Orphan Products

Development (OPD) in the U.S. Food and Drug Administration (FDA). We are pleased to report that our application **received a Priority Score of 20**, which is a competitive ranking as scores are graded 0-90 with zero being the highest score. We believe that we will likely receive the grant because scores better than 30 received funding in previous grant cycles. We will receive notification by the end of September and, if awarded, will receive the funds shortly thereafter.

We recently initiated a study of PRTX-100 in an animal model of Myasthenia Gravis (MG) and expect to have top-line results from that study sometime in the 3rd quarter of 2017. MG is an autoimmune disorder caused by anti-self antibodies that react with the neuromuscular junction causing muscle weakness and fatigability. MG remains underdiagnosed in the United States and has an estimated incidence of 14 to 20 per 100,000 population, thus approximately 36,000 to 60,000 cases in the U.S.¹ Current treatments, which include corticosteroids and immunosuppressant agents, are not optimal as they can cause severe adverse events. As neurological autoimmune disorders in general lack efficacious treatments without adverse side effects, we believe that achieving positive results in the mouse preclinical model of MG could widely expand the development and application of PRTX-100 in other neurological autoimmune conditions.

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 continue to fortify our patent estate to support our comprehensive strategy for the development and commercialization of PRTX-100 in a variety of autoimmune and inflammatory diseases. In the past year, we were granted **seven key international patents that protect and expand the uses for PRTX-100** in autoimmune diseases, including rheumatoid arthritis (RA), ITP, and MG, among others.

We are especially **grateful to the patients, clinicians, collaborators, and employees** who have contributed to our progress and who will continue to help us succeed. We believe that the next 12 months will be a period of both confirmation of the safety and efficacy of PRTX-100 as a potential treatment for ITP, as well as one of expansion of its potential indications and uses.

On behalf of our Board of Directors and management team, I **thank you for your continued interest in and support of Protalex** as we advance our plans to bring potential new treatment options to patients suffering with autoimmune diseases such as RA, ITP and MG.

Sincerely,

Arnold P. Kling
President

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 www.protalex.com 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.

¹ <http://www.myasthenia.org/HealthProfessionals/ClinicalOverviewofMG.aspx>

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