PRTX

PROTALEX

Company Presentation

December 2017

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Corporate Highlights



- Highly-purified biologic compound
- Clinical experience in six human studies
- Demonstrated safety profile
- Potential for multiple clinical uses

- Focus on Immune Thrombocytopenia (ITP)
  - Orphan disease
  - >$1B market
- Other autoimmune diseases ($Bs)

- Experienced management
- Strong scientific advisors
- Low-burn model
- Funded-to-date by majority shareholder, Niobe Ventures, LLC

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Our Leadership Team

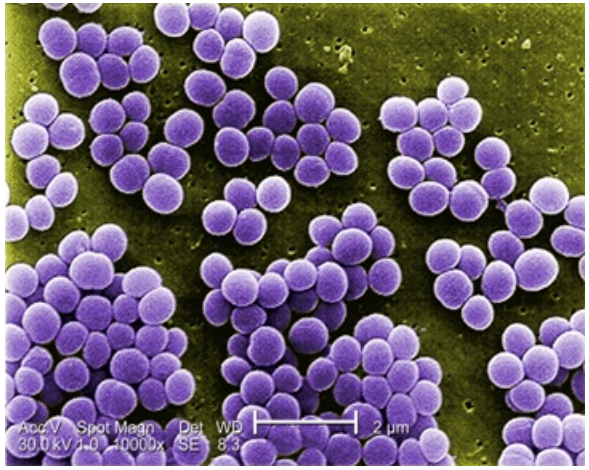
- **Arnold P. Kling** – President; Director; Principal of Niobe Ventures, LLC, experienced investor in and manager of early stage technology companies
- **James W. Dowe III** – Vice-Chair of SAB; active investor in biotechnology, computer software and investment management companies
- **William E. Gannon, MD** – Chief Medical Officer; more than 20 years experience in clinical development and regulatory affairs at Quintiles, PPD, and other companies
- **Richard Francovitch, Ph.D.** – VP of ITP Programs; 27 years pharma experience, former Head of Hematology Franchise and Global Commercial Leader for Promacta at GSK
- **Bruce McClain, MD** – Medical Director; more than 20 years experience in clinical development and product safety; senior roles at Aeras Global and MedImmune
- **Benjamin R. Bowen, Ph.D.** – Senior Advisor; background in pharma and biotech R&D at Genentech, Ciba-Geigy, and Novartis; twelve years in investment banking
- **Michelle Catalina, Ph.D.** – Director of Preclinical Studies; academic research background in immunology, former instructor at U Mass Medical Center

Commercial Thesis

- PRTX-100 is a novel immunomodulatory compound with potential application across various autoimmune indications
  - Positive therapeutic effects seen in ITP preclinical models and patients
- Six clinical studies conducted to date (ITP, RA, healthy volunteers), each demonstrating that PRTX-100 is safe and well-tolerated in humans
- Validated manufacturing process; significantly lower cost of goods relative to other biologics
- Thirteen issued patents cover compositions and methods of use in numerous autoimmune diseases

Staph Protein A (SpA) and the Rationale for PRTX-100 as Autoimmune Treatment

- Staphylococcus aureus (*S. aureus*) is a leading cause of blood-stream, bone, skin, soft tissue, pulmonary and device-related infections[1]
- In humans, the *S. aureus* bacterium does not elicit a protective immune response and patients often suffer from chronic or recurrent infections[2]
- *S. aureus* expresses protein A (SpA), which alters the immune system of the host and facilitates escape from immunosurveillance[3]

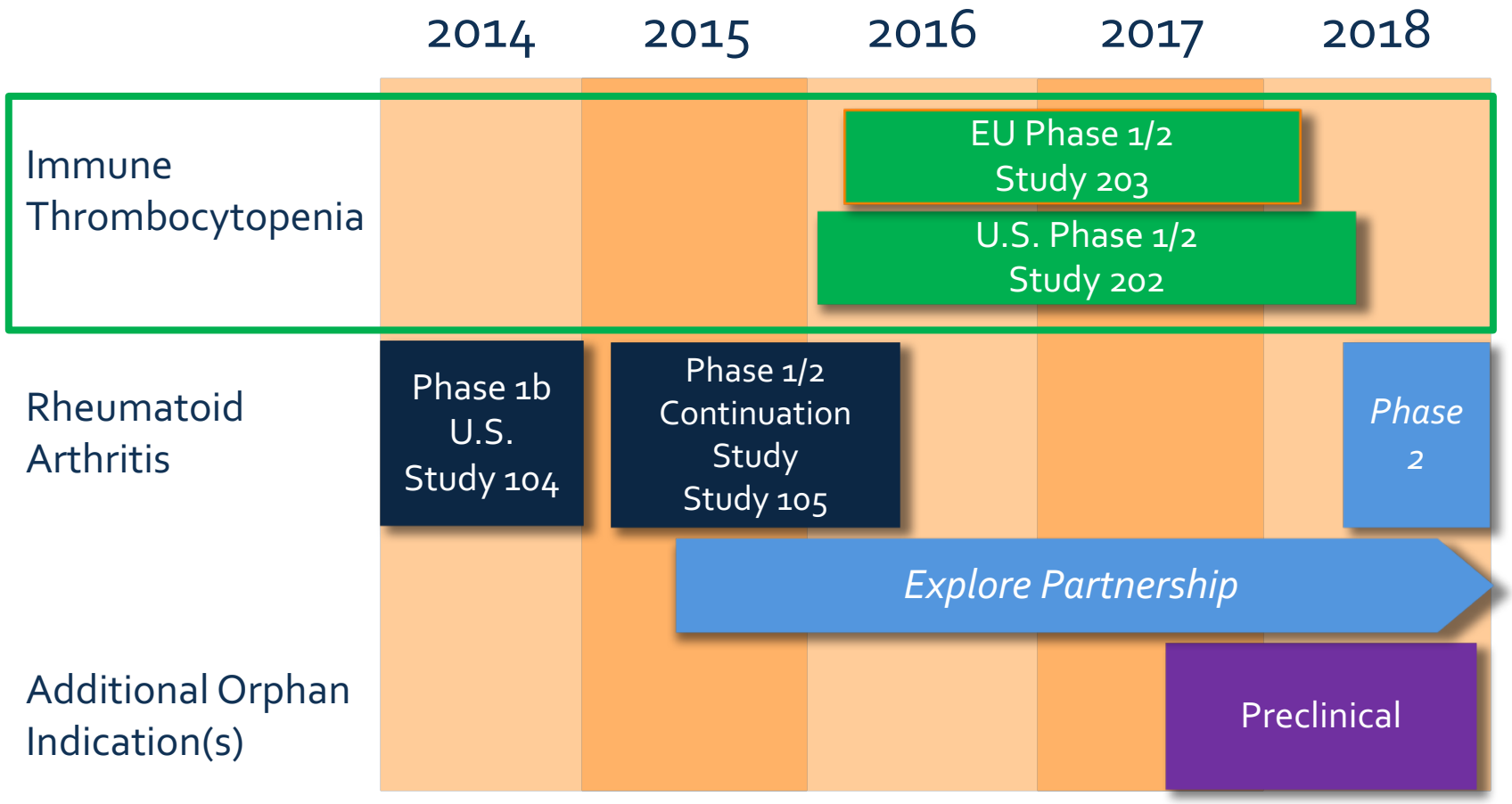


- The immunomodulatory properties of SpA make it a compelling target for study in autoimmune conditions such as ITP
- PRTX-100 is a highly purified formulation of SpA developed for therapeutic administration

1. Tong SY, et al. Clin Microbiol Rev 2015;28:603–61;
2. Bagnoli F, et al. Front Cell Infect Microbiol 2012;2:16
3. Pauli NT, et al. J Exp Med 2014;211:2331–9

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PRTX-100 Product Development Plans



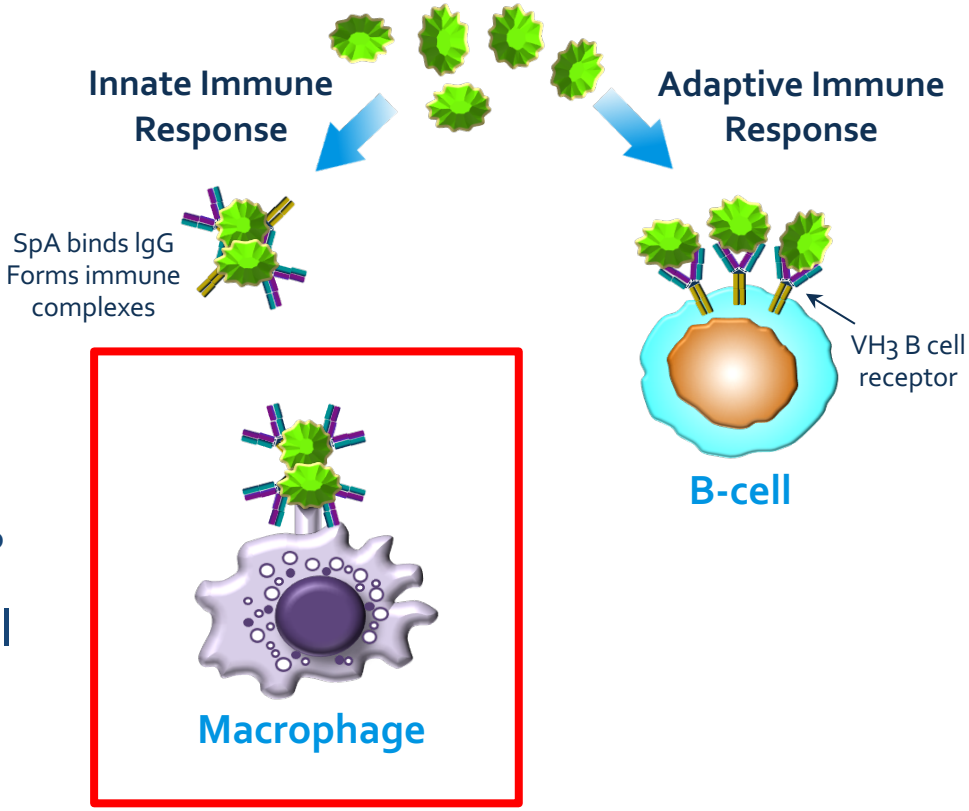
Immune Thrombocytopenia (ITP): A Rare and Serious Autoimmune Disorder

- ITP patients show very low blood platelet counts with increased risk of bruising and bleeding which can be fatal
- ITP is an autoimmune disease:
  - Afflicted people develop antibodies to their own platelets
  - These antibodies bind platelets, leading to premature destruction by white bloods cells (macrophages)
- Affects approximately 60,000 people in the US and an equal number in Europe
- Annual treatment cost of ~$80,000 for the most recently approved therapies (Promacta®, Nplate®)

Our lead drug, PRTX-100, binds antibodies into complexes that modulate immune function to inhibit platelet destruction

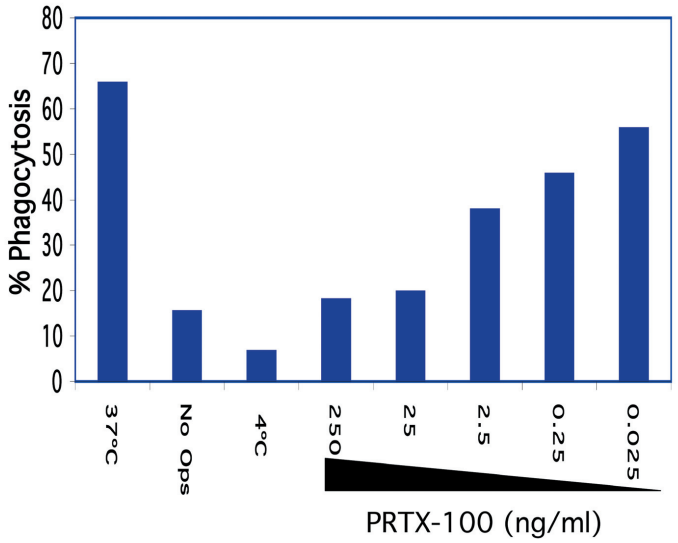
PRTX-100: Mechanisms of Action

- PRTX-100 affects macrophage activity
  - Forms immune complexes with IgG, binds to macrophages and induces a "suppressor" phenotype in macrophages
  - Macrophage suppression potentially useful in treating ITP
- PRTX-100 also modulates B-cell activity directly by binding VH3 B-cell receptors



MacLellan, et al., *Arthritis & Rheumatism*, 2011; Kim, et al. *mBio*, 2015

PRTX-100 Inhibits Platelet Phagocytosis

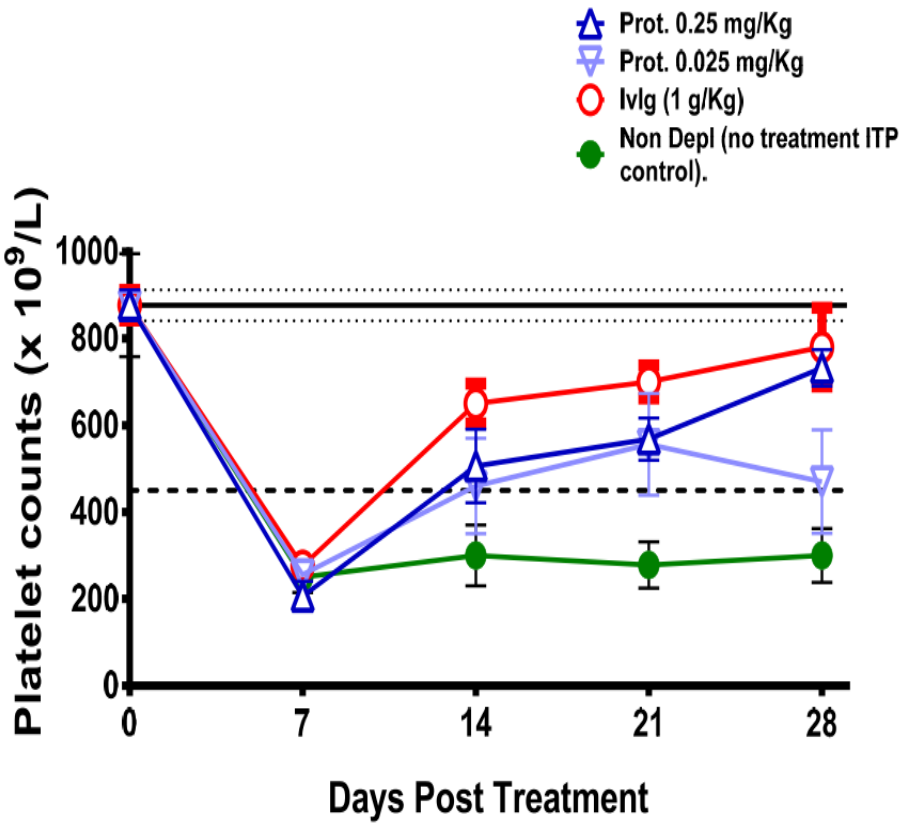


- In vitro studies used monocytes and platelets isolated from human blood
- Platelets were opsonized (coated with antibodies) and mixed with monocytes that had been treated with PRTX-100 for 48 hours
- Monocytes that were not pretreated with PRTX-100 engulfed a large % of platelets
- Pretreatment of monocytes with PRTX-100 reduced platelet phagocytosis in a dose-dependent manner

Semple, JW, et al. Poster presentation, American Society of Hematology 2015 Annual Meeting

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PRTX-100 Effectively Treats Thrombocytopenia in a Murine Model of ITP



- Chow, et al. 2010 model—involves both cellular and humoral immunity
- Thrombocytopenic SCID mice
- Mice treated on day 8 after thrombocytopenia is established
- PRTX-100 raises platelet counts in a dose-dependent manner
- Effects comparable with IVIg (Gold standard treatment for ITP)

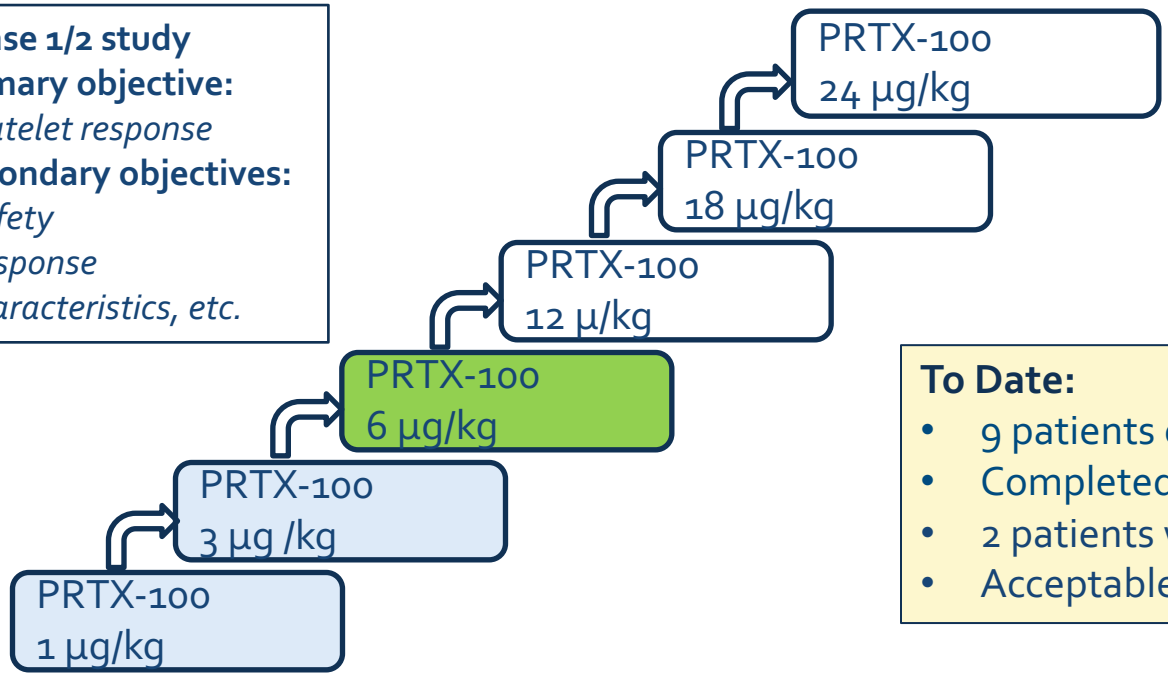
Semple, JW, et al. Poster presentation, American Society of Hematology 2015 Annual Meeting

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Study 202: Adult ITP Patients with Chronic, TPO-Refractory Disease

Phase 1/2 study
Primary objective:
- *Platelet response*

Secondary objectives:
- *Safety*
- *Response characteristics, etc.*



To Date:
- 9 patients enrolled
- Completed 1 and 3 µg/kg cohorts
- 2 patients with platelet response
- Acceptable safety profile

Treat 2-6 patients/cohort at 6 U.S. sites (opening sites in UK in Q1 2018)



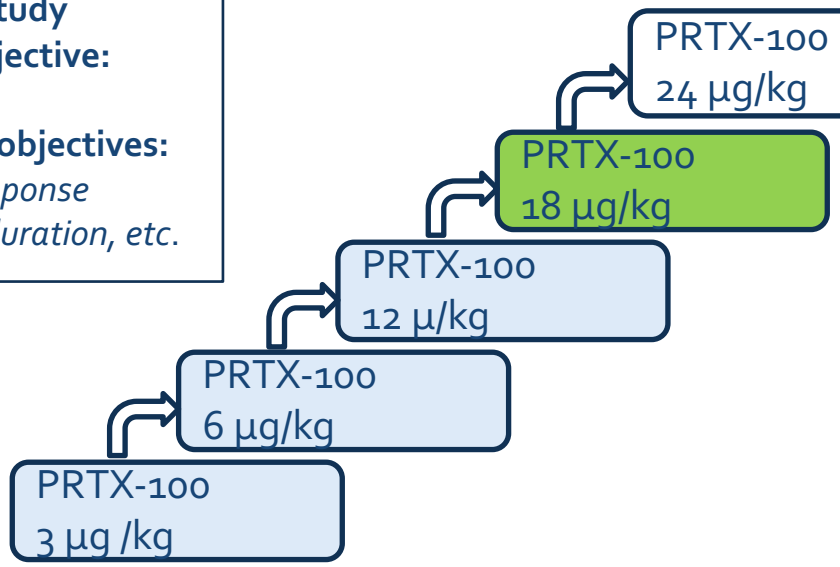
Up to 13 study visits

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Study 203: Adult ITP Patients Who Failed One Prior Treatment (Europe)

Phase 1/2 study
Primary objective:
- *Safety*

Secondary objectives:
- *Platelet response*
- *Response duration, etc.*



To Date:
- 10 patients enrolled
- Completed enrollment in 3,6, and 12µg/kg cohorts
- 1 platelet response
- Acceptable safety profile

Treat 3- 6 patients at sites in Europe (UK sites recently opened)

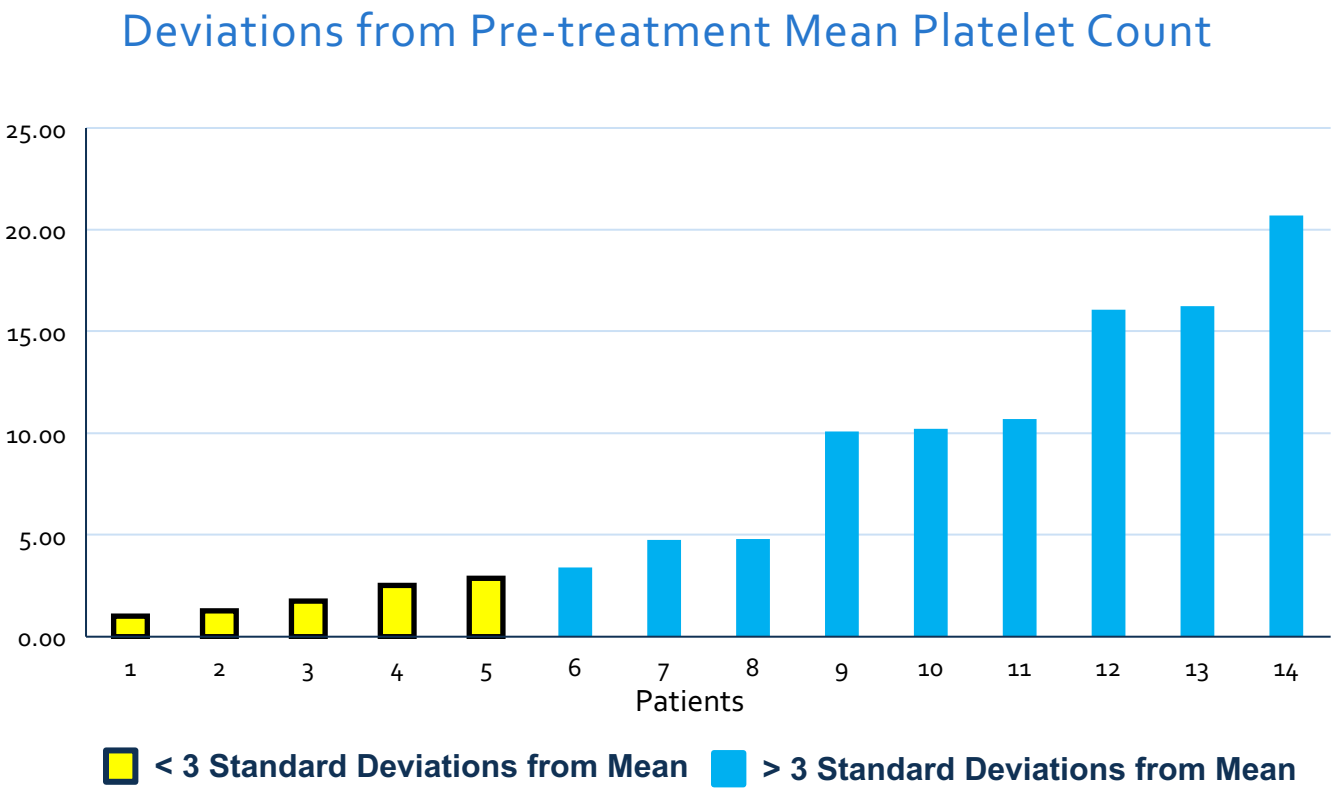


Up to 13 study visits

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PRTX-100 Effect on Mean Platelet Counts

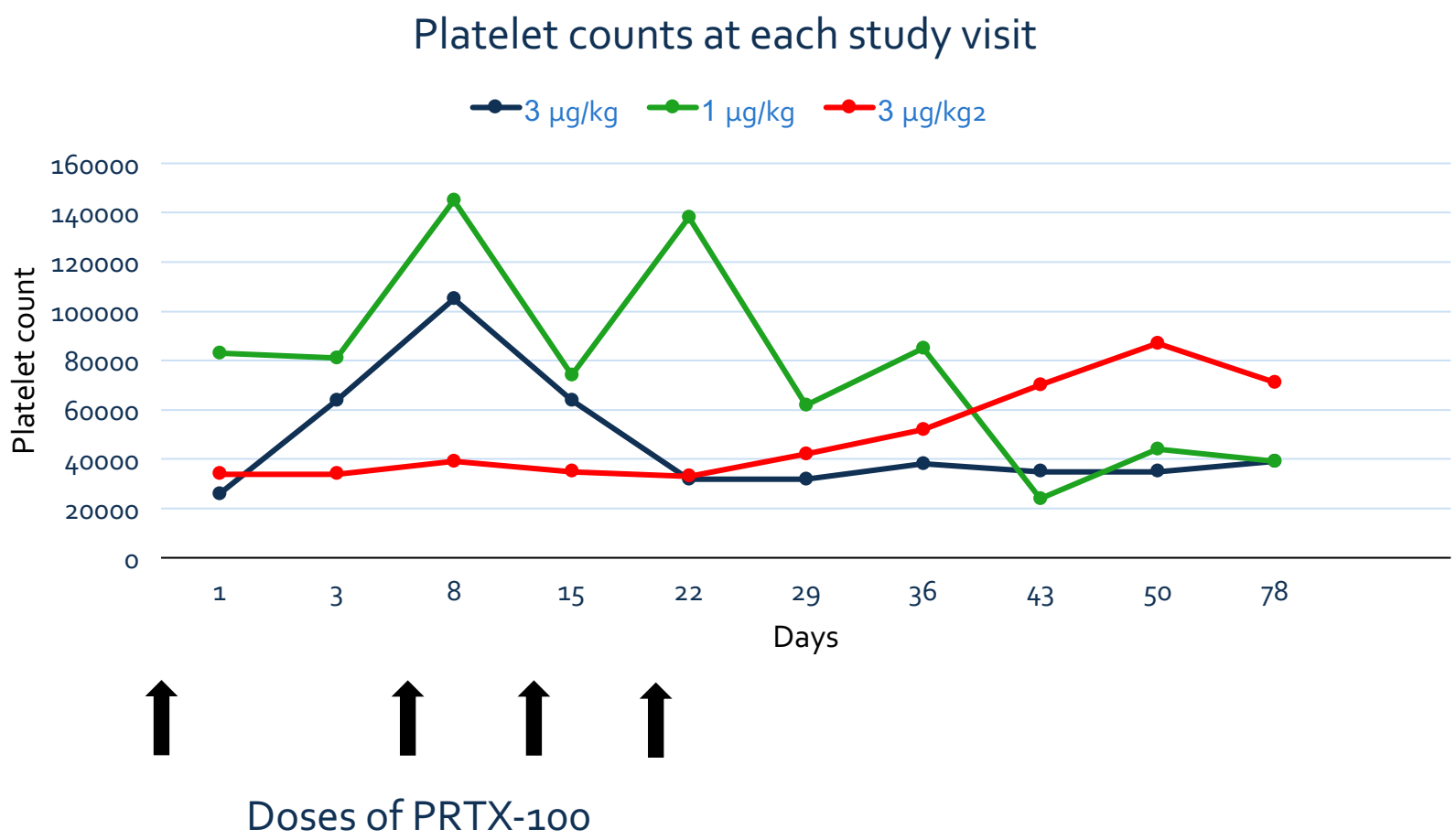
Measured by # of Standard Deviations From Pre-Treatment Mean



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Protocol Defined Responders in ITP Studies

Early and Delayed Responses Observed



Current Conclusions from ITP Studies

- PRTX-100-203 & PRTX-100-203 are ongoing early phase studies to primarily evaluate the safety and determine the maximum tolerated dose of PRTX-100 in ITP patients
- At the doses studied to date (up to 12 µg/kg), most adverse events were mild to moderate in severity, transitory in duration, and resolved spontaneously
- Evidence of activity in raising platelet counts in these early phase clinical trials at the doses studied so far are very encouraging
- Data obtained at higher doses will help direct investigations to maximize the efficacy of PRTX-100 in ITP

Protalex Recognized by FDA with a Grant for the Development of PRTX-100 in ITP

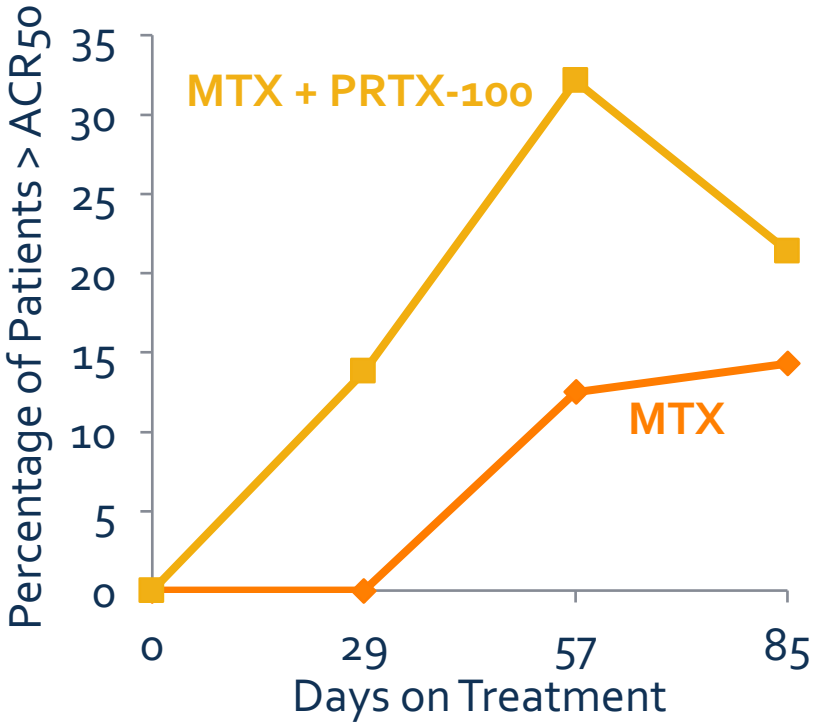
- FDA Office of Orphan Products Development (OOPD) Grants Program supports the development of rare disease products where no current therapy exists or where the proposed product has the potential to be superior to existing therapy
- FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products
- THE OOPD awarded Protalex a $403,000 grant in 2017 to support the clinical development activity of PRTX-100 in ITP

PRTX-100 Value Proposition for ITP

- Novel mechanism of action –immunomodulatory vs immunosuppression
  - Potential to work in combination with TPO-agonists
- Unlike other ITP treatments doesn't increase risk of infections by suppressing immune system activity
- Rapid onset of effect raising platelet counts within 2-7 days
- Well tolerated infusions that are completed in 30-60 minutes
- Acceptable safety profile
- May require less frequent dosing than other ITP therapies

Study 104: ACR50 Improvements in RA Patients on Background MTX Therapy

ACR50 Response Rate



MTX +/- PRTX-100

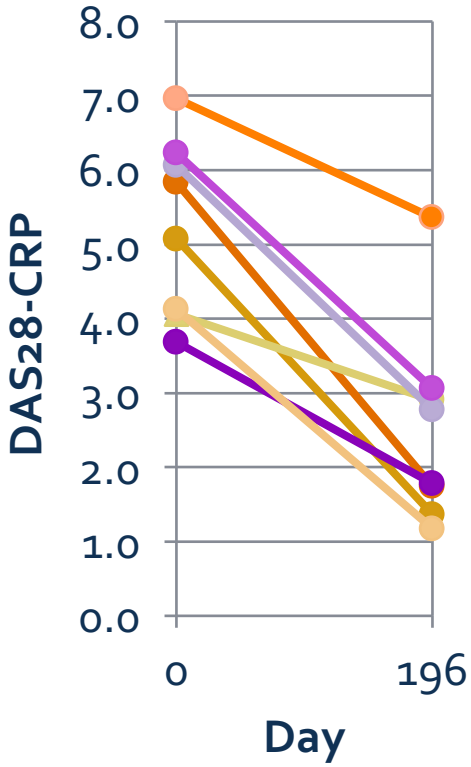
- Trial PRTX-100-104 (1-4): 41 patients w active RA randomized 3:1
- Baseline MTX vs MTX + PRTX-100, five weekly i.v. doses, 1.5, 3, 6, or 12 mcg/kg
- Last PRTX-100 dose at day 29
- No drug-related SAEs

Source: Company PRTX-100-104 CSR

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Study 105: Continuation Study

- Enrollment commenced February, 2015; last dose/visit February 2016
- Open-label, multiple fixed dose trial open to Study 104 participants who indicated a desire for additional treatment
- Eleven patients enrolled; eight completed per protocol at single site
- Primary endpoint was safety and tolerability of a fixed dose of PRTX-100 administered over an extended period
- Secondary endpoints included immunogenicity, effects on measures of disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of biomarkers and joint evaluation with ultrasound
- Patients who completed the study per protocol demonstrated a mean reduction of the DAS28CRP score from **5.25** to **2.52**; correlated with ultrasound power doppler



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PRTX-100 Overall Clinical Experience

- Safety and tolerability established in six human clinical studies involving 141 subjects (RA, ITP, healthy volunteers) receiving weekly IV doses up to 12 µg/kg for up to 6 weeks
- No treatment-related SAEs and no requirement for expedited reports to FDA
- Most AEs related to PRTX-100 administration were mild to moderate in severity
- Infusion reactions occurred in a small number of patients, characterized by headache, musculoskeletal symptoms, constitutional symptoms and transient exacerbations of joint findings. These events were managed with symptomatic therapy
- PRTX-100 was shown to have an acceptable safety profile with no deaths or SAEs attributed to it

Preclinical Activities in Other Indications

- PRTX-100 has shown to be active in autoimmune conditions leading to inflammation (RA) and cytopenias (ITP)
- Based on its MOA, PRTX-100 may impact other autoimmune diseases and Protalex is exploring preclinical proof of concept activities in additional models of human disease
- Myasthenia Gravis (MG) is chronic autoimmune neuromuscular disease
  - MG is a prototypic antibody-mediated autoimmune disorder
  - Affects ~ 60,000 people in the US
  - Plasmapheresis and IVIg are used as partially effective therapies
- Protalex is working with academic experts who use complex animal models of MG

Patents and Intellectual Property

- Patents (six issued in U.S., one in Japan, three in Europe, two in Canada, one in Hong Kong)
  - Initial U.S. patent 7,211,258, "Protein A compositions and methods of use" filed 2002 and issued with method of treatment claims for RA, juvenile RA, and systemic lupus erythematosus (SLE)
  - U.S. continuation patents expanding use, issued with method of treatment claims for:
    - ITP or autoimmune TP in 2008
    - Reducing an acute inflammatory response or inflammation in 2010
    - Psoriasis and scleroderma in 2012
    - MS in 2013
    - Type 1 Diabetes 2016
  - Japanese patent issued with composition claims treating psoriasis, scleroderma, Crohn's Disease, myasthenia gravis, ulcerative colitis, psoriatic arthritis, and pemphigus vulgaris.
  - European patents issued with composition claims relating to numerous autoimmune diseases (RA, ITP, juvenile RA, psoriasis, myasthenia gravis), dosage expansion, and treatment of inflammation.
  - Canadian patents issued Dec. 2016 with method of treatment claims relating to RA and Lupus.
  - Hong Kong patent issued September 2017 with composition claims.
- Other Intellectual Property
  - Considerable know-how in the manufacture and QA of highly purified SpA expected to remain trade secret

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Thank you