Xalud Therapeutics-NINDS Collaboration

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Overview

Xalud Therapeutics, Inc. is developing novel therapies for the treatment of neuro-inflammatory diseases including:

- Neuropathic pain
- Multiple sclerosis (MS)
- Amyotrophic lateral sclerosis (ALS)/Lou Gehrig’s Disease

Xalud is also developing treatments for inflammatory joint disorders including:

- Osteoarthritis
- Rheumatoid Arthritis

**Collaboration:** NINDS U44 SBIR Grant and UCol Boulder

**Objective:** To develop the IND-enabling safety data for our lead development candidate: XT-101
Transformative in Chronic Pain

- Single dose therapy
- Non-opioid
- No sedation
- No addiction potential
- Twelve weeks of efficacy following a single dose
- Preliminary toxicology results are clean
Multiple Impacts in Multiple Sclerosis

- Blocks progression of motor dysfunction
- Reverses extant motor dysfunction
- Reverses pain
- Additional behavioral benefits
- Increases survival
Real Patients, Real Benefits

- Companion dogs with neuropathic pain, osteoarthritis
- No sedation
- Durable efficacy
- Improved quality of life
Challenges for XT-101 Development

• XT-101 is a novel treatment for neuro-inflammatory diseases including neuropathic pain, MS and ALS, high unmet clinical needs requiring innovative approaches.

• We needed to develop scalable manufacturing and to complete our definitive efficacy and IND-enabling toxicology studies.

• The funding required for these tasks was small by venture capital or pharma standards, but
  – The time frame for most funding avenues was unacceptable
  – XT-101’s novelty was a concern

• Common issues for many development candidates
The U44 SBIR Grant Mechanism

- Milestone-driven cooperative agreement program involving participation of NINDS staff in the development of the project plan and monitoring of research progress
- Accelerate the translation of basic research discoveries into therapeutic candidates for clinical testing
- Identify new therapeutics for neurological disorders and facilitate pre-clinical testing
- Expects the submission of an IND or IDE application by the end of the project period
Benefits of the U44 Approach

- Significant non-dilutive funding ($2.3 M)
- Extramural validation of the basic research behind XT-101
- Collaboration facilitates a focused developmental path
- Xalud and NINDS jointly develop strategies to overcome emergent challenges
- Milestone basis outlines the developmental path, but also suggests alternative routes if necessary
Accomplishments/Future Milestones

• Original Milestones
  – Completing a definitive efficacy and dose-ranging study
  – Implementing a GMP compliant commercial scale manufacturing process
  – Completing a preliminary pharmacology/toxicology study

• Flexibility: One milestone, significantly modified by NINDS and Xalud, has developed into an important proof of principle

• Initiating IND-enabling GLP toxicology study
• IND submission Spring 2014
Budget/Financing

- U44 grant covers XT-101 to the brink of a Phase I/IIa in neuropathic pain
  - Significant additional funding in distinct therapeutic areas ($1.1 MM)
- Virtual company structure minimizes burn and enables dedication of current funding for research and development activities
- Multiple additional avenues with promising preliminary data leading to therapeutic expansion
- Leadership team expertise can adapt to in-licensing opportunities
Summary

• Xalud Therapeutics has flourished in collaboration with NINDS
• Novel therapies like XT-101 have both typical and unique issues
• With timeline flexibility, Federal funding opportunities are available to early stage companies with strong efficacy data
• Collaborative translation projects can help guide you through the trees
• Xalud Therapeutics needs support for GMP manufacturing and our Phase I/IIa clinical trial, as well as therapeutic expansion: $6 MM
• We are actively seeking pharma, angel, and regional investor support to get XT-101 into the clinic
• www.xaludthera.com