Leprosy Vaccine Project Overview

The Partnership

17 Years

The Investment

$6M+

The Outcome

LepVax
The world's first leprosy-specific vaccine

Supporting Partners
### Phase Ia Clinical Trial Progress Timeline and Highlights

#### 2017
- **June**
  - Submit Initial New Drug (IND) filing to U.S. Food and Drug Administration (FDA)
- **August**
  - Receive FDA approval for clinical trial
- **September**
  - Start Phase Ia clinical trial
  - LepVax enters the first stage of testing in healthy human volunteers.
- **October – November**
  - Enroll first cohort of 12 people (low vaccine dose) and complete injections
- **November – December**
  - Conduct interim safety review
  - FDA safety review committee says vaccine has excellent safety profile.
  - Enroll second cohort of 12 people (high vaccine dose)

#### 2018
- **January – March**
  - Complete injections of second cohort
  - Perform last blood draw
  - Begin one-year follow-up period
- **June – November**
  - Clinical sample processing
- **December**
  - Analyze data and clinical immunology
  - Write clinical study report

#### 2019
- **January – April**
  - Analyze data and clinical immunology
  - Write clinical study report
- **June-August**
  - Complete Phase Ia trial

**July 2019 – July 2021:** Phase Ib clinical trial in Brazil.
In the summer of 2019, the 18-month Phase Ia clinical trial for LepVax, the world’s first leprosy-specific vaccine, was completed. This study was the critical first step in testing LepVax for clinical use. Phase Ia was designed to demonstrate the vaccine’s safety and to evaluate the immune response to the vaccine.

The trial was conducted among 24 healthy adult participants in Madison, Wisconsin, divided into two cohorts, each receiving three injections one month apart. The participants were then monitored over 12 months to determine if there were any adverse reactions to the vaccine. In addition to the safety study, an initial immunology analysis was conducted to determine if the vaccine encouraged a heightened immune response in healthy participants.

The study showed that the vaccine was extremely safe and resulted in no serious adverse events. The FDA recommended that the LepVax candidate proceed to the next phase of clinical trials. The vaccine also elicited strong immune responses, peaking after the third injection. This is a significant positive indication that the LepVax will function as designed by boosting the body’s immune response to the leprosy bacteria.

The next step in the development of LepVax is to determine its safety and preliminary effectiveness in people living in a leprosy-endemic area. For the Phase Ib clinical trial we have selected long-standing partners in Brazil at Oswaldo Cruz Foundation (Fiocruz), under the Ministry of Health, the most prominent institution of science and technology in health in Latin America.

We will work with Dr. Milton Ozorio Moraes who directs one of the largest leprosy clinics in Brazil, and has been at the forefront of clinical and translational research in this disease.

The Phase Ib clinical trial preparations have already begun. The trial design has been approved and the protocol has passed the first ethical committee review. We expect to start enrolling participants in the next few months. The trial will run for two years. It is a randomized, placebo-controlled, clinical trial that evaluates the safety, immune response and preliminary effectiveness of LepVax as a treatment for leprosy. We will enroll 30 healthy participants and 24 patients with pauci-bacillary (PB) leprosy.

After showing the safety of the vaccine in the Phase Ib study, we will proceed to Phase II clinical trials of LepVax.
The LepVax clinical development plan is overseen by a Joint Steering Committee. The Committee is led by American Leprosy Missions and IDRI and includes industry and legal experts from the German Leprosy and Tuberculosis Relief Association, Aeras and other organizations as required.

The Joint Steering Committee has designed a clinical development plan which will test LepVax’s efficacy both for prevention and improving treatment for leprosy in endemic populations.

Based on laboratory results, LepVax shows promise not only in prevention of leprosy, but also in reducing nerve damage once a person has the disease.
Impact

Every two minutes someone is diagnosed with leprosy and four million people live with lifelong disabilities from this marginalizing disease. Thanks to your partnership, families may never have to hear the devastating news that they have leprosy, nor suffer its debilitating effects.

We believe this leprosy vaccine will be an exciting new way to stop the transmission of leprosy and the only way to protect people long term. What’s more, the vaccine may protect against nerve damage among those already diagnosed with leprosy, the most serious complication of leprosy.

Together we are seizing this historic opportunity to help end leprosy, and leave a lasting legacy for millions of people around the world.

Phase Ia Clinical Trial Partners

Research Partners

Supporting Partners

The P.S. and Ouida Bailey Foundation, the H.L. Snyder Medical Foundation, Leonard Wood Memorial/CLTRFI, the National Hansen’s Disease Program, and American Leprosy Missions’ generous donors.
American Leprosy Missions is a Christian global health and development organization serving vulnerable people affected by neglected tropical diseases. It works with a network of partners around the world to research and implement innovative and scalable programs to stop these diseases and improve the well-being of affected people and communities. Since 1906, ALM has provided holistic care for more than four million people in 42 countries including disease detection, diagnosis and treatment, health worker training, community development, morbidity management, disability prevention, health system strengthening, disease mapping and vaccine research.

Thanks to your partnership, children like 10-year-old Grace in Côte d’Ivoire may never have to hear the devastating news that they have leprosy. Grace is seated center, fourth from left in turquoise shirt. (Credit: Tom Bradley)