

Leprosy Vaccine Phase 1b/2a Clinical Trial Update

June 2022

Leprosy Vaccine Project Overview

The Partnership



Supporting Partners

The Investment

20
Years

\$6M+

The Outcome

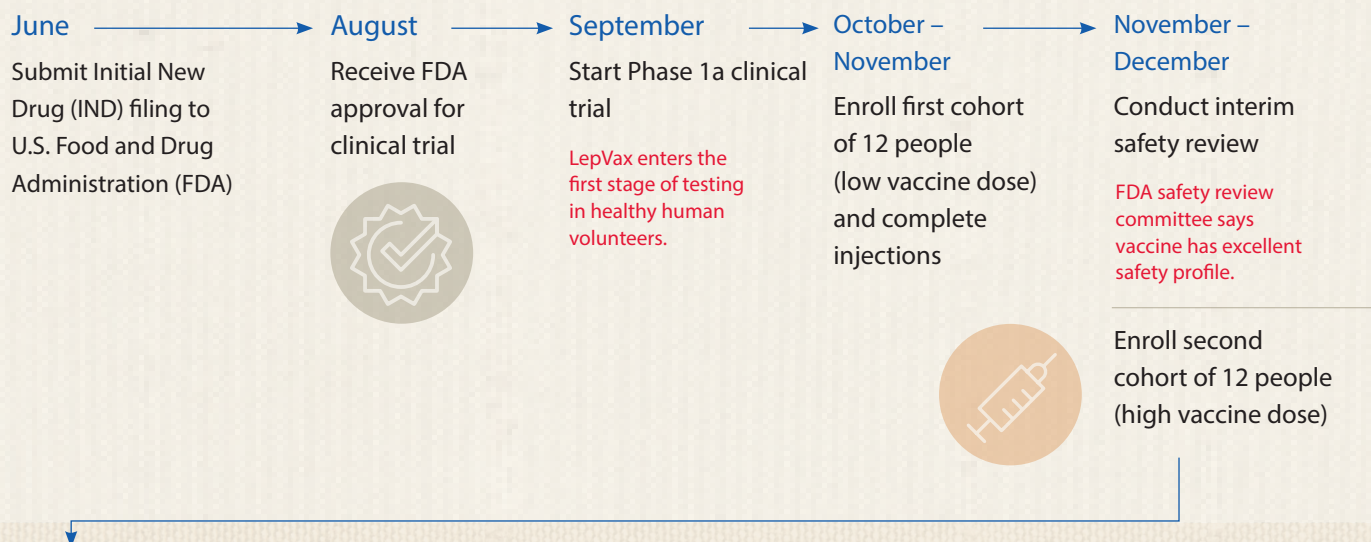


LepVax

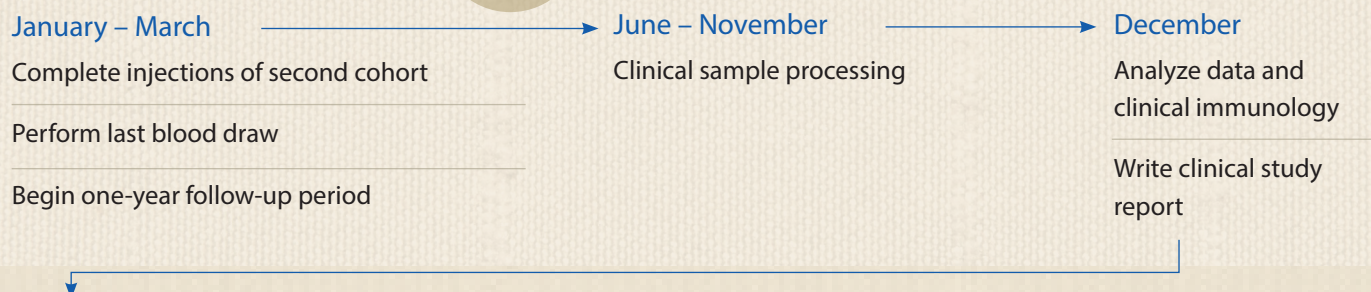
The world's first
leprosy-specific vaccine

Clinical Trial Progress Timeline and Highlights

2017



2018



2019

Phase 1a trial completed

2020 - 21

Delays due to IDRI receivership, COVID-19, and regulatory processes

2022

File revised Phase 1b/2a regulatory paperwork with ANVISA

Begin Phase 1b/2a trial

July 2022 – October 2024: Phase 1b/2a clinical trial in Brazil

Phase 1a Results Summary

Immune response and vaccine safety in healthy people in a region where leprosy is not endemic

In the summer of 2019, the 18-month Phase 1a clinical trial for LepVax, the world's first leprosy-specific vaccine, was completed. Phase 1a 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.

Next Steps: Phase 1b/2a

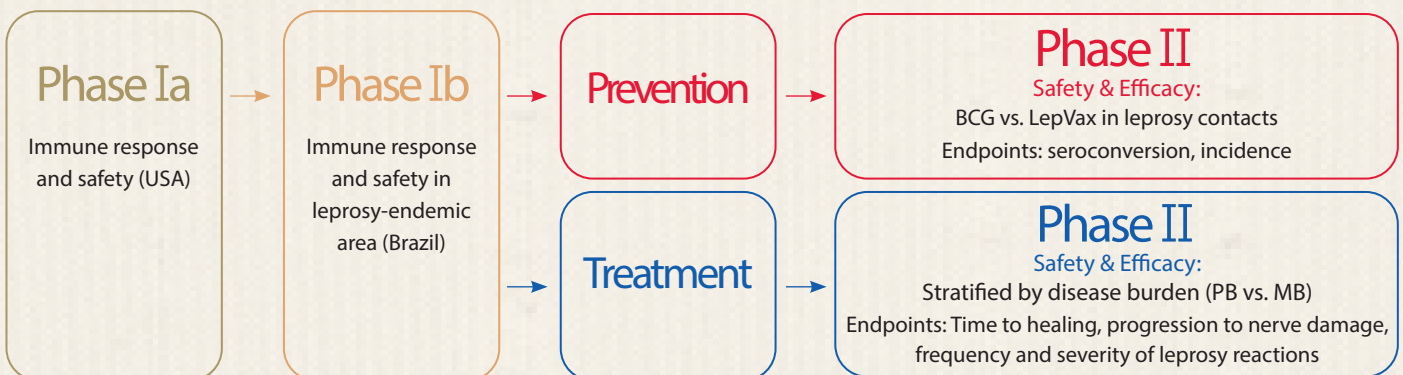
Immune response and vaccine safety in both healthy and leprosy-affected people in a region endemic for leprosy

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 1b/2a clinical trial we 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. 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 leprosy.

The 1b/2a trial in Brazil has continued to move forward despite multiple challenges. In early 2020, ALM's lab partner and developer of LepVax, IDRI, filed for receivership with the goal of being restructured to ensure ongoing financial viability. The COVID-19 pandemic also caused interruptions in the trial timeline, with both Fiocruz and IDRI focusing on pandemic response. During this time, ALM and IDRI reached an agreement regarding the transfer of materials to FioCruz to allow the 1b/2a test phase to begin.

From August 2021 to May 2022, ALM filed updated regulatory paperwork with the Brazilian food and drug administration, ANVISA. Approval is expected in summer of 2022, after which Fiocruz will enroll subjects in the two-year Phase 1b/2a clinical trial, expected to complete in October 2024. The LepVax Vaccine Advisory Board will reconvene in 2023 to guide and monitor the trial.

LepVax Clinical Development Plan



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.

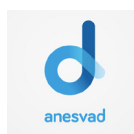
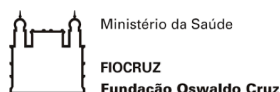
About American Leprosy Missions

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 research.



Simon and his nine-year-old daughter Monique (second from right) have been diagnosed with leprosy. While treatments exist for their condition, only a vaccine can prevent Monique's siblings, Moumoye (7) and Dimanche (5) from facing the same diagnosis. (Credit: Tom Bradley)

Phase 1a and 1b/2a Clinical Trial 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.