



## Leprosy Vaccine Phase 1b/2a Clinical Trial Update

August 2021

### Leprosy Vaccine Project Overview

#### The Partnership



#### The Investment

19  
Years  
**\$6M+**

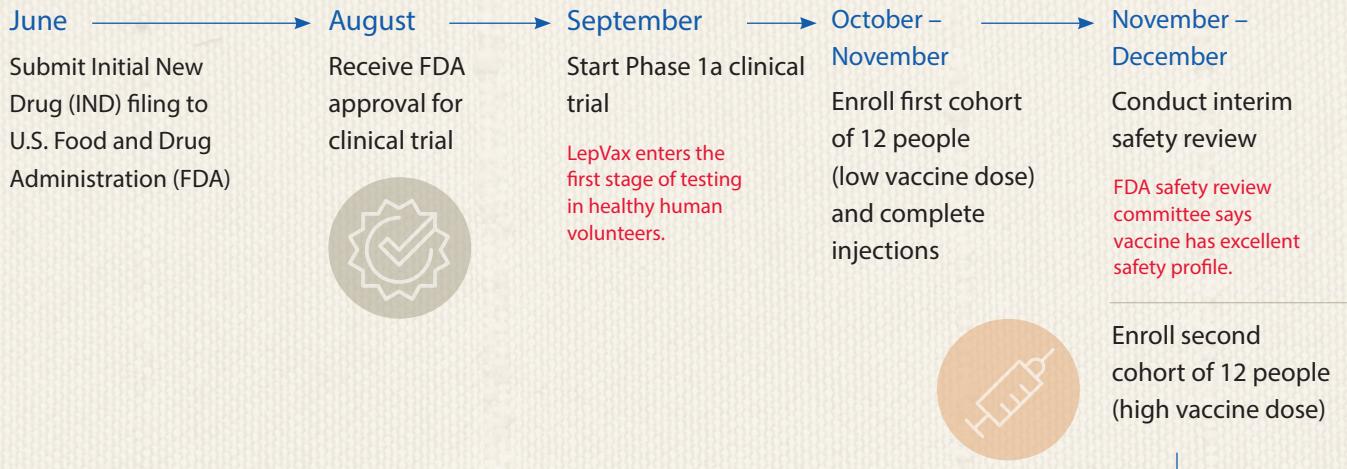
#### The Outcome



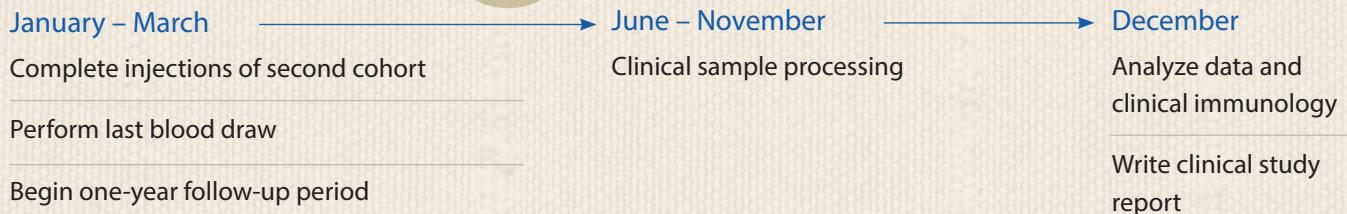
**LepVax**  
The world's first  
leprosy-specific vaccine

## Clinical Trial Progress Timeline and Highlights

# 2017



# 2018



2019

Phase 1a trial completed



2020

Delays due to IDRI receivership and COVID-19

2021

August  
Phase 1b/2a revised regulatory paperwork filed with ANVISA

November 2021 – November 2023: 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

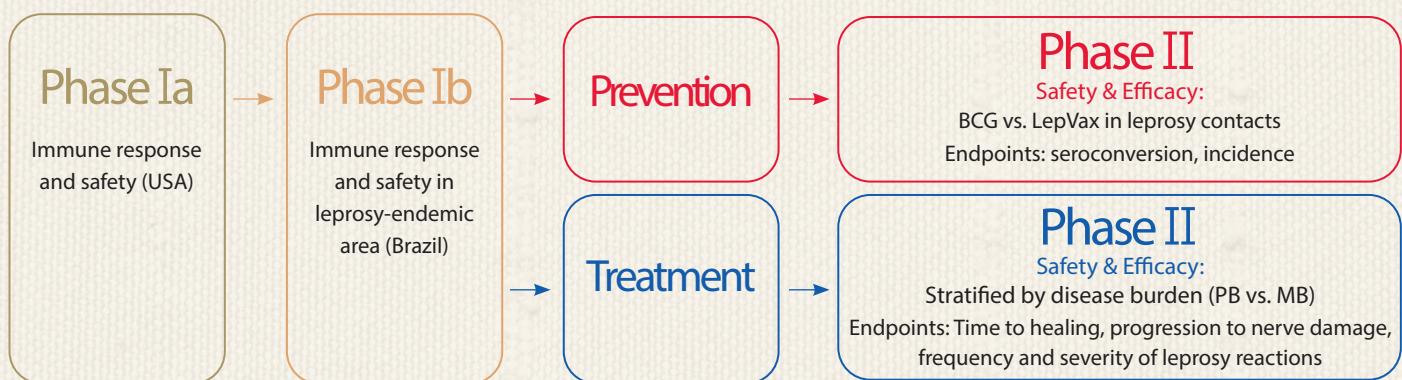
### Immune response and vaccine safety in both healthy and leprosy-affected people in a region endemic for leprosy

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 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. 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 many challenges throughout 2020. ALM's lab partner and developer of LepVax, IDRI, filed for receivership with the goal of being restructured to ensure ongoing financial viability in early 2020. The COVID-19 pandemic also caused interruptions in the trial timeline. Fiocruz, the 1b/2a trial implementer in Brazil, has been focused largely on pandemic response, while IDRI has been concentrating on their COVID-19 vaccine work. During this time, ALM and IDRI reached an agreement regarding the transfer of materials to FioCruz in Brazil to allow the 1b/2a test phase to begin.

In August 2021, updated regulatory paperwork was filed with the Brazilian food and drug administration, ANVISA. Approval is expected by November 2021. Depending on the COVID-19 situation, the two-year Phase 1b/2a clinical trials can officially start once approval is received.

## 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.

## 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.



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)