

Publication details IDRI's promising leprosy vaccine candidate

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A publication in Nature Partner Journals (*npj*) Vaccines indicates that post-exposure prophylaxis with LepVax, IDRI's leprosy vaccine candidate, not only appears safe but, unlike BCG (a tuberculosis vaccine that provides some protection against leprosy), alleviates and delays the neurologic disruptions caused by *Mycobacterium leprae* infection in ninebanded armadillos. This is an important finding because armadillos are the only other host of *M. leprae* that closely recapitulates many of the structural, physiological and functional aspects of leprosy observed in humans, including progressive and irreversible nerve damage.

Characterized by the World Health Organization as a "neglected tropical disease," <u>leprosy</u> (also known as Hansen's disease) is caused by Mycobacterium leprae. Nearly a quarter of a million people are diagnosed with leprosy each year, with the infection progressing to cause disfiguration of the skin and mucous membranes as well as progressive and irreversible <u>nerve</u> damage. While drug therapy exists for leprosy, it must be taken for many months, has many side effects and often is given too late to prevent the damage caused by the bacterial infection that leads to lifelong disability.

"This report demonstrates the selection and advancement of the first defined subunit vaccine—LepVax—developed specifically for leprosy," said Malcolm Duthie, Ph.D., a senior scientist at IDRI. IDRI and The National Hansen's Disease Laboratories (NHDP), under a research agreement with the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health, conducted



mouse experiments to demonstrate that the <u>vaccine</u> is immunogenic and can interrupt M. leprae infection. They also developed cutting edge neurological methods in nine-banded armadillos that were used to evaluate the effect of LepVax on nerve injury as an innovative advance to the field. "Our results indicate that post-exposure immunization in nine-banded armadillos was not only safe but limited and delayed nerve damage," Duthie added.

In stark contrast to BCG, which precipitated rapid and severe motor nerve conduction abnormalities in previously infected armadillos, motor <u>nerve injury</u> was appreciably delayed in armadillos treated three times at monthly intervals with LepVax. The data supported a successful Investigational New Drug (IND) application with the U.S. Food & Drug Administration, allowing advancement of LepVax into a Phase 1 clinical trial in humans in the U.S.

More information: Malcolm S. Duthie et al. LepVax, a defined subunit vaccine that provides effective pre-exposure and post-exposure prophylaxis of M. leprae infection, *npj Vaccines* (2018). <u>DOI:</u> <u>10.1038/s41541-018-0050-z</u>

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