

NanoBio And Porton Biopharma receive approval to advance Anthrax Vaccine

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NanoBio Corporation, a US based biopharmaceutical company focused on developing and commercializing vaccines and anti-infective treatments announced the progression of a novel intranasal anthrax vaccine into a pre-clinical IND-enabling toxicology study funded by the U.S. National Institute of Health's National Institute of Allergy and Infectious Diseases (NIAID). The vaccine combines NanoBio's novel intranasal nanoemulsion (NE) adjuvant with recombinant protective antigen (rPA) for anthrax from Porton Biopharma Ltd (PBL). Following the pre-clinical toxicology study, the vaccine will progress to a Phase 1 clinical trial.

The advanced development of the vaccine candidate is the result of a modification to PBL's existing NIAID contract, which totals more than \$24 million throughout its eight-year term if all options are exercised. The modification, valued at \$5.6 million, supports further research of the vaccine components and technologies that accelerate the immune responses for use in post-event settings following the intentional release of the Category A priority pathogen *Bacillus anthracis*, the bacterium that causes the disease anthrax.

Under the contract, NanoBio, PBL and Public Health England are partnering to produce a more effective vaccine than the currently licensed injectable product, by enabling immunity to be achieved in fewer doses and via intranasal delivery.

"Based on studies completed in the primary animal challenge model for anthrax, our vaccine offers the potential to enhance immunity with fewer doses and easier administration," said David Peralta, chief executive officer of NanoBio. "Our partnership with PBL and Public Health England is critical to efficiently progressing our intranasal NE-rPA vaccine candidate to human clinical trials."

Anthrax is caused by the spore-forming bacterium *Bacillus anthracis*, and most commonly infects wild and domestic animals. Anthrax occurs in humans when they are either exposed to infected animals or to the organism directly, which could occur following a bioterrorist attack. In humans, the mortality of untreated cutaneous anthrax ranges up to 25 percent, but increases

to nearly 100 percent in inhalational and intestinal cases.

The currently available vaccination schedule for anthrax consists of three primary injections at zero, one, and six months, two booster doses at months twelve and eighteen, and then followed by annual boosters for prolonged protection. Epidemiological evidence indicates the current vaccine may cause acute side effects and may only provide partial protection from certain strains.