

PBD BIOTECH EXPANDS ITS PATENT PROTECTION FOR INCIPIENT TB TEST ACTIPHAGE®

Blood-based test for detecting those at risk of disease progression starts trials in Africa

PBD Biotech has obtained grant of its patent application for its Actiphage® incipient tuberculosis diagnostic within the regional African Intellectual Property Organization (OAPI). This covers the mainly French-speaking countries of West Africa.

Actiphage is a unique diagnostic for early-stage infection. It can identify live cells of *Mycobacteria tuberculosis* (M.tb) from a blood sample, providing evidence that a person is carrying an active infection that will progress to full disease unless treated (incipient TBI).

Improved diagnostics for identifying people with incipient TBI, before they show clinical symptoms of the disease, is a strategic priority in the WHO #EndTB strategy. PBD Biotech holds two patent portfolios in this area: 2015 'Mycobacteria detection using bacteriophages', and 2020 'Methods relating to Tuberculosis', which specifically covers its tests for incipient TB.

Jane Theaker, Chief Executive of PBD Biotech, says: "Actiphage offers a potential game-changer in the detection and treatment of people with incipient TB. By identifying those with active disease before they start to transmit the bacteria, it offers potential to break the cycle of infection.

"We are currently working in Zambia and South Africa on clinical studies. We are pleased to report on the grant of this patent as it provides evidence of our commitment to expand our operations and patent portfolio, while protecting our interests in this competitive market."

The patent is supported by a study published in *Clinical Infectious Diseases*: 'A Novel, High-sensitivity, Bacteriophage-based Assay Identifies Low-level Mycobacterium Tuberculosis Bacteraemia in Immunocompetent Patients with Active and Incipient Tuberculosis' (DOI: 10.1093/cid/ciz548). The study was led by Raman Verma and Pranabashis Haldar of the National Institute for Health Research Respiratory Biomedical Research Centre at University of Leicester.

Using a novel, phage-based blood assay, the researchers reported the first concordant evidence to demonstrate associations of Mtb bacteraemia with progressive phenotypes of latent infection and active pulmonary tuberculosis (PTB). The researchers concluded that Actiphage offers promise as a blood-based diagnostic tool for infectious PTB to allow for earlier diagnoses in patients unable to expectorate sputum.

The study was in a well-characterized, immunocompetent human cohort and offered a sensitivity of 73% and specificity of 100% in symptomatic patients with suspected PTB. For all patients, Actiphage had a specificity of 94% with no change in sensitivity.

Actiphage was identified by the recent TAG Pipeline Report as the only test in development able to detect bacteraemia. It offers clear advantages as a rapid, low-cost assay that offers a microbiological diagnosis in the absence of sputum.

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About PBD Biotech (www.pbdbio.com)

PBD Biotech Limited specialises in the use of novel bacteriophage-based technology. The company has developed proprietary, patented technology that can be used to detect the presence of mycobacteria that cause tuberculosis in humans and animals.

This includes human TB – *Mycobacterium tuberculosis* (Mtb) – where the technology has application as a screening tool, as well as Bovine TB – *Mycobacterium bovis* (m.bovis) – and *Mycobacterium avium* subsp.*paratuberculosis* (MAP; Johne's Disease), which are significant causes of morbidity and loss of productivity in the agricultural industry.