PBD BIOTECH RAISES FURTHER £2.4M FOR ITS BREAKTHROUGH TUBERCULOSIS BLOOD TEST

Promising human TB trials drive route to market

Human tuberculosis is second only to Covid as the world's most fatal infectious disease; although treatable, there remains a global unmet need to diagnose the disease at an earlier stage and to identify carriers that may develop the disease. To address these objectives, PBD Biotech has developed a rapid screening blood test that shows promise for identifying people with the disease as well as a subgroup with pre-clinical infection at higher risk of developing the disease, offering the potential to revolutionise management of TB. The company has raised follow-on funding of £2.4M to support further clinical trials.

PBD Biotech's Actiphage® blood test is sensitive and specific, and clinical studies at the Leicester Respiratory NIHR Biomedical Centre have shown that it is able to diagnose patients with pulmonary TB and identify contacts with recent exposure that have very early stage infection and may be at higher risk of developing TB in the future. By enabling rapid screening of a population for TB, Actiphage offers a breakthrough in disease prevention and treatment. Further trials of Actiphage are currently running in the UK, South Africa and Zambia.

Human TB, along with Bovine TB and Johne's Disease in ruminants, is caused by mycobacteria. PBD Biotech has pioneered the use of a phage to detect live mycobacterial infection at very low levels in a sample of blood, creating the opportunity for identification of its DNA using PCR.

The follow-on funding will be used to further develop Actiphage to address a global unmet need for a non-sputum-based test for human TB and as a blood and milk test for Johne's Disease, also known as MAP or paratuberculosis.

The funding has come from a consortium led by fund managers Mercia and the Foresight Group, both investing from the Midlands Engine Investment Fund, alongside the University of Nottingham and private investors.

Promising outcomes from the human clinical trials, together with a clearly defined target product profile for human TB, and an absence of the need for regulation in many countries for Johne's, has enabled significant progress.

Sandy Reid of Mercia said: "While TB is regarded as a disease of the developing world, it is a major burden globally with around 10 million active infections at any one time. PBD's test not only detects the disease at an early stage but could also be used to select the correct antibiotic and monitor patients undergoing treatment. The funding will help the company build further evidence of the test's effectiveness."

Jane Theaker, CEO of PBD Biotech, comments: "We are delighted to receive follow-on funding from this supportive group of investors.

"Since the last round in March 2021, we have presented findings from a clinical study of Actiphage at the prestigious ECCMID (European Congress of Clinical Microbiology & Infectious Diseases) conference. The results showed that Actiphage could detect non-symptomatic carriers and identify those that may be at greater risk of developing TB. This breakthrough has excited public health professionals worldwide and has prompted trials in many countries.

"In preparation for market acceptance of the human TB diagnostics, we have invested in our QA systems, upgrading them to ISO 13485 in readiness, working with our ISO 13485 and ISO9001 approved suppliers, and grown our team with seasoned professionals.

“To develop our mycobacterial diagnostic for animal health, we have launched a commercial Johne’s Testing Service, which has involved technology transfer to an independent laboratory and the creation of a system for timely collection and analysis of samples of blood and bulk milk directly from farms. This is providing a flow of samples needed to refine and enhance the technology and invaluable input from the end users.

"Our US division is creating partnerships with key labs in North America and we are working with labs in the UK, France and the Netherlands.”

A diagnostic for Bovine TB remains an ambition, once the target product profile and commercial route to market has been agreed with national governments.

The Midlands Engine Investment Fund project is supported financially by the European Union using funding from the European Regional Development Fund (ERDF) as part of the European Structural and Investment Funds Growth Programme 2014-2020 and the European Investment Bank.

Find out more about Actiphage at pbdbio.com.

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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.