Funded by the European Union

Novel Immunotherapies for Tuberculosis and other Mycobacterial Diseases (ITHEMYC)

The Horizon Europe programme has funded the ITHEMYC project to establish a critical path for selection of promising innovative adjunct TB immunotherapies and progress 2 of these immunotherapies to completion of preclinical proof of concept.

Tuberculosis (TB) remains one of the most devastating infectious diseases worldwide, killing over 4,000 people every day. In addition, anti-microbial resistance is a growing threat. There has been significant progress in development of new drug regimens effective against drug sensitive and drug resistant TB, emerging novel vaccines and advancements in point-of-care diagnostics. However, treatment shortening remains a highly challenging goal, and novel treatment strategies for TB are needed.

For decades, TB treatment has been primarily based on “kill-the-bug” approaches. Drug discovery efforts were based around searching for new antibiotics, and drug development was focused on microbiological endpoints. However, there has been a steady realization in the field that these approaches may have inherent limitations in terms of the length and complexity of treatment. Immunotherapies offer a complementary approach for attacking TB in a way that could result in superior results for patients. The rationale for using immunotherapeutic agents is to modulate the immune response to TB and accelerate bacillary clearance.

The ITHEMYC project advances beyond the current state of the art by combining existing TB drug treatment regimens and immunotherapies to develop novel therapeutic options with the potential to shorten treatment duration, improve outcomes and prevent relapse. Mechanism of action studies will be performed in physiologically relevant models involved in innate immunity against *Mycobacterium tuberculosis* (*Mtb*), as well as *in vivo* evaluation of the most promising immunotherapies and evaluating their treatment shortening potential in conjunction with chemotherapy or therapeutic vaccines. In addition*, in silico* modelling will be applied to facilitate both *in vitro* and *in vivo* preclinical progression and to predict the therapeutic effect in the clinic.

The consortium

The multidisciplinary consortium brings together leading expertise and capacity to tackle the challenges of working in new scientific areas to combat the global burden of tuberculosis. Aside from the EU, ITHEMYC receives co-funds by the United Kingdom's funding agency UKRI. The consortium will be coordinated by the Tuberculosis Vaccine Initiative (TBVI), will run for 4 years and consists of 11 partners:

- TuBerculosis Vaccine Initiative (TBVI) (Coordinator)
- GSK (GSK)
- Centre National de la Recherche Scientifique (CNRS)
- Université Paul Sabatier - Toulouse III (UPS)
- Global Alliance for TB Drug Development (TB Alliance)
- Institut de Investiagcio en Ciences de la Salut Germans Trias I Pujol (IGTP)
- Università degli Studi di Catania (UNICT)
- Department of Health (UKHSA)
- Alma Mater Studiorum - Università di Bologna (UNIBO)
- Johns Hopkins University (JHU)
- Tel-Aviv University (TAU)