

Launch of UNITE4TB partnership marks a new era in Tuberculosis treatment development

The partnership will accelerate the development of new Tuberculosis (TB) drug regimens as part of the Innovative Medicines Initiative (IMI), a public-private European Research & Development Consortium

15 July 2021, Munich, Germany. To advance anti-tuberculosis (TB) science and enable the progression of new, safe, and affordable treatment solutions for TB patients worldwide, a new consortium of 30 partners from 13 countries has officially launched. The LMU University Hospital Munich and the German Center for Infection Research (DZIF) take on a central role in this consortium named "Academia and industry united innovation and treatment for tuberculosis", or UNITE4TB for short. Thus, for example, Professor Michael Hoelscher, Director of the Tropical Institute at the LMU Hospital and Coordinator of the DZIF Research Area "Tuberculosis", is co-initiator and Scientific Lead of the seven-year research project, which is funded with 185 million euros. The aim of UNITE4TB is to accelerate and improve the clinical evaluation of combinations of existing and novel drugs, with the goal of developing new and highly active TB treatment regimens for drug-resistant and -sensitive TB.

Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). The growing emergence of multidrug-resistant TB is well-recognised as a public health challenge and has sparked new interest and investment in anti-TB drug development. Despite increased activity in the field, an integrated approach to TB drug development is still limited.

Anja Karliczek, Germany's Federal Minister of Education and Research, says: "Europe's UNITE4TB project creates an important new platform for research to combat tuberculosis. Science and industry will jointly test their clinical candidates and share research results. The objective is to develop effective combinations for new, urgently needed solutions to treat tuberculosis. This public-private partnership will set a new standard in the fight against global diseases such as TB. UNITE4TB is a remarkable example of international research collaboration. I am delighted that Germany is supporting the consortium with funding of around 25 million euros to the two German Associated Partners. I am confident that UNITE4TB will contribute towards achieving the goal of ending tuberculosis by 2030 that was adopted by the G20 Heads of State and Government at the UN General Assembly."

The funding from the Federal Ministry of Education and Research (BMBF) focuses especially on the further development of BTZ-043, which is the first antibiotic developed in Germany for decades that has been achieved through a cooperation between academic institutions. The active ingredient was discovered by researchers at the Leibniz Institute for Natural Product Research and Infection Biology – Hans Knöll Institute (Leibniz-HKI) – and has been further developed in partnership by the Leibniz-HKI and the LMU University Hospital in a research collaboration within the BMBF-funded infection research networks DZIF (German Centre for Infection Research) and Zwanzig20 Konsortium InfectControl since 2014. The new drug has already successfully passed the early clinical trials.

To effectively treat drug-resistant tuberculosis, it has so far been necessary to combine three or four drugs. In the UNITE4TB project, science and industry are going to provide respective drug

candidates available to make these combinations possible. In addition to the antibiotic BTZ-043, the Tropical Institute at LMU University Hospital Munich is also contributing many years of expertise in tuberculosis research to UNITE4TB together with the German Center for Infection Research (DZIF). The LMU University Hospital and the DZIF are responsible in various work packages for e.g., the development of new biomarkers and the implementation of clinical phase IIb/c studies, and they participate in the development of study design and analysis, artificial intelligence & machine learning. Furthermore, the LMU University Hospital and the DZIF are Associated Partners of the EFPIA consortium in UNITE4TB and take on central tasks in the project leadership and project and communication management.

UNITE4TB is the newest project of the [IMI AMR Accelerator](#), a public-private collaboration with the shared goal of progressing the development of new medicines to treat or prevent resistant bacterial infections. “Tuberculosis is a major threat to public health worldwide. By bringing together leading experts from the public and private sectors in Europe and beyond, UNITE4TB is well placed to deliver results that will accelerate the development of better treatment regimens to tackle this disease,” says Dr Pierre Meulien, Executive Director of IMI.

With European Federation of Pharmaceutical Industries and Associations (EFPIA) and Associated Partners on board, UNITE4TB has access to the majority of the most innovative TB compounds, currently in late pre-clinical, clinical phase 1, and early phase 2 stage. The consortium will deliver an efficient, global clinical trials network equipped to conduct phase 2 trials. State-of-the-art adaptive trial designs will be implemented, and advanced modelling, artificial intelligence and machine learning techniques will be employed. All of this will allow for the selection and testing of novel combination regimens with a high probability of success in subsequent phase 3 clinical trials.

In addition to the German EFPIA/Associated Partners, the LMU University Hospital Munich and DZIF, various other academic partners from Germany, such as the Forschungszentrum Borstel, Leibniz Lungenzentrum, the Helmholtz Zentrum München, the University of Hamburg, and TBnet are involved in UNITE4TB.

UNITE4TB is the largest public-private collaboration on clinical TB drug development in the history of the EU. It will set a new standard for anti-TB regimen development, enhancing the efficiency with which new treatments are delivered to TB patients across the world.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101007873. The JU receives support from the European Union’s Horizon 2020 research and innovation programme and EFPIA, Deutsches Zentrum für Infektionsforschung e. V. (DZIF), and Ludwig-Maximilians-Universität München (LMU). EFPIA/AP contribute to 50% of funding, whereas the contribution of DZIF and the LMU University Hospital Munich has been granted by the German Federal Ministry of Education and Research.

Further information: www.unite4TB.org

For the media (not for publication)

For more information and interview requests, please send an email to: media@unite4tb.org

Notes to editors

1. About UNITE4TB

UNITE4TB is a public-private partnership with representation from academic institutions, small- and medium-sized enterprises (SMEs), public organisations, and pharmaceutical companies. Over the next 7 years, the consortium will be active in approximately 40 trial sites on four continents (Europe, Asia, Africa and South America), with the goal of delivering novel phase 2 clinical trials that will accelerate the development of new TB drugs and regimens. Achieving this goal will facilitate fulfilment of one of the main unmet needs in the TB field: better-tolerated drug regimens of shorter duration that can be deployed to tackle tuberculosis across various drug-resistance patterns and co-morbidities. For more information, visit the consortium website: www.unite4TB.org

2. Consortium partners

Academic/SME partners

- **Stichting Radboud Universitair Medisch Centrum (Radboudumc)** (The Netherlands)
- **London School for Hygiene and Tropical Medicine (LSHTM)** (United Kingdom)
- **University of Oxford** (United Kingdom)
- **Forschungszentrum Borstel, Leibniz Lungenzentrum** (Germany)
- **Lygature** (The Netherlands)
- **Lancaster University** (United Kingdom)
- **University College London** (United Kingdom)
- **TASK** (South Africa)
- **Vita-Salute San Raffaele University (UniSR)** (Italy)
- **Helmholtz Zentrum München** (Germany)
- **KNCV Tuberculosis Foundation (KNCV)** (The Netherlands)
- **Critical Path Institute, Limited** (Ireland)
- **European Lung Foundation** (United Kingdom)
- **Instituto de Saude Publica da Universidade do Porto (ISPUP)** (Portugal)
- **University of Liverpool** (United Kingdom)
- **Institut de Recherche Pour le Developpement** (France)
- **University of Hamburg** (Germany)
- **University of California San Francisco (UCSF)** (USA)
- **TB Alliance** (USA)
- **FIND** (Switzerland)
- **University of Milano (UMIL)** (Italy)

- **University St Andrews** (United Kingdom)
- **Uppsala University** (Sweden)
- **European Respiratory Society** (Switzerland)
- **TBnet** (Germany)

EFPIA/Associated Partners

- **German Center for Infection Research / Deutsches Zentrum für Infektionsforschung (DZIF)** (Germany)
- **LMU University Hospital Munich** (Germany)
- **GlaxoSmithKline Investigación y Desarrollo S L (GSK)** (Spain)
- **Janssen Pharmaceutical** (Belgium)
- **Otsuka Novel Products GmbH** (Germany)

[View a detailed overview of all partner information on the UNITE4TB website](#)