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PRESS RELEASE

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Tuberculosis: New drug substance BTZ-043 is being tested on patients for the first time

A crucial step in the development of a promising new drug which has also proven to be effective against multidrug-resistant pathogens in preclinical tests

The Tropical Institute at the Hospital of the Ludwig-Maximilians-University (LMU) Munich is currently conducting a clinical study led by Professor Michael Hoelscher. Since mid-November, the first tuberculosis patients in Cape Town, South Africa, have been treated with the new drug substance BTZ-043 for the first time. The study is carried out within the PanACEA consortium in cooperation with the TASK Applied Science Clinical Research Centre, the University of Cape Town Lung Institute (UCTLI), and the Radboud University Medical Center.

BTZ-043 was discovered at the Leibniz Institute for Natural Product Research and Infection Biology - Hans Knöll Institute (Leibniz-HKI) in Jena. Since 2014, the new chemical entity has been developed in a consortium of scientists from the Leibniz-HKI and the Tropical Institute at the Hospital of the LMU Munich within the framework of the German Center for Infection Research (DZIF). The study is funded by the German Federal Ministry of Education and Research (BMBF) and the European and Developing Countries Clinical Trials Partnership (EDCTP).

Tuberculosis is the most common cause of death worldwide caused by bacterial infections. According to the World Health Organization (WHO), approximately 1.5 million people die from tuberculosis every year, particularly in Southeast Asia, Africa and the Western Pacific region. An enormous challenge in the treatment of tuberculosis is the increased incidence of resistant pathogens against which only a few antibiotics are still effective. The WHO is, therefore, placing great hopes in the development of drugs

based on new chemical entities. BTZ-043, a benzothiazinone, is such a new drug candidate.

With the start of the study in Cape Town, the international research team has reached a decisive point: A Phase I study conducted in Germany showed good tolerability of BTZ-043. If BTZ-043 proves to be safe and effective in the current study (Phase II), this would be a major step in the development of a new drug. In the near future, this could replace one of the less effective drug compounds used in either standard or drug resistant therapy and contribute to a safer and/or shorter treatment of tuberculosis.

In the study, the BTZ-043 will be administered in two clinical centers in Cape Town to a total of 80 tuberculosis patients over a period of 14 days. The first step is to find an optimal dose for the drug candidate by achieving the best balance between efficacy and tolerability. In the second step, these results will be confirmed in many more patients and both the efficacy and the tolerability will be compared with the current standard treatment for tuberculosis. All participating patients will be referred to a local health center 14 days after completion of their study. There, their treatment will be continued according to the national guidelines.

In mid-November 2019, the first patients for treatment with BTZ-043 were included in the study. First results on tolerability and efficacy are expected by the middle of next year. After visiting the study site in Cape Town, Professor Michael Hoelscher from the Tropical Institute at the LMU Hospital expressed his optimism: "Following the promising results of the Phase I study in Germany, we see a great chance that the good tolerability of BTZ-043 will be confirmed in the treatment of tuberculosis patients. We are confident that we will also see good results in the first efficacy data." Project Manager Dr. Julia Dreisbach from the Tropical Institute confirms: "In order to ensure patient safety, we are working together with our long-standing partners in South Africa and the most experienced study teams worldwide around Professors Andreas Diacon and Rodney Dawson."

The development of new drugs, which are primarily intended for developing countries, is largely financed from public funds. Of note is that the first antibiotic developed in Germany in decades was achieved through cooperation between academic institutions. This is also a major achievement for the Federal Ministry of Education and Research, who in a strategic decision has decided to promote translational research in medicine through the establishment of the German Centres for Health Research.

The German Center for Infection Research (DZIF) with its Translational Project Management Office (TPMO) has scientifically accompanied and supported the preclinical and pharmaceutical development of BTZ-043. Further financing partners for the development of BTZ-043 are the consortium InfectControl 2020, which is funded by the BMBF, and the Free State of Thuringia. As a sponsor, the LMU Hospital is responsible for the preclinical and clinical development as well as the quality and safety of the drug. The substance is manufactured by a medium-sized company, Hapila GmbH in Gera.



EDCTP

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European & Developing Countries Clinical Trials Partnership (EDCTP)

The European & Developing Countries Clinical Trials Partnership (EDCTP) funds clinical research to promote the development of new or better medicines, vaccines, microbiocides, diagnostics for HIV/AIDS, tuberculosis, and malaria as well as other poverty-related infectious diseases in sub-Saharan Africa. The focus is on Phase II and III clinical trials.

Further information: <http://www.edctp.org>

PanACEA

PanACEA is a consortium of 5 European and 11 African institutions with scientists from 11 countries and 16 organisations whose mission is the development of new combined therapies for tuberculosis. In addition to conducting clinical trials, the PanACEA network supports African partners in

establishing a research infrastructure and in carrying out their research projects.

Further information: <http://panacea-tb.net>

German Center for Infection Research (DZIF)

At the German Center for Infection Research (DZIF), about 500 scientists and physicians from 35 institutions nationwide jointly develop new approaches for the prevention, diagnosis and treatment of infectious diseases. Their aim is to translate research results into clinical practice rapidly and effectively. With this, the DZIF paves the way for developing new vaccines, diagnostics and drugs in the fight against infections.

Further information: www.dzif.de.

Source:

Global tuberculosis report 2019. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

<https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf>

Caption of press photo:

The staff of the TASK Applied Science Clinical Research Centre in Cape Town together with the teams of TCD Global and of the Hospital of the Ludwig-Maximilians-Universität (LMU) München. Copyright: Tropical Institute at the Hospital of the LMU Munich.

University Hospital of the Ludwig-Maximilians-Universität (LMU) Munich

At the University Hospital of Munich (LMU), around 500,000 patients are treated annually on an outpatient, day-care and inpatient basis at the locations Campus Großhadern and Campus Innenstadt. The 29 specialist clinics, 13 institutes and seven departments, as well as the 50 interdisciplinary centres, have slightly more than 2,000 beds at their disposal. Of a total of 9,700 employees, around 1,700 are physicians and 3,200 nursing staff. The Munich University Hospital has been a public-law institution since 2006.

The Medical Faculty and Hospital of the Ludwig Maximilian University Munich are involved in ten DFG Collaborative Research Centres (SFB 824, 870, 914, 1054, 1064, 1123, 1243, 1321, 1335, 1371), five Transregios (TRR 127, 128, 152, 205, 237) and two DFG Research Training Groups (GK 2274, 2338). Faculty and hospital are the only locations in Germany where all six German Centres for Health Research (cancer, diabetes, metabolic, cardiovascular, infectious, pulmonary and neurodegenerative diseases) are located. In addition, there are the excellence institutions "Munich Cluster for Systems Neurology" (SyNergy), "Center for Integrated Protein Sciences" (CIPSM) and "Munich Center of Advanced Photonics" (MAP) as well as the graduate schools "Graduate School of Systemic Neurosciences" (GSN-LMU) and "Graduate School of Quantitative Biosciences Munich (QBM)".

The DFG supports the Clinician Scientist Program In Vascular Medicine (PRIME) and the Else-Kröner-Fresenius Foundation three research colleges (immunotherapy for the treatment of cancer, translational psychiatry, rare diseases of the immune system).

Further information can be found at www.klinikum.uni-muenchen.de