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# BioVersys, TASK and GSK receive 2.7 million Euro from EDCTP for Phase 2a Clinical Trial

## BVL-GSK098 AND ETHIONAMIDE COMBINATION IS BEING DEVELOPED FOR THE TREATMENT OF MULTI-DRUG RESISTANT TUBERCULOSIS INFECTIONS

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**BioVersys and consortium partners TASK Foundation and GSK have been awarded 2.7 million Euro from European and Developing Countries Trial Partnership (EDCTP) for the further development of BVL-GSK098 with ethionamide in a Phase 2a tuberculosis clinical trial study.**

BioVersys AG, a privately owned, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections with applications in Anti-Microbial Resistance (AMR) and targeted microbiome modulation, announced today that a consortium of BioVersys, the TASK Foundation and GSK have been awarded 2.7 million Euro funding from the EDCTP to conduct a Phase 2a tuberculosis (TB) clinical trial study with BioVersys' clinical candidate BVL-GSK098 in combination with ethionamide (Eto).

- BVL-GSK098 has been developed from BioVersys' award winning Transcriptional Regulatory Inhibitory Compounds (TRIC) platform in a successful collaboration with GSK, the Institut Pasteur de Lille and University of Lille. BVL-GSK098 is currently being studied in First in Human (FiH) Phase 1 clinical trials, supported by the IMI2 AMR Accelerator from the EU (TRIC-TB Project), which is anticipated to be completed in 2H 2021. BVL-GSK098 in a fixed combination with Eto has also received Qualified Infectious Disease Product designation from the U.S. FDA in June 2020, for oral use in the treatment of pulmonary tuberculosis, making BVL-GSK098 eligible for FDA priority review, Fast Track designation, and a five-year extension of market exclusivity upon approval.

- The World Health Organization (WHO) considers Eto a crucial pillar of TB treatment, especially against MDR (multidrug-resistant) and XDR (extensively drug-resistant) strains. BVL-GSK098 boosts the activity of Eto (bEto), resulting in an increase of Eto efficacy by at least three-fold *in vivo,* that could allow for lower efficacious doses of Eto in human anti-TB treatments with a reduction in dose dependent adverse effects in TB patients. Furthermore, preclinical data shows that BVL-GSK098 overcomes pre-existing resistance against Eto, isoniazid (INH) and rifampicin in *Mycobacterium tuberculosis,* by employing novel bioactivation pathways for Eto. Therefore, a bEto combination has the potential to not only be part of an effective MDR-TB regimen but also the potential to replace INH in first-line TB regimens.

**Prof. Andreas Diacon, Founder, Director & CEO at TASK: "**TASK is excited to participate in this new EDCTP funded research project, particularly in the many potential uses for this 2-drug combination, and the opportunity to collaborate with BioVersys and GSK. We hope to see in this Early Bactericidal Activity (EBA) trial how a new anti-TB molecule, BVL-GSK098 augments the activity of the well-established second line drug ethionamide at a lower and well-tolerated dose on tuberculosis. This in an effort to find a combination of BVL-GSK098 and low-dose Eto that is best tolerated."

**Dr. Glenn Dale, Chief Development Officer of BioVersys:** "We are very pleased to receive the award from the EDCTP, as it will allow to confirm the promising data shown for bEto *in vitro* and in animal efficacy models for the first time in TB patients. The direct comparison of bEto to INH in this EBA proof of concept trial, will enable to elucidate the full potential of bEto as a fast-acting drug combination to be added to both drug-sensitive (DS) and MDR/XDR drug regimens."

**Dr. David Barros-Aguirre VP and Head of Tuberculosis Research Unit, Global Health R&D, GSK: "**GSK is committed to the discovery of novel treatments for tuberculosis, an area of high unmet medical need. The bEto-TB project gives us the opportunity to clinically validate the use of a selective booster of the anti-TB therapy ethionamide discovered by BioVersys and GSK to reduce the efficacious dose of ethionamide. We hope that a reduction in the dose of ethionamide will improve tolerability, lead to greater therapeutic benefit and expand the use of ethionamide in future TB regimes."

**Dr. Marc Gitzinger, CEO and co-founder of BioVersys:** "We are delighted and grateful to receive this grant from the EDCTP, supporting the further development of BVL-GSK098 in combination with Eto. bEto is an innovative combination therapy that is in-line with the global need to conserve our current antimicrobial therapeutic armory, by reinvigorating a WHO's essential medicine, Eto, a valuable weapon against DS and MDR-TB. We look forward to continuing to work with GSK on this project and warmly welcome the opportunity to work with TASK, a world leading clinical trials center for TB."

**About tuberculosis – TB**

Tuberculosis remains a formidable Global Health challenge particularly considering the fact that about 1.7 billion people, 23% of the world's population, are estimated to have a latent TB infection, and are thus at risk of developing active TB disease during their lifetime, as currently estimated by World Health Organization (2018).[1] 1.5 million people died from TB in 2018 and it remains one of the top 10 causes of death worldwide and the leading cause from a single infectious agent (above HIV/AIDS).[1] In 2018, there were an estimated 10 million new TB cases worldwide, 5.7 million men, 3.2 million women, 1.1 million children and 860 thousand were people living with HIV. Multidrug-resistant TB remains a public health crisis and a health security threat. WHO estimates that there were 484'000 new cases with resistance to rifampicin – the most effective first-line drug, of which 78% had MDR-TB. Worldwide, only 56% of MDR-TB patients are currently successfully treated.[2] In the modern world of global travel, and ease with which infections spread, it is very worrying to note that three countries accounted for almost half of the world's cases of MDR/RR-TB in 2018: India (27%), China (14%) and the Russian Federation (9%). Furthermore, 3.4% of all new and 18% of reoccurring TB cases were MDR/RR-TB and about 6.2% of MDR-TB cases had extensively drug-resistant TB (XDR-TB) in 2018.[2]

**About bEto-TB**

This project brings a new anti-TB molecule, BVL-GSK098, to the current drug armamentarium. BVL-GSK098 greatly augments the activity of, and overcomes resistance to, the well-established second line drug Eto at a lower and well-tolerated dose. The objectives of this consortium are to determine the early bactericidal activity (EBA) of the combination of BVL-GSK098 and various doses of Eto. We will also evaluate the comparative anti-TB activity of bEto to that of standard dose INH and thus explore the potential for bEto as a replacement of INH in the current first-line regimen or to add a novel bactericidal drug to future regimens.

Statements or views expressed in this release are of those of the respective organizations or persons and the European Developing Countries Trial Partnership is not responsible for any use of the information contained herein.

**About the European and Developing Countries Trial Partnership (EDCTP)**

The mission of the EDCTP is to contribute to the reduction of the individual, social, and economic burden of poverty-related infectious diseases in sub-Saharan Africa. EDCTP funds collaborative clinical research that accelerates the development of accessible, suitable, and affordable medical interventions (drugs, vaccines, microbicides, and diagnostics) to identify, prevent or treat infectious diseases. EDCTP has prioritized HIV, tuberculosis (TB) and malaria research, while also contributing to clinical developments for diarrhoeal diseases, lower respiratory tract

[1] Global Tuberculosis Report 2019 WHO
[2] http://www.who.int/en/news-room/fact-sheets/detail/tuberculosis

infections and emerging or re-emerging infectious diseases of particular relevance for Africa, such as Ebola and yellow fever.

**About TASK**
TASK is a social enterprise committed to developing, testing, and progressing novel medicines, vaccines, and diagnostics in various medical therapeutic areas, most notably in anti-tuberculosis drugs, aimed at improving global health care. Since its inception in 2005, TASK has grown exponentially and diversified into six distinct independent clinical research sites; a mycobacteriology bio-safety level 3 laboratory; a phase I to II clinical trial hospital with twenty-four beds; two registered dispensing pharmacies; a data management centre; regulatory, quality control and compliance office and a clinical research training academy. Over the last 15 years TASK has completed multiple research projects, many of global significance, and contributed to progressing the scientific field of TB medicine and vaccine development, most notably with early bactericidal activity (EBA) studies and clinical trials that in part led to the registration of Bedaquiline. Find us at https://task.org.za/ and follow us on Twitter @taskapplied.

**BioVersys AG** is a privately-owned clinical stage Swiss pharmaceutical company focusing on research and development of small molecules acting on novel bacterial targets with applications in Anti-Microbial Resistance (AMR) and targeted microbiome modulation. With the company's award-winning TRIC technology we can overcome resistance mechanisms, block virulence production and directly affect the pathogenesis of harmful bacteria, towards the identification of new treatment options in the antimicrobial and microbiome fields. By this means BioVersys addresses the high unmet medical need for new treatments against life threatening resistant bacterial infections and bacteria-exacerbated chronic inflammatory microbiome disorders. Our most advanced R&D programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase 1), and Tuberculosis (BVL-GSK098, Phase 1) in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille. BioVersys is located in the Technologiepark in the thriving biotech hub of Basel, please visit www.bioversys.com. Follow us on LinkedIn and Twitter @Bioversys.

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