PRESS RELEASE

BIOVERSYS SUCCESSFULLY COMPLETES PHASE I CLINICAL TRIALS OF BVL-GSK098

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BioVersys AG announces successful completion of Phase I clinical trials with BVL-GSK098

BioVersys AG, a privately-held clinical stage, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections with applications in antimicrobial resistance (AMR) and targeted microbiome modulation, announced today the successful completion of Phase I clinical trials of BVL-GSK098.

- BVL-GSK098 was 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. The compound represents a totally new concept of overcoming resistance by boosting the activity of an existing antibiotic.
- This is a major milestone of the TRIC-TB project that continues to receive funding from the EU IMI-JU2 programme under the AMR Accelerator umbrella.

The analysis of preliminary, blinded data from these studies show a very favorable safety, tolerability and pharmacokinetic profile of BVL-GSK098 at therapeutically effective doses in healthy volunteers.

Dr. Glenn E. Dale, Chief Development Officer of BioVersys: "We are pleased by the favorable safety profile of BVL-GSK098 at the doses studied in our clinical trials. The positive data will allow us to rapidly transition to a Phase IIa clinical study in patients with pulmonary TB later this year to test the Early Bactericidal Activity (EBA), safety, tolerability and pharmacokinetics of ethionamide (Eto) alone and in combination with BVL-GSK098."

Dr. Pierre Meulien, Executive Director of the Innovative Health Initiative (IHI), which manages Innovative Medicines Initiative (IMI) projects: "This fantastic achievement by the IMI project TRIC-TB highlights the ability of public-private partnerships to make progress in challenging areas such as tuberculosis, where we urgently need new and better treatment regimens. It is also an important contribution to the goals of IMI's wider AMR Accelerator programme, which has a strong focus on tuberculosis."

Dr. David Barros-Aguirre VP and Head of Tuberculosis Research Unit, Global Health R&D, GSK: "GSK is committed to the discovery of shorter, simpler and safer treatments for tuberculosis. The TRIC-TB programme is an outstanding example of a public-private partnership between academia, biotech and the pharmaceutical industry which, with funding from the EU IMI-JU2 programme, is enabling us to work together and deliver innovative treatment options for patients."

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Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys: "As the need for novel anti-tuberculosis therapies increases following the deleterious impact of COVID-19 on TB patients, we are delighted to see the excellent safety data coming out of our FiH studies of BVL-GSK098, and eagerly anticipate initiating a Phase 2a clinical trial with BVL-GSK098 and Eto later this year. Aside from the value to patients, the TRIC-TB program is a clear example of how public-private partnerships successfully enable biotech companies to deliver innovation, even in challenging indications such as tuberculosis. The combination of academic excellence provided by our partners in Lille, large industry in the form of GSK, the capacities of BioVersys and the public funding from EU IMI, was instrumental in achieving this milestone."

About TRIC-TB Project

Ethionamide (Eto) and prothionamide (Pto) are recommended by the World Health Organization (WHO) for use as second-line agents in the treatment of drug-resistant pulmonary TB and TB meningitis. Despite their usefulness as a TB drugs, Eto/Pto cause dose-dependent adverse events that negatively impact treatment adherence. Eto/Pto are prodrugs and their antibacterial activity can be linked to the level of bioactivation inside Mycobacterium tuberculosis (Mtb). The clinical candidate BVL-GSK098 acts on transcriptional regulators of Mtb, stimulating novel bioactivation pathways for Eto resulting in an increase of Eto efficacy, while simultaneously overcoming Eto resistance and keeping potent activity on MDR strains, including to a vast majority of isoniazid-resistant strains. BVL-GSK098 renders Eto rapidly bactericidal and reduces the emergence of Eto resistance development in vitro and in vivo. Based on pre-clinical data, it is expected that BVL-GSK098 could lower the efficacious human oral dose of Eto by at least 3-fold, with the potential to significantly minimize dose-dependent side effects and improve patient compliance allowing to finally tap into the full potential of this 60 year old drug. TRIC-TB has the potential to deliver a novel, fast acting TB agent potentially replacing isoniazid in TB therapy. With the completion of the Phase 1 a major milestone of the TRIC-TB was achieved. Follow TRIC-TB on Twitter @TRIC_TB.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853800. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EPFIA.

About tuberculosis (TB)

Tuberculosis (TB) is one of the leading causes of death worldwide. Its causative agent is the bacterial pathogen Mycobacterium tuberculosis (Mtb). Until the COVID-19 pandemic, more people were dying of TB each year than of any other disease caused by a single infectious agent. The COVID-19 pandemic has led to reductions in the diagnosis of TB and in access to treatment, reversing years of global progress in reducing the number of deaths. In 2020, the first year-on-year increase (of 5.6%) of TB deaths since 2005 was observed and the total number of TB deaths returned to the level of 2017 with 1.5 million deaths. This number is forecasted to further increase in 2021 and 2022.[1] 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]

Statements or views expressed in this release are of those of the respective organizations or persons and the IMI2 JU is not responsible for any use of the information contained herein.

About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). It was set up to improve health by speeding up the development of, and patient access to, the next generation of medicines, particularly in

[1] Global Tuberculosis Report 2021 WHO
[2] http://www.who.int/en/news-room/fact-sheets/detail/tuberculosis

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areas where there is an unmet medical or social need. It works by facilitating collaboration between the key players involved in healthcare research, including universities, pharmaceutical companies, other companies active in healthcare research, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. This approach has proven highly successful, and IMI projects are delivering exciting results that are helping to advance the development of urgently-needed new treatments in diverse areas. IMI projects are now managed by the Innovative Health Initiative (IHI), which builds on the successes of IMI and is a cross-sectoral public-private partnership involving a wider range of health industries.

- More info on IHI: https://www.ihi.europa.eu/
- Twitter: @IHIEurope
- More info on IMI AMR accelerator: https://amr-accelerator.eu/project/tric-tb/
- Working Group of new TB drugs: https://www.newtbdrugs.org/pipeline/compound/bvl-gsk098

About BioVersys

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 antimicrobial 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 research and development programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase II-ready), and tuberculosis (BVL-GSK098, Phase II-ready) in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille. BioVersys is located in the Technologiepark in the biotech hub of Basel.

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About GSK

GSK is a science-led global healthcare company. For further information please visit https://www.gsk.com/en-gb/about-us/