PRESS RELEASE

BIOVERSYS AND GSK SUCCESSFULLY COMPLETE IMI2 PROGRAMME REACHING CLINICAL MILESTONE

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BioVersys and GSK successfully complete IMI2 programme reaching clinical milestone

BioVersys AG, a multi-asset, clinical stage biopharmaceutical company focusing on research and development of novel antibacterial products for serious life-threatening infections caused by multi-drug resistant ("MDR") bacteria, announced today that in partnership with GSK they have successfully completed the Innovative Medicines Initiative (IMI2) funded programme, TRIC-TB, and reached a key milestone of delivering a Phase 2-ready tuberculosis clinical candidate, alpibectir.

The achievements of TRIC-TB an EU public private partnership program have been highlighted in a TRIC-TB newsletter released today by the IMI2's Antimicrobial Resistance (AMR) Accelerator Programme. For more details, please visit here.

Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys: "The completion of the TRIC-TB public private partnership program and successful delivery through early clinical development of a new anti-TB molecule is a great achievement. The TRIC-TB project was designed and conducted with only two partners and as such a role model for a lean and efficiently run programme between BioVersys and GSK. We are extremely grateful for the trust bestowed upon us by the European Union's IMI2 programme and the funding that BioVersys has received that has enabled the translation of this exciting new TB treatment paradigm that is currently being investigated in Phase 2a in patients."

Dr. Niklas Blomberg, Executive Director, Innovative Health Initiative (IHI): "Tuberculosis poses a serious threat to public health worldwide, yet developing new treatments is highly challenging. The success of TRIC-TB in advancing a novel approach to tackling TB demonstrates how public-private partnerships can make a difference in even the toughest areas of health R&D."

Dr. David Barros-Aguirre, VP and Head of Global Health Medicines R&D Unit, Global Health R&D, GSK: "Every year, 10 million people fall ill with TB and challenges such as increasing resistance to current treatments are hindering efforts to reduce that number. New treatment regimens are much needed, so we're really pleased that the TRIC-TB program has been completed, signifying progress towards meeting that goal. Partnerships are vital for TB research and development, and the partnership between BioVersys and GSK on this European Union IMI2 programme is a great example of what can be achieved when we work together to get ahead of TB."

The TRIC-TB Project has received funding from the EU IMI-JU2 programme under the AMR Accelerator umbrella.

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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 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 alpibectir (formerly 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 Phase 1 a major milestone of the TRIC-TB Project 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). Worldwide, an estimated 10.6 million people developed TB in 2022 and an estimated 1.30 million died from TB. WHO estimates that there were 410'000 new cases with resistance to rifampicin – the most effective first-line drug – most of them were multi-drug resistant (MDR) MDR-TB remains a public health crisis and a health security threat. Worldwide, only 63% of MDR-TB patients are currently successfully treated.[1] In the modern world of global travel, and ease with which infections spread, it is very worrying to note that two-thirds of the global total of TB cases was in eight countries: India (27%), Indonesia (10%), China (7.1%), the Philippines (7.0%), Pakistan (5.7%), Nigeria (4.5%), Bangladesh (3.6%) and the Democratic Republic of the Congo (3.0%). Furthermore, 3.3% of all new and 17% of reoccurring TB cases were MDR/RR-TB.

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

[1] Global Tuberculosis Report 2023 WHO

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About BioVersys
BioVersys AG is a multi-asset, clinical stage biopharmaceutical company focused on identifying, developing and commercializing novel antibacterial products for serious life-threatening infections caused by multi-drug resistant ("MDR") bacteria. Derived from the company's two internal technology platforms (TRIC and Ansamycin Chemistry), candidates are designed and developed to 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. This enables BioVersys to address the high unmet medical need for new treatments against life-threatening resistant bacterial infections and bacteria-exacerbated chronic inflammatory microbiome disorders. The company's most advanced research and development programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase 2), and tuberculosis (alpibectir, Phase 2a, in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille, France). BioVersys is located in the biotech hub of Basel, Switzerland.

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