# PRESS RELEASE

# BIOVERSYS ANNOUNCES FIRST PATIENT DOSED IN PHASE 2A CLINICAL TRIAL WITH BVL-GSK098

**Basel, Switzerland. January 31, 2023, 9am CET**

## BioVersys AG announces first patient dosed in Phase 2a clinical trial 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, that the first patient has been dosed in Phase 2a clinical trial with BVL-GSK098.

- BVL-GSK098 is a small molecule 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 and significantly potentiating the activity of an existing antibiotic, ethionamide (Eto) or prothionamide (Pto), for the treatment of tuberculosis (TB).
- In recently completed Phase 1 studies, BVL-GSK098 was generally safe and well tolerated, and showed a favorable pharmacokinetic profile at therapeutically effective doses in healthy volunteers.
- Today's announcement is a major milestone of the bEto-TB project, which is funded by the European & Developing Countries Clinical Trials Partnership (EDCTP2 programme), supported by the European Union.

**Dr. Glenn E. Dale, Chief Development Officer of BioVersys:** "Following the very promising safety profile in Phase 1, we are excited to be testing BVL-GSK098 for the first time in patients, with its new concept of overcoming resistance by boosting activity of Eto against *Mycobacterium tuberculosis*. This Early Bactericidal Activity (EBA) Phase 2a study will test the efficacy, safety, tolerability and pharmacokinetics of BVL-GSK098 in combination with various doses of Eto in patients with pulmonary TB."

**Prof. Andreas Diacon, Founder, Director & CEO at TASK:** "At TASK we are excited to once again bring a novel, promising antibiotic to a tuberculosis patient for the very first time. BVL-GSK098 will, if successful, make an existing, low-cost and safe antibiotic much more potent and can be developed much quicker than a completely new substance. For ethionamide, the antibiotic boosted by BVL-GSK098, there is abundant safety data accumulated over many decades. BVL-GSK098 is particularly promising in tuberculosis meningitis where we urgently need more and better antibiotics."

**Dr. David Barros-Aguirre VP and Head of Global Health Medicines R&D Unit, Global Health R&D, GSK:** "Today's announcement marks an exciting moment for the TRIC-TB partnership and our efforts to improve the treatment options available for patients with tuberculosis. At GSK, we are committed

**BioVersys AG**
c/o Technologiepark Basel

Hochbergerstrasse 60C
CH-4057 Basel
Switzerland

Phone +41 61 633 22 50
www.bioversys.com
info@bioversys.com

to getting ahead of disease together, and positive results from this trial with compound BVL-GSK098 could validate a new concept to both overcome resistance and improve potency of an existing drug like ethionamide. This proof of concept study could bring us closer to new combination therapies to change the trajectory of the TB epidemic, that continues to have a devastating impact on many of the most vulnerable communities around the world."

**Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys:** "The global presence and recent increase in tuberculosis cases during the COVID-19 pandemic should serve as a reminder that we still urgently need new anti-TB drugs to help improve treatments and eradicate this devastating disease that affects 10 million people each year, and still kills 1.5 million annually. We are very grateful for the continued support of the European Union, and in particular the EDCTP, with their support we are testing BVL-GSK098 for the first time in a Phase 2a proof of concept trial, with the ultimate goal of developing a safer more efficacious therapy and shortening TB treatment times."

**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. The programme has previously received funding from the EU IMI 2 JU (TRIC-TB) and the Wellcome Trust.

Project description website: https://www.task.org.za/beto/

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

**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]

**About the European & Developing Countries Clinical Trials 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

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

clinical developments for diarrhoeal diseases, lower respiratory tract 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.

**About GSK**

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

**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 2-ready), and tuberculosis (BVL-GSK098, Phase 2a) 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.

**BioVersys contacts**

**Eliane Schmidt**, Executive Assistant to CEO, Tel. +41 61 633 22 50; Mail: info@bioversys.com
Website: www.bioversys.com.

The bEto-TB project (grant reference: RIA2019AMR-2657) is part of the EDCTP2 programme supported by the European Union.