BioVersys Announces First Subjects Dosed in Phase 1 Clinical Trial of BVL-GSK098

BVL-GSK098 IS BEING DEVELOPED FOR THE TREATMENT OF MULTIDRUG-RESISTANT TUBERCULOSIS INFECTIONS

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BioVersys has reached another major milestone by moving a second program into clinical development with the start of Phase 1 testing for BVL-GSK098 in healthy volunteers.

BioVersys AG, a privately owned, multi-asset Swiss pharmaceutical company focused on developing small molecules for multidrug-resistant bacterial infections with applications in Anti-Microbial Resistance (AMR) and targeted microbiome modulation, today announced that the first healthy volunteers have received BVL-GSK098 in a Phase 1 clinical trial designed to evaluate the safety, tolerability, and pharmacokinetics of BVL-GSK098 in healthy human volunteers through Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) studies.

- BVL-GSK098 is a novel compound potentiating and overcoming the resistance against ethionamide (Eto) or prothionamide (Pto) for the treatment of tuberculosis (TB). BVL-GSK098 targets bacterial transcriptional regulators, a groundbreaking approach that is being assessed globally for the first time in a clinical trial. BVL-GSK098 is developed in combination with Eto or Pto for the treatment of TB in collaboration with GSK. The program is supported by the IMI2 AMR Accelerator from the EU (TRIC-TB Project). The program originates from BioVersys and its partners at the University of Lille and Pasteur Institute Lille, France.

- BVL-GSK098 has completed GLP toxicology studies and shown excellent in vitro and in vivo efficacy in animal models against multidrug-resistant TB (MDR-TB), including overcoming pre-existing resistance mechanisms in *Mycobacterium tuberculosis* by employing novel bioactivation pathways for Eto. Furthermore, this combination has also proven to be effective against Isoniazid (INH) and Rifampicin (RIF) resistant strains. BVL-GSK098 in a fixed combination with Eto was granted QIDP Designation from the U.S. FDA in June 2019 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.

Dr. Sergio Lociuro, Chief Scientific Officer of BioVersys: “We are very excited to be testing BVL-GSK098 in a Phase 1 clinical trial, to evaluate its safety and pharmacokinetics in healthy volunteers. Although combinations for fighting resistance and/or potentiating the action of a drug are well known in the AMR field (e.g. beta-lactams/beta-lactamase inhibitors), this is the first time that such an approach is applied in the TB field. Indeed, BVL-GSK098 combined with Eto or Pto offers the potential of increasing the potency of these drugs at significantly better tolerated low doses, while making them more bactericidal, faster-acting and active against Eto-Pto- and INH-resistant strains.”

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Dr. David Barros-Aguirre, VP and Head of Global Health Pharma Research Unit, Global Health Pharma R&D, GSK: "GSK is committed to the discovery of novel treatments for tuberculosis including the drug-resistant forms of *Mycobacterium tuberculosis*. Entering clinical trials is an important milestone in our successful collaboration with BioVersys as we develop BVL-GSK098 within the IMI-2 TRIC-TB program, towards a potential treatment to optimize the beneficial effects of ethionamide."

Dr. Marc Gitzinger, CEO and co-founder of BioVersys: "More than 1.5 million people die every year from Tuberculosis through a lack of efficacious treatments and access to medicines. In the midst of the current Covid-19 pandemic, this death toll is expected to rise significantly. At BioVersys we remain committed to developing innovative and life-saving treatments for patients suffering from drug-resistant infections, and the combination of BVL-GSK098 and Eto (or Pto) has the potential to improve patient outcomes, reduce treatment times, and even replace INH in first-line TB therapy."

Dr. Seng Chin Mah, Chairman of BioVersys: "The BioVersys team has achieved yet another significant milestone by progressing a second program, BVL-GSK098, a novel treatment for highly resistant TB infections, into clinical development. This takes place within weeks of BV100 entering clinical development. We have now met all our immediate term goals for clinical development and look forward to executing on the next phase of our strategic plan as a significant innovator of urgently needed medicines in the AMR field.

TRIC-TB Project – the objective is to progress clinical candidates that potentiate the efficacy of and reverse the resistance to the anti-tubercular pro-drug ethionamide (Eto). The World Health Organization (WHO) considers Eto a crucial pillar of TB treatment, especially against MDR (multidrug-resistant) and XDR (extensively drug-resistant) strains. Our "booster" molecules act on novel bacterial transcription regulator targets, resulting in an increase of Eto efficacy by at least three-fold in vivo. This allows the use of lower efficacious doses of Eto in human anti-tuberculosis treatments and with a resultant reduction in dose dependent adverse effects in TB patients. Furthermore, data shows that the small molecules overcome pre-existing resistance mechanisms against Eto in *Mycobacterium tuberculosis* by employing novel bioactivation pathways for Eto, thus increasing the level of bioactivation. TRIC-TB has the potential to deliver a novel, fast acting TB agent potentially replacing Isoniazid as first line TB therapy. Follow TRIC-TB on Twitter @TRIC_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 the Innovative Medicines Initiative
The Innovative Medicines Initiative (IMI) is working 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 does this 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

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

enterprises (SMEs), patient organizations, 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 is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Through the IMI2 programme, IMI has a budget of €3.3 billion for the period 2014-2020. Half of this comes from the EU's research and innovation programme, Horizon 2020. The other half comes from large companies, mostly from the pharmaceutical sector; these do not receive any EU funding, but contribute to the projects 'in kind', for example by donating their researchers' time or providing access to research facilities or resources.

- More info on IMI: www.imi.europa.eu
- Follow us on Twitter: @IMI_JU

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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