BioVersys Receives QIDP Designation from the U.S. FDA for the Development of a fixed combination of BVL-GSK098 and ETH

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

Basel, Switzerland. June, 23rd, 2020. 09:00 CEST

BioVersys develops BVL-GSK098, in collaboration with GSK, as an entirely new mechanism to potentiate and overcome resistance of ethionamide in tuberculosis.

BioVersys AG a privately owned, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections, announced today that its clinical candidate BVL-GSK098 in a fixed combination with ethionamide (ETH) has received Qualified Infectious Disease Product (QIDP) designation from the U.S. FDA for oral use in the treatment of pulmonary tuberculosis (TB). QIPD status automatically gives priority review designation to the first application or efficacy supplement submitted for a specific drug product and indication for which QIDP designation is granted. Subject to some statutory limitations, a drug that is designated as a QIDP will receive a 5-year extension to any exclusivity for which the application qualifies upon approval.

BVL-GSK098 originates from BioVersys' award winning Transcriptional Regulator Inhibitory Compound (TRIC) platform in a successful collaboration with GSK, the Pasteur Institute Lille and University of Lille (with the groups of Nicolas Willand, Alain Baulard and Benoit Deprez) with previous financial support from the Wellcome Trust. BVL-GSK098 has completed GLP toxicology studies and is being prepared to enter First in Human (FiH) clinical trials in 2H 2020. The development of BVL-GSK098 has also been supported since May 2019 by the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) through a grant of €6.92 million.

The World Health Organization (WHO) considers ETH a crucial pillar of TB treatment, especially against MDR (multidrug-resistant) and XDR (extensively drug-resistant) strains. BVL-GSK098 boosts the *in vitro* and *in vivo* activity of the well-known anti-tubercular pro-drug ETH, resulting in an unprecedented increase of ETH efficacy *in vivo*. This boosting of activity would allow for lower efficacious doses of ETH in human anti-TB treatments and is predicted to result in a reduction in dose dependent adverse effects in TB patients. Furthermore, data shows that BVL-GSK098 overcomes pre-existing resistance mechanisms in *Mycobacterium tuberculosis* against ETH by employing novel bioactivation pathways for ETH.

Dr. Sergio Lociuro, Chief Scientific Officer of BioVersys: "The combination of BVL-GSK098 and ETH offers a novel, fast acting anti-tuberculosis treatment with the potential to replace Isoniazid in first-line TB therapy. Current TB therapies are a combination of four or more drugs and treatment times range from 6-18 months depending on the resistance profile of *Mycobacterium tuberculosis*. We believe the combination of BVL-GSK098 and ETH together will contribute to improving patient out-comes by overcoming MDR-TB infections and reducing treatment times."

Hochbergerstrasse 60c | CH-4057 Basel | Switzerland
Phone +41 61 633 22 56 | www.bioversys.com | info@bioversys.com

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 and in particular to the drug resistant forms of *Mycobacterium tuberculosis*. The QIDP designation from the FDA recognizes this high unmet need and represents an important step in our collaboration with BioVersys to develop BVL-GSK098, within the IMI-2 TRIC-TB program, as a potential treatment to optimize the beneficial effects of ethionamide."

Dr. Marc Gitzinger, CEO and co-founder of BioVersys: "Tuberculosis is still the single biggest infectious disease killer of our time and novel treatment regimens are urgently needed. The receipt of QIDP designation from the FDA is an important step forward and validation of BVL-GSK098 and our TRIC-TB program. We remain committed to developing innovative and life-saving AMR treatments for exceptionally high unmet medical needs."

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 (ETH). The World Health Organization (WHO) considers ETH 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 ETH efficacy by at least three-fold in vivo. This allows the use of lower efficacious doses of ETH 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 ETH in *Mycobacterium tuberculosis* by employing novel bioactivation pathways for ETH, 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]

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) 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 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

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

Hochbergerstrasse 60c | CH-4057 Basel | Switzerland
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BioVersys AG is a privately owned 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 are in preclinical development for nosocomial infections (hospital infections), and tuberculosis in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille. In 2020 BioVersys plans to launch its first Phase I clinical trials. BioVersys is located in the Technologiepark in the thriving biotech hub of Basel, please visit www.bioversys.com. Follow us on Twitter @Bioversys.

BioVersys Contact: Alina Lundin, Executive Assistant to CEO, Tel. +41 61 633 22 50; Mail: info@bioversys.com