



BioVersys announces a EUR 6.92 Million funding of its TRIC-TB project by the IMI2 JU and extends its successful collaboration with long term partners

Basel, Switzerland, June 20, 2019. 13:00 CET

BioVersys has been awarded EUR 6.92 Million funding for TRIC-TB from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement N° 853800. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

BioVersys is pleased to announce that it has received an IMI2 JU grant of 6.92 million EUR to fund further preclinical through to first clinical development of candidate molecules from the TRIC-TB project which have been developed in a successful collaboration with GSK, the Institut Pasteur de Lille and University of Lille (with groups of Nicolas Willand, Alain Baulard and Benoit Deprez). The project previously received valuable financial support from the Wellcome Trust.

TRIC-TB is one of BioVersys' leading pipeline assets directed at tuberculosis (TB), based on BioVersys' award winning Transcriptional Regulatory Inhibitory Compounds (TRICs) Platform which reaches a significant new milestone with the selection of two pre-clinical candidates and validation through the support of the IMI2 JU and the extension of the R&D collaboration with GSK. The funding provided by the IMI2 JU under the AntiMicrobial Resistance (AMR) Accelerator Program will allow for this unique Global Health project to continue its progress through IND enabling studies and into First in Human studies by early 2020.

Dr. Marc Gitzinger, CEO and co-founder of BioVersys: "We are grateful for the funding being provided to BioVersys for TRIC-TB by the IMI2 JU, European Union's Horizon 2020 research and innovation programme and EFPIA. To meet the challenge of the burgeoning AMR problem, continued R&D investment is vitally important. BioVersys is determined to make a difference in AMR patient care world-wide by delivering efficacious, novel therapeutic treatment options that can deliver better patient outcomes. We are also delighted to continue our successful collaboration with GSK as we progress together compounds that will soon enter clinical studies."

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*, an area of high unmet medical need. The TRIC-TB project is an opportunity to extend our collaboration with BioVersys from discovery through to clinical development in patients with TB. The project applies an innovative approach by selectively influencing transcriptional regulation to tackle resistance to current TB drugs. We believe this approach has the potential to provide a readily implementable solution to multi-drug resistant TB patients worldwide.

Dr. Serio Lociuoro, CSO of BioVersys: "We are pleased that the IMI2 JU has provided this grant to BioVersys which supports the further development in tuberculosis of this new class of molecules against a new target class (Transcription Regulators). Over the last years we have worked very closely with GSK on this program and achieved a number of important milestones together and we now look forward to continuing our successful partnership."



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.

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 1.6 million people died from TB in 2017 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 2017, there were an estimated 10 million new TB cases worldwide, 5.8 million men, 3.2 million women and 1.0 million children, 900 thousand (9%) were people living with HIV (72% in Africa). There were an estimated 458’000 new cases of isoniazid and rifampicin resistant (MDR-TB) and an additional 100’000 people with rifampicin-resistant TB (RR-TB), the most effective drug available. Worldwide, only 55% 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 2017: India (24%), China (13%) and the Russian Federation (10%). Furthermore, 3.6% of all new and 17% of reoccurring TB cases were MDR/RR-TB in 2017.

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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 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 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.

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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-exacerbation chronic inflammatory

¹ Global Tuberculosis Report 2018 WHO

² <http://www.who.int/en/news-room/fact-sheets/detail/tuberculosis>



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.

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