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PRESS RELEASE

BioVersys Receives QIDP Designation from the U.S. FDA for the Development of BV100

Basel, Switzerland, May 27, 2019. 09:00 CET

BioVersys to develop BV100 in critical care indications

BioVersys AG a privately owned, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections with applications in Anti-Microbial Resistance (AMR) and targeted microbiome modulation, announced today that its preclinical candidate BV100 has received Qualified Infectious Disease Product designation from the U.S. FDA for intravenous use in the treatment of ventilator-associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI).

BV100, a narrow spectrum compound with exceptional in vitro and in vivo antimicrobial activity on Acinetobacter baumannii is being developed initially for the treatment of multidrug-, extensively drug- and pandrug-resistant (MDR, XDR & PDR) ventilator-associated bacterial pneumonia (VABP) and hospital-acquired bacterial pneumonia (HABP) infections.

Dr. Glenn Dale, Chief Development Officer of BioVersys: “We are very pleased to receive QIDP designation from the FDA for BV100 and we are looking forward to working with the FDA to rapidly make this exceptionally potent antibiotic compound available to people suffering with life-threatening multidrug-resistant Acinetobacter infections.”

The QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act of 2012 to incentivize the development of new antibiotics that can treat serious or life-threatening infections. Under the QIDP program, BioVersys will get certain incentives for the development of BV100, such as eligibility for priority FDA review, Fast Track designation, and a five-year extension of market exclusivity will be granted upon approval of the first QIDP indication for BV100.

Dr. Marc Gitzinger, CEO and co-founder of BioVersys: “The receipt of QIDP designation from the FDA is an important step forward and validation of BioVersys’ continued commitment to develop innovative and potentially life-saving AMR treatments, in a field where we have a lack of truly novel therapeutic options and an exceptionally high unmet medical need.”

Dr. Seng Chin Mah, Chairman of BioVersys: “The FDA’s QIDP designation represents a significant regulatory milestone in the transition of BioVersys into a clinical stage company focused on innovation and value creation. We are committed to rapidly advancing our diverse pipeline and bringing these much-needed therapies to patients as quickly as possible.”

Combating resistant bacterial infections is an ever-increasing global health problem towards which BioVersys is developing a pipeline of differentiated experimental drugs. Our most advanced compounds for nosocomial infections and Tuberculosis will be ready to enter first Phase I clinical trials in H1 2020.

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

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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 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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