PRESS RELEASE

BIOVERSYS ANNOUNCES FIRST SUBJECTS DOSED IN ADDITIONAL PHASE 1 CLINICAL TRIALS OF BV100

Basel, Switzerland. November 3, 2021, 9am CEST

BioVersys AG doses first subjects in multiple ascending dose and renal impairment Phase 1 clinical trials with BV100

BioVersys AG, a privately owned 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 the dosing of the first subjects in both a multiple ascending dose (MAD) and renal impairment (RI) Phase 1 clinical trials with BV100.

- The MAD study will be the first time that subjects will have received multiple doses of BV100, allowing for empirical confirmation of BV100 drug levels at steady state as well as evaluating safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD).

- The RI study will assess the PK and safety in subjects with varying degrees of renal insufficiency, including End-Stage Renal Disease (ESRD).

BV100 is a potential breakthrough hospital antibiotic to treat serious infections caused by Carbapenem Resistant *Acinetobacter baumannii* (CRAB) in indications of ventilator-associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI), for which there are little to no effective and safe treatment options. BioVersys has developed a proprietary human IV formulation of BV100 for the CRAB hospital market and elucidated the unique mode of action that accounts for its tremendous potency and coverage of clinical CRAB isolates.

BV100 is currently being studied in a number of Phase 1 clinical studies, having already completed GLP toxicology studies. BV100 has shown outstanding *in vitro* and *in vivo* efficacy in several animal models, with unprecedented *in vitro* strain coverage against CRAB and a very low propensity to develop resistance. BV100 was granted QIDP Designation by the U.S. FDA in May 2019 for use in the treatment of VABP, HABP and BSI, making BV100 eligible for priority FDA review, Fast Track designation, and a five-year extension of market exclusivity upon approval of the first QIDP indication.

The swift progression of the clinical development for BV100 will pave the way for the Phase II/III program with the ultimate goal of bringing this important medicine as soon as possible to patients suffering from pneumonia caused by carbapenem resistant *Acinetobacter baumannii* (CRAB).

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Dr. Glenn E. Dale, Chief Development Officer of BioVersys: "Clinicians currently have very limited treatment options for highly resistant *Acinetobacter baumannii* infections. These Phase 1 studies will generate data to work out the dosing regimen for subsequent registration trials and allow physicians to have a better understanding of how renal impairment affects the pharmacokinetics of BV100."

Dr. Marc Gitzinger, CEO and founder of BioVersys: "BioVersys continues to progress its clinical pipeline addressing the most difficult to treat bacterial pathogens such as *Acinetobacter baumannii*, in our mission to bring novel life-saving antibiotics to patients suffering from drug-resistant infections. BV100 represents a potential breakthrough therapeutic option for patients suffering from CRAB infections for which the mortality rate often approaches 50% due to a lack of available working antibiotics."

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 programmes 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.

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