



BIOVERSYS SUCCESSFULLY COMPLETES THREE PHASE I CLINICAL TRIALS OF BV100

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BioVersys AG announces successful completion of three Phase I clinical trials with BV100

BioVersys AG, a privately-held 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 successful completion of three Phase I clinical trials.

- Single-ascending dose (SAD) study,
- Multiple-ascending dose (MAD) study
- Renal impairment (RI) study.

The analysis of preliminary, blinded data from these studies showed a favorable safety, tolerability and pharmacokinetic profile of BV100 at doses within therapeutic range in healthy volunteers and people with varying degrees of renal impairment.

BV100 is a much needed injectable formulation of rifabutin to treat serious infections caused by Carbapenem Resistant *Acinetobacter baumannii* (CRAB) in patients with ventilator-associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI). Today, mortality is typically around 50% in these patients and there are little to no effective and safe treatment options.

Additionally, the discovery of a novel mode of action of BV100 on the active uptake of rifabutin into the Gram-negative bacterial species, *Acinetobacter baumannii*, allows us to target RNA-polymerase in Gram negative bacteria for the first time with a human-relevant dose. This results in strong bactericidal activity.

Dr. Glenn E. Dale, Chief Development Officer of BioVersys: “We are pleased by the favorable safety of BV100 at the doses studied in our clinical trials. This positive data paves the way for a Phase II clinical trial that will be conducted in patients with nosocomial pneumonia caused by *Acinetobacter baumannii* including CRAB. The combination of the injectable formulation and the novel mode of action will position BV100 as a potential breakthrough therapy in CRAB-infected patients.”



Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys: “We are very excited by the completion of these three studies within a short period of time. Our clinical development program for BV100 is on track and we also have the right team in place to execute on the next phase of the program. BV100 is protected by three patent applications globally, recently receiving allowance in the US. BV100 remains an important clinical asset in our diverse and value adding pipeline and has the potential to become a critical life-saving therapy for patients afflicted with resistant CRAB infections.”

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 programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase II-ready), and tuberculosis (BVL-GSK098, Phase I) in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille. BioVersys is located in the Technologiepark in the biotech hub of Basel.

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