PRESS RELEASE

BioVersys completes BV100 Phase 1 clinical trial in China

Ad hoc announcement pursuant to Art. 53 LR

Basel, Switzerland. April 22, 2026, 7.00am CEST

- **Completing the Phase 1 clinical trial in China paves the way for Chinese sites to join the global BV100 Phase 3 RIV-TARGET trial by the end of 2026.**
- **The Phase 3 RIV-TARGET trial is expected to enrol ~300 patients across ~100 sites in ~15 countries, and has recently achieved the first patient, first visit milestone.**
- **BV100 is a potential best-in-class anti-infective agent in treating hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB).**
- **Noteworthy targets: initiation of Chinese sites in Phase 3 (by end-2026); Phase 2b RIV-CARE interim analysis (by end-2026); Phase 3 RIV-TARGET top-line data (expected within ~2 years).**

BioVersys AG (SIX: BIOV), a multi-asset, clinical stage biopharmaceutical company focusing on research and development of novel antibacterial products for serious life-threatening infections caused by multi-drug resistant (MDR) bacteria, announced today the completion of the clinical assessment of BV100 in healthy subjects in the Phase 1 clinical study conducted in China.

The completion of this mandatory Phase 1 safety and pharmacokinetic clinical trial in China is crucial in the development of BV100. With this accomplishment, BioVersys can initiate the process to onboard Chinese sites in the global Phase 3 RIV-TARGET trial of BV100. BV100 was generally safe and well tolerated in this Phase 1 study in Chinese healthy volunteers.

Dr. Glenn E Dale, Chief Development Officer: "We are pleased with the development of our lead clinical asset BV100, and our progress toward including Chinese sites in the global Phase 3 RIV-TARGET trial. Our ultimate aim is to provide BV100 access to patients in need across high-burden regions worldwide."

CRAB infections are a serious health threat throughout the world, and the incidence rates are particularly high in China and Asia. Combined with very high resistance rates of 60-80% to carbapenems, *Acinetobacter baumannii* is a leading cause of death attributable to antimicrobial resistance in China.[1] Based on recent epidemiology data, BioVersys estimates that over 1 million patients annually are at risk of severe CRAB pneumonia and bloodstream infections in China alone.

The global Phase 3 RIV-TARGET registration trial will assess BV100 in critically ill patients with hospital-acquired or ventilator-associated bacterial pneumonia (HABP or VABP), suspected or confirmed to be

[1] J Adv Res. 2025 Jun 11:S2090-1232(25)00430-8. *Burden of bacterial antimicrobial resistance in China: a systematic analysis from 1990 to 2021 and projections to 2050*

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due to carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex (CRABC). The RIV-TARGET trial, which recently announced the first patient, first visit milestone, is expected to enrol approximately 300 patients across ~100 sites in ~15 countries, with top-line results expected within the next two years.

In parallel to the Phase 3 RIV-TARGET trial, BioVersys has initiated an open-label Phase 2b differentiation trial (RIV-CARE) in South-East Asia in H1 2026, comparing BV100 with the best-available-therapy in multiple geographies. The Phase 2b trial will support differentiation and adoption of BV100, as the trial will provide real-world evidence of clinical practices in settings with very high drug resistance levels, with interim analysis planned for end of 2026. In November 2025, BioVersys announced that the ADVANCE-ID clinical trial network will support and collaborate with BioVersys in conducting the Phase 2b study. This support has been made possible thanks to the generous contribution of Wellcome who strengthened the ADVANCE-ID network with SGD 22 million (c. USD 17m or CHF 14m).

About BV100
BV100 is a novel formulation of rifabutin suitable for intravenous administration, with a recently discovered novel mode of action showing an active uptake of rifabutin into the Gram-negative bacterial species, *Acinetobacter baumannii*. For the first time, BV100 allows for the targeting of the RNA-polymerase enzyme in Gram-negative bacteria with a human-suitable dose. BV100 is being developed for the treatment of infections caused by *Acinetobacter baumannii calcoaceticus complex* (ABC), including carbapenem-resistant ABC (CRABC) in critically important indications of ventilator associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI). 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.

About *Acinetobacter baumannii*
Acinetobacter baumannii calcoaceticus complex (ABC) are Gram-negative bacteria found in the environment (e.g., in soil and water) and an opportunistic pathogen in humans, typically infecting critically ill and immunocompromised patients, that can result in severe pneumonia and bloodstream infections in addition to affecting other parts of the body. ABC is considered a significant worldwide threat in the healthcare setting given its ability to survive for prolonged periods on surfaces, combined with its ability to develop or acquire resistance to standard of care antibiotics, e.g. carbapenems. Carbapenem-resistance as well as multi-drug resistance (MDR) rates for ABC are among the highest recorded for any bacteria in current times (The Lancet 2022; 399: 629–55). Incidence and resistance rates for ABC are trending upwards and COVID-19 has exacerbated this significantly. BioVersys forecasts the annual number of carbapenem-resistant *A. baumannii* infections in hospitals to have surpassed one million globally and due to the limited treatment options, such infections come with high (up to 50%) mortality rates.

About BioVersys
BioVersys AG is a multi-asset, clinical stage biopharmaceutical company focused on identifying, developing and commercializing novel antibacterial products for serious life-threatening infections caused by multi-drug resistant ("MDR") bacteria. Derived from the company's two internal technology platforms (TRIC and Ansamycin Chemistry), candidates are designed and developed to 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. This enables BioVersys to address the high unmet medical need for new treatments against life-threatening resistant bacterial infections and bacteria-exacerbated chronic inflammatory microbiome disorders. The company's most advanced research and development programs address nosocomial infections of Acinetobacter baumannii (BV100, Phase 3), and tuberculosis (alpibectir, Phase 2, in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille, France). BioVersys is located in the biotech hub of Basel, Switzerland.

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