PRESS RELEASE

BioVersys announces first patient first visit in HABP/VABP pivotal Phase 3 RIV-TARGET trial of BV100

Ad hoc announcement pursuant to Art. 53 LR

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- **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).**
- **The RIV-TARGET Phase 3 clinical trial (NCT07326540) aims to compare BV100 plus low-dose polymyxin B to colistin plus high-dose ampicillin-sulbactam in patients with suspected HABP or VABP due to carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex (CRABC).**
- **The start of Phase 3 follows the successful Phase 2 study that showed an overall 50% reduction in mortality compared with best available therapy.**
- **Global pivotal Phase 3 trial is on track to enroll last patient by the end of 2027 and will support first regulatory approval submissions in 2028.**

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 first patient first visit in its global pivotal Phase 3 clinical trial for BV100. The Phase 3 trial is designed to evaluate BV100 in critically ill patients with hospital-acquired or ventilator-associated bacterial pneumonia (HABP or VABP), suspected or confirmed to be due to carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex (CRABC). The RIV-TARGET Phase 3 global trial is expected to enroll approximately 300 patients across ~100 sites in ~15 countries.

CRABC is a highly drug-resistant Gram-negative pathogen that is recognized as a critical priority by global health authorities. BV100 is a novel intravenous formulation of rifabutin based on the newly identified mode of action for the active uptake of rifabutin into the *Acinetobacter baumannii-calcoaceticus complex.* BV100 is being developed for MDR hospital infections caused by *Acinetobacter baumannii,* including carbapenem-resistant *Acinetobacter baumannii* (CRAB) strains. BV100 has Qualified Infectious Disease Product (QIDP) Designation by the U.S. FDA, making BV100 eligible for priority FDA review, Fast Track designation, and a five-year extension of market exclusivity in the US.

Dr. Glenn E Dale, Chief Development Officer of BioVersys: "CRAB resistant infections have become a major cause of death in hospital settings over the last two decades, with mortality rates reaching 50% due to limited treatment options. The halving of the mortality rate demonstrated by BV100 in its Phase

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2 trial is encouraging, and we look forward to seeing the Phase 3 trial progress and potentially offer physicians and patients a new therapeutic option before the end of the decade."

Dr. Marc Gitzinger, Chief Executive Officer of BioVersys: "Achieving first patient first visit in the RIV-TARGET trial marks a significant milestone for BioVersys in the development of BV100 and more importantly for patients suffering from CRABC infections. We are very proud of the extensive work that has brought us to this point by the BV100 team, partners and clinical centres worldwide. We expect top-line Phase 3 results within the next two years. Data from this trial will be a critical part of subsequent regulatory submissions for marketing authorisations globally. In parallel, we are conducting the RIV-CARE open label Phase 2b trial to collect further safety experience and evidence of clinical efficacy, with a first interim read-out expected towards the end of 2026. The BV100 development program intends to demonstrate best-in-class anti-infective treatment qualities for suspected HABP or VABP due to CRABC. We continue on our quest to make a difference for AMR patients afflicted with serious unmet medical needs."

Phase 3 trial design

The global Phase 3 trial is a randomized, active-controlled two-part parallel-group trial to evaluate the efficacy and safety of BV100 plus low-dose polymyxin B in patients with HABP or VABP suspected or confirmed to be due to CRABC infection (RIV-TARGET). Part A is the pivotal, randomized, comparative portion of the trial, employing a partially blinded design aiming to enroll approximately 300 HABP/VABP patients with suspected or confirmed CRABC infections. Patients will be randomized 1:1 to receive either [1] BV100 combined with low-dose polymyxin B or [2] colistin combined with high-dose ampicillin-sulbactam, with both arms allowing meropenem as background in case of polymicrobial infections. The primary efficacy endpoint is defined as 28-day all-cause mortality (ACM) in the CRABC microbiological modified intention-to-treat (CRABC m-MITT) population. Secondary efficacy endpoints will include clinical cure status at the test of cure (ToC) in CRABC m-MITT, ventilator free days, time spent in intensive care unit (ICU) and time in hospital. As part of the study protocol, data safety monitoring boards (DSMBs)[1] will be convened at regular intervals to review trial progress.

The Phase 3 trial also includes an open-label, non-randomized, additional single group (Part B) to evaluate the efficacy and safety of BV100 plus low-dose polymyxin B in patients with HABP or VABP due to CRABC known to be resistant to colistin or polymyxin B prior to study entry and patients for whom colistin or polymyxin B regimen has failed prior to study entry. Approximately 25 patients are expected to be enrolled in Part B.

This pivotal Phase 3 trial follows the successful completion of a Phase 2 trial in documented *Acinetobacter baumannii* VABP patients. BV100 combined with polymyxin B demonstrated a clear survival benefit, resulting in a 50% relative reduction in 28-day ACM compared with best available therapy (BAT), in VABP patients suffering from confirmed CRAB infections (28-day ACM: 60% for BAT vs 25% for BV100), and was generally safe and well tolerated. The current Phase 3 trial mimics the successful study design of the positive Phase 2 trial and is expected to read-out towards the end of

[1] The DSMB review is the periodic evaluation of unblinded or partially unblinded clinical trial data by an independent committee of experts to determine whether the study should continue, be modified, or be stopped based on safety, efficacy, or futility considerations.

2027. Subsequent regulatory submissions aimed at commercial approval are planned in 2028 initially for the US, Europe and China.

In parallel to the Phase 3 pivotal trial, an open-label Phase 2b differentiation trial (RIV-CARE) will be initiated in H1 2026 comparing BV100 with BAT in multiple geographies. The Phase 2b trial aims to provide real world evidence of clinical practices in settings with very high drug resistance levels. Interim analysis is planned for the end of 2026.

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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