



Data published in Nature Communications highlights unique Mechanism of Action of Alpibectir in combination with Ethionamide (AlpE)

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- BioVersys and partners publish in the prestigious journal of Nature Communications pre-clinical development data of AlpE (alpibectir and ethionamide), an innovative drug combination that overcomes drug-resistance to *Mycobacterium tuberculosis* (*Mtb*).
- Alpibectir is a potential first-in-class molecule for treating drug-resistant tuberculosis (TB) by targeting new bioactivation pathways exploited by ethionamide in *Mtb*.
- Pre-clinical data show that alpibectir potentiates ethionamide (Eto) bioactivation, resulting in rapid killing of the bacteria and restoring Eto susceptibility in resistant *Mtb* strains.
- AlpE, is currently being studied by BioVersys' partner GSK in a pulmonary tuberculosis Phase 2b trial, expected to finalize recruitment by end of 2027, and by BioVersys in a tuberculosis meningitis Phase 2 trial that was recently initiated.

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 publication of pre-clinical data in the prestigious journal of Nature Communications, for its innovative anti-tuberculosis combination AlpE.¹

Alpibectir, a small molecule acting through a novel mode of action, represents a new concept of overcoming drug-resistance in *M. tuberculosis*, by potentiating the activity of an existing antibiotic, ethionamide, and was identified in a research collaboration with GSK and the academic groups of Dr. Alain Baulard, Prof. Benoit Deprez and Prof. Nicolas Willand. Tuberculosis is one of the leading causes of death by infectious diseases globally, as existing standard of care treatments diminish in efficacy due to growing drug resistance.

Following the recently published clinical proof-of-concept for AlpE in pulmonary TB², BioVersys and collaborators now publish pre-clinical evidence supporting the potential of AlpE to provide a new therapeutic option to treat tuberculosis:

- In *in vitro* studies, AlpE showed potent activity against a diverse set of *M. tuberculosis* clinical strains, including those resistant to standard of care treatments. AlpE was also active against intracellular *M. tuberculosis*.

¹[Alpibectir–Ethionamide combination \(AlpE\) for the treatment of tuberculosis | Nature Communications](#)

²[Revival of Ethionamide by Alpibectir | New England Journal of Medicine](#)



- In *in vivo* studies, AlpE rapidly reduced bacterial load levels and improved survival, demonstrating clear translation from *in vitro* to *in vivo* proof of concept.

Through the BioVersys and GSK partnership, alpipectir has completed Phase 1 and two Phase 2a pulmonary TB trials and is considered to be generally safe and well tolerated. Currently, AlpE is being studied in a pulmonary TB Phase 2b trial in combination with first-line TB drugs (NCT05807399), within [IMI2 UNITE4TB](#) project and BioVersys recently initiated a Phase 2 trial in meningeal TB (NCT07350174).

Dr. Michel Pieren, Clinical Project Team Leader at BioVersys: “The data provide a compelling scientific foundation in understanding the potential positioning of AlpE in future drug regimens to treat TB and thus for the next stages of clinical development. Alpipectir is the product of a successful public private partnership between BioVersys an academic consortium from Lille, France and large pharma, GSK. We are grateful to all our partners and funders for their support in the development of AlpE.”

Dr. Alain Baulard, Director of Research Inserm at CILL, Institut Pasteur de Lille: “Alpipectir reprograms the transcriptional landscape of *M. tuberculosis*, increasing the activity of ethionamide. Elucidating the precise mechanism of action of a novel drug is not only a scientifically rewarding process, it is also instrumental in anticipating potential resistance escape routes, rationalizing the design of synergistic therapeutic regimens, and ultimately paving the way for next-generation treatment strategies. This has been a truly exciting and passionate journey, one that has brought together biologists and chemists and bridged the public and private sectors. I am firmly convinced that alpipectir will soon expand the therapeutic arsenal available to clinicians and their patients.”

Prof. Nicolas Willand, of M2SV, University of Lille: “This scientific work is the culmination of a decade of intensive research into an innovative concept based on enhancing existing anti-tuberculosis drugs to make them effective again against resistant strains. It also represents a breakthrough in the detailed understanding of the mechanisms of action of alpipectir at the molecular level. Finally, it is the result of a fruitful collaboration between leading academic research units in the field of anti-infectives, private and public pharmaceutical companies seeking new alternatives to existing treatments.”

Dr. David Barros-Aguirre, Head of Global Health Medicines R&D, GSK: “The publication of these pre-clinical data for AlpE supports the continued progress of this potential treatment in clinical development and shows the value of collaborative research. GSK, alongside our partners, remains deeply committed to changing the trajectory of tuberculosis.”

The pre-clinical and clinical development of alpipectir has been strongly supported by the European Union’s Innovative Medicines Initiative 2 (IMI2) through the TRIC-TB project (grant agreement No 853800), under which some studies described in the Nature Communications publication were funded.

About tuberculosis (TB)

Tuberculosis (TB) remains one of the leading causes of death worldwide. It is caused by the bacterial pathogen *Mycobacterium tuberculosis* (Mtb). According to the WHO Global Tuberculosis Report 2025, an estimated 10.7 million people developed TB in 2024, and approximately 1.23 million died from TB. Drug resistance continues to pose a major challenge. There were about 390,000 people who developed rifampicin-resistant TB (RR-TB) or multidrug-resistant TB (MDR-TB) in 2024. MDR-TB remains a public health crisis and a health security threat, with global treatment success rates at only 71%.



The major burden of TB is concentrated within 30 high TB burden countries, accounting for 87% of the global total in 2024. Of those, the top eight countries for TB cases worldwide were, India (25%), Indonesia (10%), the Philippines (6.8%), China (6.5%), Pakistan (6.3%), Nigeria (4.8%), the Democratic Republic of the Congo (3.9%) and Bangladesh (3.6%). Globally, 8.3 million people were reported as newly diagnosed with TB in 2024. Significantly, it remains that 3.2% of new TB cases and 16% of previously treated cases are MDR/RR-TB.

About Alpipectir

Alpipectir (previously known as BVL-GSK098) is a small molecule developed from BioVersys' award winning Transcriptional Regulatory Inhibitory Compounds (TRIC) platform in a successful collaboration with GSK, the Institut Pasteur de Lille and the University of Lille. Alpipectir acts through a novel mode of action, potentiating the activity of the anti-TB drug ethionamide (Eto). Alpipectir is being studied for its potential to, lower the efficacious human dose of Eto, minimizing of dose-dependent side effects, and overcome Eto resistance. The combination alpipectir/Eto (AlpE) is being developed for the treatment of pulmonary TB and TB meningitis. In 2023 AlpE was granted orphan-drug designation (ODD) for the treatment of tuberculosis, by the U.S. Food and Drug Administration (U.S. FDA) providing for certain [incentives](#) including seven years US market exclusivity. Similarly in 2025, AlpE was granted Orphan Designation from the European Medicines Agency (EMA), providing for certain [incentives](#) including 10-year EU market exclusivity.

About TRIC-TB Project (grant agreement No 853800)

Ethionamide (Eto) and prothionamide (Pto) are recommended by the World Health Organization (WHO) for use as second-line agents in the treatment of drug-resistant pulmonary TB and TB meningitis. Despite their usefulness as TB drugs, Eto/Pto cause dose-dependent adverse events that negatively impact treatment adherence. Eto/Pto are prodrugs and their antibacterial activity can be linked to the level of bioactivation inside Mycobacterium tuberculosis (Mtb). The clinical candidate alpipectir (formerly BVL-GSK098) acts on transcriptional regulators of Mtb, stimulating novel bioactivation pathways for Eto, that has resulted in an observed increase of Eto efficacy, while simultaneously overcoming Eto resistance and keeping potent activity on MDR strains, including to a vast majority of isoniazid-resistant strains. BVL-GSK098 renders Eto rapidly bactericidal and reduces the emergence of Eto resistance development in vitro and in vivo. Based on pre-clinical data, the TRIC-TB project started to explore whether BVL-GSK098 could ultimately, lower the efficacious human oral dose of Eto by at least 3-fold, minimize dose-dependent side effects, and support patient compliance. With the completion of Phase 1 a major milestone of the TRIC-TB Project was achieved and a novel, fast acting TB agent with the potential to replace isoniazid in TB therapy has been brought into clinical development.

About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). It was set up to improve health by speeding up the development of, and patient access to, the next generation of medicines, particularly in areas where there is an unmet medical or social need. It works by facilitating collaboration between the key players involved in healthcare research, including universities, pharmaceutical companies, other companies active in healthcare research, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. This approach has proven highly successful, and IMI projects are delivering exciting results that are helping to advance the development of urgently-needed new treatments in diverse areas. IMI projects are now managed by the Innovative Health Initiative (IHI), which builds on the successes of IMI and is a cross-sectoral public-private partnership involving a wider range of health industries.

- More info on IHI: <https://www.ihieurope.eu/>
- Twitter: @IHIEurope
- More info on IMI AMR accelerator: <https://amr-accelerator.eu/project/tric-tb/>

About Lille Center for Infection and Immunity (CIIL)

The CIIL, University of Lille, CNRS UMR9017, Inserm U1019, Institut Pasteur of Lille, and Lille University Hospital) brings together 11 research teams and more than 220 members. CIIL develops a research program spanning from fundamental knowledge of the molecular and cellular mechanisms of infectious and chronic inflammatory respiratory diseases to the development and improvement of diagnostics, as well as vaccines and treatments. This vision requires the deployment of an interdisciplinary approach by bringing together complementary expertise covering a wide range of fields, from epidemiology, molecular and cellular virology, bacteriology, and parasitology, to the immunological bases of infectious and non-infectious



diseases and clinical applications. CIIL members study, in particular, host–pathogen interactions in bacterial, viral, and parasitic diseases, the immune response to these infections, and immune dysfunctions associated with non-infectious respiratory diseases.

About the Research Unit M2SV-Drugs and Molecules for Living Systems

U1177 « Drugs & Molecules for Living Systems » is a multidisciplinary research team operated by Université de Lille, INSERM and Institut Pasteur de Lille. The team aims at inventing drug candidates to fulfil unmet medical needs through innovative modes of action. Areas currently explored are infectious diseases, immunity, metabolism and CNS diseases. Two IND designations have been obtained in the last four years as well compassionate use for repurposed medicines. The team benefits from state of the art discovery platforms including a 200k compound library, automated screening platforms in BSL2 and BSL3 as well as a dedicated pharmacokinetics laboratory. It is founded by Université de Lille, INSERM and Institut Pasteur de Lille. It receives funds from Europe, French Ministry of Research, Region Hauts de France, and Métropole Européenne de Lille. Advanced projects are supported by two technology transfer offices: Inserm Transfert and SATT Nord.

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 (alpipectir, 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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