Press Release

Swiss startup Juvabis announces start of Phase I study of its best-in-class aminoglycoside antibiotic apramycin

Juvabis' clinical candidate apramycin will be evaluated in a Phase I randomised, double-blinded, placebo-controlled Single Ascending Dose study in healthy volunteers. Progression into clinical trials marks the achievement of an important milestone of the Innovative Medicines Initiative's ENABLE project in its fight against antimicrobial resistance.

Zurich, Switzerland, November 18, 2019 – Juvabis AG today announced the start of a Phase I First-in-Human study to evaluate the safety, tolerability, and pharmacokinetics of apramycin, an aminoglycoside antibiotic that has demonstrated encouraging efficacy against multidrug-resistant bacteria, so-called superbugs. Recruitment in the study is underway, and enrolment is expected to be completed by Q1 2020.

Apramycin is developed in collaboration with the ENABLE consortium, a public-private partnership funded by the Innovative Medicines Initiative (IMI), focused on accelerating the development of new antibiotics for the treatment of Gram-negative systemic infections. Pierre Meulien, Executive Director of IMI, commented: "Developing new antibiotics is extremely difficult and is fraught with challenges. ENABLE's achievement is testament to the power of collaboration through public-private partnerships – by working together, the project partners have accelerated the development of a potential new antibiotic."

Extensive preclinical profiling has demonstrated the efficacy of apramycin against a variety of WHO priority pathogens including carbapenem-resistant Enterobacteriaceae and *Acinetobacter baumannii*. Apramycin has also been proven effective against aminoglycoside resistant pathogens, a feature that distinguishes apramycin from all other aminoglycosides currently approved for the treatment of Gram-negative systemic infections. After successful completion of Phase I clinical studies, apramycin will be further developed for the treatment of critical and complicated systemic infections for which there is a high medical need worldwide.

Sven Hobbie, CEO of Juvabis, said: "Initiation of this study is an important step in our efforts to fight antimicrobial resistance. We are excited about the results of the preclinical profiling, which highlight apramycin's potential to become a best-in-class aminoglycoside antibiotic. Our close collaboration with ENABLE has been of critical importance to our rapid progress and aligned us to the high competitive standards set forth by the consortium."

Neil Pearson, Coordinator of ENABLE and Senior Scientific Director Medicinal Chemistry at GSK, said: "The entry of apramycin, the IMI ENABLE project's most advanced programme, into Phase I exemplifies the great potential of public-private partnerships. We are pleased to have played a part by providing preclinical and clinical study design expertise and guidance and look forward to the study results in 2020." Anders Karlén, Leader of ENABLE Managing Entity and professor at Uppsala University, highlighted: "Reaching this milestone shows how

efficient the unique ENABLE drug discovery and development engine functions. This has been a group effort and we are excited to see apramycin moving forward in the clinical development programme."

The molecular and biological differentiation of apramycin from other aminoglycoside antibiotics in clinical use was first discovered by researchers at the University of Zurich (UZH) in Switzerland, an early consortium member of ENABLE. The Swiss biotech start-up Juvabis has since acquired a worldwide exclusive license from UZH for the commercialization of apramycin in human therapy.

About University of Zurich and Juvabis

The University of Zurich (UZH) and its start-up company Juvabis AG joined forces with ENABLE in 2016. Juvabis strives to design next-generation aminoglycoside antibiotics that evade mechanisms of bacterial drug-resistance and at the same time display a superior safety profile when compared to benchmark drugs. UZH's proprietary technology platform of engineered ribosomes has led to the identification of apramycin's favourable antimicrobial profile and facilitated the rational design of additional lead scaffolds that hold promise for addressing various infectious disease indications.

About ENABLE

In ENABLE, over 40 European partners from academia and industry, co-led by GlaxoSmithKline and Uppsala University, joined forces in a 6-year project funded by the Innovative Medicines Initiative (IMI) to develop novel antibiotics against key Gram-negative bacteria such as *E. coli, K. pneumoniae, P. aeruginosa* and *A. baumannii*. ENABLE has rapidly succeeded in building a bottom-up drug development engine with an engaged group of highly competent scientists all working towards new drugs. Contact Laura Griestop for any communication related question (info@nd4bb-enable.eu). ENABLE is part of the ND4BB programme.

The research leading to these results has received funding from the Innovative Medicines Initiative Joint Undertaking under grant agreement n°115583, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution. The ENABLE project is also financially supported by contributions from Academic and SME partners. www.imi.europa.eu.

About IMI

The Innovative Medicines Initiative (IMI) is working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. It does this by facilitating collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organizations and medicines regulators. IMI is a partnership between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations).
http://www.imi.europa.eu/