



Nosopharm
First-in-class Anti-Infectives



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Nosopharm joins European Gram-negative Antibacterial Engine (ENABLE) project to combat antibiotic resistance

The company aims to advance NOSO-95179, a promising antibacterial compound, to clinical stage for the treatment of

multidrug-resistant Gram-negative infections

Nosopharm, a biotechnology company specialized in the research and development of new antibacterial molecules, today announces it has been selected to join ENABLE (European Gram-negative Antibacterial Engine), a project working to advance the development of potential antibiotics against multidrug resistant Gram-negative infections.

ENABLE is one of seven projects in the New Drugs For Bad Bugs (ND4BB) consortium, part of the Innovative Medicines Initiative's (IMI's) antibiotic resistance program. This €100m (\$106m) project aims to identify at least three antibacterial lead molecules with promising antibacterial activity, two antibacterial clinical candidate molecules and to enter at least one compound into preclinical and Phase 1 clinical studies.

Nosopharm will strengthen ENABLE's R&D portfolio as it brings the most advanced program to date to the project: NOSO-95179, a first-in-class antibiotic for the treatment of multidrug-resistant hospital-acquired infections. Participation in the project will allow Nosopharm to access significant technical expertise and financial support to complete a Phase 1 clinical trial. ENABLE will fund 75% of Nosopharm's internal R&D costs while the program is active. Nosopharm will also participate in collaborative research with ENABLE's expert partners across Europe.

The project will strengthen the company's IP as all NOSO-95179 results will be owned by Nosopharm.

Its selection brings encouraging recognition from global anti-infective experts for NOSO-95179 as a promising antibacterial preclinical candidate for the treatment of life-threatening multidrug-resistant Gram-negative infections. Nosopharm will also benefit from guidance of ENABLE-active members from the European Federation of Pharmaceutical Industries and Associations (EFPIA).

"IMI is delighted that projects such as ENABLE can support SMEs to advance programs through the most challenging phases of development," said Pierre Meulien, executive director of the Innovative Medicines Initiative (IMI). "This is an example of how public-private partnerships such as IMI can address critical scientific and commercial challenges for the benefit of patients."

"We welcome Nosopharm's program into the Innovative Medicines Initiative ENABLE project. We are excited to support SMEs like Nosopharm in this very challenging scientific area," said Professor Anders Karlén, project coordinator, Uppsala University. "We believe that this collaboration in a public-private partnership context is an excellent way to develop the potential of novel antibacterial agents."

"Being selected for ENABLE strengthens Nosopharm's position among the most innovative companies in the **antibacterial R&D community**," said Philippe Villain-Guillot, president of Nosopharm. "This is a major milestone in the development of our NOSO-95179 candidate. We aim to start IND-enabling studies in 2018 and launch our first-in-man clinical trial in 2019. We would like to warmly thank the IMI and the **ENABLE** team for their trust and support."

Hospital pathogens with multiple antibiotic resistances are responsible for at least 380,000 infections and 25,000 directly related deaths per year in the European Union⁽¹⁾. The annual treatment and social costs have been estimated at some €1.5 billion (\$1.59bn). From a global perspective, antimicrobial resistance could kill up to 10m people every year by 2050 and could cost \$100 trillion (€94tn) to the world economy⁽²⁾. In 2013, 21% of *Klebsiella pneumoniae* strains in the European Union had combined resistance to cephalosporins, aminoglycosides and fluoroquinolones (+38% compared to 2010) and 18% of *Pseudomonas aeruginosa* strains were resistant to carbapenems (+4% compared to 2010)⁽³⁾.

(1) European Center for Disease Prevention and Control, ECDC/European Medicines Agency

(2) Review on Antimicrobial Resistance

(3) ECDC/European Antimicrobial Resistance Surveillance Network, EARS-Net

About ENABLE

Launched in early 2014, ENABLE is a project within the ND4BB program working to advance the development of potential antibiotics against multidrug resistant Gram-negative infections. ENABLE has been highlighted as a potential collaborator in the recent US National Action Plan for Combating Antibiotic-Resistant Bacteria report issued by the White House in March 2015.

<http://nd4bb-enable.eu/>

About ND4BB

IMI's New Drugs 4 Bad Bugs (ND4BB) program represents an unprecedented partnership between industry, academia and biotech organizations to combat antibiotic resistance in Europe by tackling the scientific, regulatory and business challenges that are hampering the development of new antibiotics. It is made up of seven projects, including ENABLE.

<http://www.imi.europa.eu/content/nd4bb>

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/>

About NOSO-95179

NOSO-95179 is the most advanced molecule of Nosopharm's pipeline. It was discovered consecutively to the lead optimization of NOSO-95, the first molecule of the new class of Odilorhabdin antibiotics. The discovery stems from a bacterium of the Xenorhabdus genus. NOSO-95179 inhibits bacterial translation with a new mode of action. Its target indication is the treatment of carbapenem-resistant Enterobacteriaceae (CRE) infections. NOSO-95179 shows clear in vitro antibacterial activity against multidrug-resistant clinical isolates (e.g., NDM-1), along with in vivo efficacy in different murine infection models and good tolerability. No cross-resistance with currently used antibiotics was observed. This underpins its significant potential for treating nosocomial infections that seriously endanger patients' lives. NOSO-95179 is currently undergoing a program of pharmacological optimization with a view to moving it into the regulatory preclinical phase.

About Nosopharm

Nosopharm is a biotechnology company specialized in the research and development of new antibacterial molecules. Nosopharm discovered and developed NOSO-95179, a first-in-class antibiotic for the treatment of multidrug-resistant hospital-acquired infections. Nosopharm has developed a unique expertise in the medicinal chemistry of Odilorhabdin, the new class of antibiotics to which NOSO-95179 belongs. Nosopharm is also working on the development of second-generation Odilorhabdins with an extended spectrum of antibacterial activity. Founded in 2009, Nosopharm is based in Nîmes, France and has a staff

of seven.

The company raised €1.9m (\$2m) in private equity and received €1.3m (\$1.38m) in grants from DGA, Bpifrance, Region Languedoc-Roussillon and FEDER.

<https://www.nosopharm.com/en>

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