PRESS RELEASE



CARB-X GRANTS DEBIOPHARM AN ADDITIONAL \$12.3 MILLION TO ADVANCE DEVELOPMENT OF NOVEL ANTIBIOTIC AGAINST GONORRHEA

28th Lausanne. Switzerland, Boston, USA -May 2025 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company aiming to establish tomorrow's standard-of-care to cure cancer and infectious diseases, is honored to share that it was awarded further funding from the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a global non-profit partnership that accelerates antibacterial research and development to protect lives from bacterial infections. This grant will support the continued clinical development of **Debio 1453**, a firstin-class antibiotic with a novel mechanism of action to treat Neisseria gonorrhoeae infections.

The initial grant of \$7.9 million USD has been instrumental in progressing Debio 1453 through preclinical research. The newly awarded grant is projected to amount to \$12.3 million USD, broken down into 2 parts. Part 1 will contribute to further advancing Debio 1453 to Phase I first-in-human (FIH) evaluation. Part 2 of the grant will be considered by CARB-X based upon the achievement of predetermined milestones. Altogether, CARB-X's award to Debiopharm is projected to reach more than \$20 million USD in total to secure the transition of Debio 1453 from a preclinical to a clinical stage asset, including the timely commencement of Phase 2 evaluation, in line with their commitment to addressing the rising threat of drug-resistant bacteria.

"We are very pleased to receive this additional commitment from CARB-X for Debio 1453. This further confirms our strong pre-clinical proof-of-concept obtained for the treatment of gonorrhea," **explained Morgane Vanbiervliet, Director, Global Development and Licensing.** "CARB-X's commitment closely aligns with our own vision to establish a new standard of care for the treatment of *N. gonorrhoeae* infections, by developing an antibiotic with an entirely new mechanism of action and offering a crucial treatment alternative against multi-drug-resistant infections."

"Debio 1453 represents an approach to resistance targeting that CARB-X is proud to support. With its novel mechanism of action and novelty in chemistry, this first-in-class antibiotic has the potential to offer a durable solution to treating gonorrhea, for which all but one antibiotic has been rendered ineffective," **said Erin Duffy, PhD, R&D Chief of CARB-X.** "We are excited to continue supporting Debiopharm as the project advances into human clinical studies, marking a vital step toward delivering new treatment options for doctors and patients around the world."

Debio 1453 is a potent inhibitor of the essential fatty acid synthesis enzyme Fabl found in *N. gonorrhoeae* and a few other bacterial species. It was shown to rapidly trigger bactericidal activity *in vitro* and *in vivo* against *N. gonorrhoeae*, offering potential for treating difficult *N. gonorrhoeae* infections.

Due to its growing resistance to existing antibiotics, *N. gonorrhoeae* has become a major public health concern. New treatments are urgently needed to prevent serious complications like pelvic inflammatory disease, infertility, and increased risk of other infections. Gonorrhea can also be transmitted from a pregnant mother to her baby, potentially causing sepsis and neonatal conjunctivitis, which can, in turn, lead to blindness if untreated. In 2023, the United States reported a total of 601,319 cases of gonorrhea, making it the second most common nationally notifiable STI in the country.¹ In the same year, 96,969 confirmed cases of

gonorrhea were reported in 28 EU/EEA countries, with a notification rate of 25.0 cases per 100,000 individuals. This marks a 31% increase from 2022.² The development of new antibiotics effective against *N. gonorrhoeae* is ranked high priority by the WHO and drug-resistant *N. gonorrhoeae* is considered an urgent threat by the US CDC.

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About CARB-X

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) is a global non-profit partnership dedicated to supporting early-stage antibacterial research and development to address the rising threat of drug-resistant bacteria. CARB-X supports innovative therapeutics, preventatives and rapid diagnostics. CARB-X is led by Boston University and funded by a consortium of governments and foundations. CARB-X funds only projects that target the most serious, resistant bacteria identified on global priority lists, syndromes with the greatest global morbidity and mortality, and performance characteristics necessary for patients. https://carb-x.org/ | X (formerly Twitter) @CARB_X

Debiopharm's commitment to patients

Debiopharm aims to develop innovative therapies that target high unmet medical needs primarily in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then hand stewardship to large pharmaceutical commercialization partners to maximize patient access globally.

Visit us: www.debiopharm.com/drug-development/

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References

- 1. U.S. Centers for Disease Control and Prevention (CDC). National Overview of STIs in 2023 I STIs Statistics I CDC (<u>https://www.cdc.gov/sti-statistics/annual/summary.html</u>)
- European Centre for Disease Prevention and Control. An agency of the European Union. Gonorrhoea – Annual Epidemiological Report for 2023 (<u>https://www.ecdc.europa.eu/en/publications-data/gonorrhoea-annual-epidemiological-report-2023</u>)

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