PRESS RELEASE

DEBIOPHARM PUSHES THE BOUNDARIES OF INNOVATION IN ANTIBIOTIC DEVELOPMENT AGAINST GONORRHEA WITH FIRST-IN-HUMAN DEBIO 1453 TRIAL

First participant dosed with Debiopharm's Debio 1453, a new drug candidate to address the high unmet need of multidrug-resistant infections with Neisseria gonorrhoeae

Lausanne, Switzerland – August 26th, 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, today announced the dosing of the first healthy volunteer in its randomized, double-blind, placebo-controlled, Phase I trial Debio 1453-101 (NCT07035769) '**A First-in-Human Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Single and Multiple Oral Doses of Debio 1453P in Healthy Adults**'. Debiopharm's **Debio 1453** aims to enhance the current range of treatment options by offering a novel antibiotic with an entirely new mechanism of action against *Neisseria gonorrhoeae (N. gonorrhoeae)* infections.

Debiopharm is leveraging their expertise in combating bacterial infections through the development of a new antibiotic with a novel way to target the bacterium. Ultimately, Debio 1453 has the potential to create a truly novel therapeutic option, free from current resistance issues, and become a durable game changer for patients with gonorrhea.

"The first clinical administration of our novel antibiotic is a pivotal milestone. This step brings us closer to providing a first-in-class innovative therapeutic option for those affected by gonorrhea, particularly for patients with hard-to-treat infections where effective treatments are greatly needed", expressed Alireza Shamaei-Tousi, Principal Clinical Scientist.

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, is supporting the development of Debio 1453 with overall funding projected to exceed $20 million USD in total, based on the achievement of predetermined milestones.

About Gonorrhea

Gonorrhea is a sexually transmitted infection caused by *N. gonorrhoeae*. 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 sexually transmitted infections (STIs). 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 2020, the WHO estimated that there were 82.4 million new infections among adults globally.[1] 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.[2] 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.[3] More recently, public health officials in England have reported a concerning rise in antibiotic-resistant gonorrhea cases in the first five months of 2025, surpassing the total for the previous year.[4] The development of new antibiotics effective against N. gonorrhoeae is ranked as a high priority by the WHO, and drug-resistant *N. gonorrhoeae* is considered an urgent threat by the US CDC.

About Debio 1453

Debio 1453 is an anti-gonococcal antibiotic with a novel mechanism of action. Debio 1453 exerts antimicrobial activity by inhibiting the bacterial fatty acid (FASII) pathway, which is essential for the growth of *N. gonorrhoeae*. Debio 1453 specifically targets FabI, an essential enzyme for the growth of *N. gonorrhoeae*. Because FabI is a novel anti-gonococcal target, Debio 1453 is active *in vitro* against all antibiotic-resistant phenotypes of *N. gonorrhoeae* that have been tested to date. Debio 1453 shows very potent activity against *N. gonorrhoeae* while reducing selective pressure on other bacteria that constitute the "healthy microbiota". The potential benefits of Debiopharm's FabI inhibitors for gonorrhea include high efficacy, a favorable resistance profile, no cross-resistance to existing antibiotics, encouragement of stewardship, appropriate antibiotic prescribing, due to targeted spectrum, and suitability for both oral and intramuscular administration. Debio 1453 exhibits rapid bactericidal activity against *N. gonorrhoeae,* providing potential for the treatment of hard-to-treat *N. gonorrhoeae* infections. In addition, Debio 1453 demonstrates promising *in vitro* activity against *Chlamydia trachomatis*, the cause of the STI chlamydia, which is often co-associated with *N. gonorrhoeae* infections.

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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.

For more information, please visit www.debiopharm.com

Learn more about the Debio 1453 clinical trial on our patients website
https://patients.debiopharm.com/gonorrhea/

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