NUZOLVENCE® (Zoliflodacin), First-in-Class Oral Antibiotic for Gonorrhoea, Receives U.S. FDA Approval

- The US FDA has approved NUZOLVENCE® (zoliflodacin) for oral suspension, the first new antibiotic developed exclusively for the treatment of gonorrhoea in decades.
- The decision marks a major turning point in the treatment of drug-resistant gonorrhoea.
- This innovative not-for-profit approach paves the way for a new antibiotic R&D model in the global fight against AMR.

Geneva (Switzerland), 12 December 2025 - The Global Antibiotic Research & Development Partnership (GARDP) today announced that the US Food and Drug Administration (FDA) has approved NUZOLVENCE® (zoliflodacin) for oral suspension, a first-in-class, single-dose, oral antibiotic for the treatment of uncomplicated urogenital gonorrhoea in adults and pediatric patients 12 years of age and older, weighing at least 35 kg. This is the first new treatment solely for gonorrhoea in decades and the first to be developed using a novel not-for-profit approach to antibiotic research and development (R&D) aimed at tackling the rise and spread of antimicrobial resistance (AMR).

With more than 82 million new gonorrhoea infections occurring globally each year, zoliflodacin offers much-needed hope for patients with this sexually transmitted infection (STI). *Neisseria gonorrhoeae* has developed resistance to almost all antibiotics used to treat it, with only one last remaining recommended antibiotic treatment, ceftriaxone. Now we are seeing resistance even to this, with a six-fold increase of these kinds of resistant infections in some regions in recent years. Without new and effective antibiotics, like zoliflodacin, gonorrhoea is in danger of becoming one of the first diseases to become once again untreatable because of AMR.

Zoliflodacin was developed as part of a public-private partnership with Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (NASDAQ: INVA), which is the marketing authorization holder in the United States and was responsible for filing the New Drug Application (NDA) with the FDA. The zoliflodacin approval follows a pivotal phase 3 clinical trial, that was sponsored and led by GARDP, and met its primary objective when compared against the current global standard of care. The findings of this trial were published on 11 December in *The Lancet*. Also, in previous *in vitro* studies, zoliflodacin has been shown to be active against all multidrug-resistant strains of *N. gonorrhoeae* tested, with no cross-resistance with other antibiotics.

“This approval marks a huge turning point in the treatment of multidrug-resistant gonorrhoea, which until now has been outpacing antibiotic development,” said Dr Manica Balasegaram, Executive Director of GARDP. “Zoliflodacin shows that a different public-private partnership approach to antibiotic development is possible — one that prioritizes global health needs,

strengthens access where the burden is highest, and protects the effectiveness of new drugs for the long-term."

The phase 3 trial, for example, was not just the largest clinical trial ever conducted for a new treatment against gonorrhoea, it was also one of the most geographically and demographically diverse. Involving 930 participants across 16 trial sites within five countries in four continents – including Belgium, the Netherlands, South Africa, Thailand, and the U.S. – the trial was designed to be conducted in regions with high prevalence of gonorrhoea and include underrepresented populations, such as women, adolescents and people living with HIV.

"Gonorrhoea continues to be a significant public health concern worldwide, and the growing challenge of antimicrobial resistance only heightens the urgency for new treatment options," said Dr. Edward (Ned) Hook, MD, Emeritus Professor of Medicine at the University of Alabama at Birmingham and protocol chair of the study. "The decades-long absence of new gonorrhoea treatments, combined with rising antibiotic resistance, has created significant challenges in managing this common and potentially serious sexually transmitted infection."

Zoliflodacin belongs to a new class of antibiotics, called spiropyrimidinetriones, which has a unique mechanism of action in the way that it inhibits a crucial bacterial enzyme called type II topoisomerase, which is essential for bacterial function and reproduction. Zoliflodacin is being developed exclusively for the treatment of gonorrhoea. By focusing solely on this indication, the aim is to limit the clinical use of this new treatment to the targeted infection only. This approach can help to minimize the likelihood of excessive use, which could potentially contribute to the development of resistance, and therefore preserve the usefulness of zoliflodacin in treating gonorrhoea infections for longer.

"As clinicians, we see the devastating impact drug-resistant gonorrhoea can have on people's lives in Thailand," said Dr Rossaphorn Kittiyaowamarn, Principal Investigator for Bangrak STI Medical Center, Thailand's Ministry of Public Health site. "With the number of cases on the rise, there is also huge value in carrying out trials in high-burden countries and among high-burden populations to bring about effective treatment options. Having a single-dose, oral treatment like this will be a game changer for gonorrhoea control. This is essential to reduce the burden of disease for individuals and to prevent the spread of highly drug-resistant gonorrhoea globally."

GARDP has the right to register and commercialize zoliflodacin in more than three-quarters of the world's countries, including all low-income countries, most middle-income countries, and several high-income countries. Entasis Therapeutics, Inc., the original license holder and an affiliate of Innoviva Specialty Therapeutics, retains the commercial rights for zoliflodacin in the major markets in North America, EU, and Asia-Pacific.

Innoviva Specialty Therapeutics will continue to collaborate with GARDP to advance regulatory filings with the European Medicines Agency. In addition, GARDP is taking steps to obtain market authorization initially in Thailand and South Africa. These countries were selected not only because they are important partners for GARDP, but also because they played a key role in the

phase 3 trial. In November 2025, zoliflodacin was submitted for priority review in Thailand, with a submission in South Africa planned for early 2026. GARDP is committed to generating more data where required to support expanded access to zoliflodacin.

GARDP's work on zoliflodacin has been funded with support from the governments of Germany (BMFTR and BMG), UK (GAMRIF, part of DHSC, and DFID, which is now part of FCDO), Japan (MHLW), the Netherlands (Ministries of VWS and BZ), Switzerland (FOPH), The Grand Duchy of Luxembourg, as well as the Canton of Geneva, South African Medical Research Council (SAMRC), and the Leo Model Foundation. This builds on initial work by AstraZeneca, who first identified the new chemical entity, that was to become zoliflodacin, and on a critical phase 2 clinical trial sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID).

About GARDP

The Global Antibiotic Research & Development Partnership (GARDP) is a not-for-profit global health organization driven to protect people from the rise and spread of drug-resistant infections, one of the biggest threats to us all. By forging the public and private partnerships that matter, we develop and make accessible antibiotic treatments for people who need them. Vital support for our work comes from the governments of Canada, Germany, Japan, Monaco, the Netherlands, Switzerland, the United Kingdom, the Canton of Geneva, the European Union, as well as the Gates Foundation, Global Health EDCTP3, GSK, the RIGHT Foundation, the South African Medical Research Council (SAMRC) and Wellcome. GARDP is registered under the legal name GARDP Foundation. www.gardp.org

Media Contact:

Duncan Graham-Rowe
dgrahamrowe@gardp.org