Thai FDA approves NUZOLVENCE® (zoliflodacin) just six months after US authorization

Advancing faster access to a much-needed new treatment for gonorrhoea

- *Thai FDA approves NUZOLVENCE® (zoliflodacin), a first-in-class, single-dose, oral antibiotic for uncomplicated urogenital gonorrhoea.*
- *Approval comes just six months after US FDA approval, making Thailand the second country to approve the drug.*
- *Sets a new benchmark for rapid access to innovative medicines through collaboration between GARDP and Dr. Reddy's.*

Bangkok (Thailand), Geneva (Switzerland) and Hyderabad (India), 27 July 2026 – The GARDP Foundation (known as GARDP) and Dr. Reddy's Laboratories today announced that the Thai Food and Drug Administration (FDA) has approved NUZOLVENCE® (zoliflodacin), a first-in-class, single-dose, oral antibiotic for the treatment of uncomplicated urogenital gonorrhoea. The approval follows a priority review submission led by Dr. Reddy's Laboratories, with support from GARDP.

NUZOLVENCE® is indicated for the treatment of uncomplicated urogenital gonorrhoea due to *Neisseria gonorrhoeae* in adults and paediatric patients 12 years of age and older, weighing at least 35 kg. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Zoliflodacin was developed as part of a public-private research and development (R&D) partnership with Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (NASDAQ: INVA). Innoviva Specialty Therapeutics is the marketing authorization holder in the United States. Zoliflodacin was submitted for priority review in Thailand in November 2025, a process led by the global pharmaceutical company, Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; together with its subsidiaries, known as "Dr. Reddy's"), with support from GARDP.

The Thai FDA approval comes just six months after the drug was initially approved by the United States Food and Drug Administration (US FDA), making Thailand the second country to approve the new chemical entity (NCE). This sets a new benchmark for how quickly innovative treatments can reach low- and middle-income countries (LMICs) beyond initial high-income market approvals and marks a major milestone in efforts to expand rapid access to new antibiotics globally.

The approval is particularly significant given the growing threat of antimicrobial resistance (AMR), which is making gonorrhoea increasingly difficult to treat with existing antibiotics. The Thai FDA has granted approval for NUZOLVENCE®, reflecting Thailand's strong commitment to AMR as a national public health priority. 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).[1]

"As a global pharmaceutical company, Dr. Reddy's purpose is to make innovative and affordable medicines accessible to patients worldwide," said **Deepak Sapra, Chief Executive Officer, API and Services, Dr Reddy's.** "The approval of zoliflodacin by the Thai FDA is a significant step forward in ensuring timely access to an innovative treatment for gonorrhoea, including infections caused by multidrug-resistant strains. It underscores a new paradigm for global health access - where patients in LMICs can benefit from breakthrough medicines within months of their first approval rather than waiting years. This milestone reflects the power of collaboration in advancing equitable and sustainable access to critical new therapies."

The zoliflodacin approval follows a pivotal phase 3 clinical trial that was sponsored and led by GARDP and which met its primary objective when compared against the current global standard of care. The findings of this trial were published on 11 December 2025 in *The Lancet.* Supporting these clinical

References

[1] World Health Organization (WHO), "Gonorrhoea Fact Sheet," 2020. Available at: WHO Gonorrhoea Fact Sheet

findings, in previous *in vitro* studies, zoliflodacin has also 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 turning point not only for the treatment of gonorrhoea, but for how new antibiotics can be made available to people globally,” said **Peter Beyer, Deputy Executive Director of GARDP**. “This is proof that our novel antibiotic R&D model works and demonstrates the important role that product development partnerships like GARDP play in ensuring that antibiotics with high public health value are able to progress even when the market remains unattractive. GARDP is now committed to supporting its partners in working towards making zoliflodacin available to patients in Thailand.”

The approval reflects the coordinated efforts of GARDP, Dr. Reddy's Laboratories and its subsidiary, Aurigene Pharmaceutical Services Limited (APSL), in advancing zoliflodacin. APSL played an important role in supporting the product's development, while Dr. Reddy's led the regulatory submission strategy and engagement with the Thai FDA. Building on this approval, GARDP, Dr. Reddy's and APSL will continue to work closely with healthcare stakeholders in Thailand to support commercialization, ensure reliable supply, and facilitate broad patient access to this important new treatment.

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 NUZOLVENCE® in the major markets, such as North America and the European Union. In addition to Thailand, GARDP is taking steps to obtain market authorization in 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.

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), the European Commission through its Health Emergency Preparedness and Response Authority (DG HERA), 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 NCE 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 Dr Reddy’s

Dr. Reddy’s Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of ‘Good Health Can’t Wait,’ we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.com.

About GARDP

GARDP (the Global Antibiotic Research & Development Partnership) 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, GARDP develops and makes accessible antibiotic treatments for people who need them. Vital support for our work comes from the governments of Germany, Japan, Monaco, the Netherlands, Switzerland, the United Kingdom, the Canton of Geneva, the European Commission, 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 in Switzerland. www.gardp.org.

References

[1] World Health Organization (WHO), "Gonorrhoea Fact Sheet," 2020. Available at: WHO Gonorrhoea Fact Sheet

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[1] World Health Organization (WHO), "Gonorrhoea Fact Sheet," 2020. Available at: WHO Gonorrhoea Fact Sheet