



NUZOLVENCE® (zoliflodacin) nominated for prestigious 2026 Prix Galien USA Award, recognizing a new public-private partnership model for antibiotic innovation

Geneva, Switzerland, 11 August 2026 – The GARDP Foundation (known as GARDP) today welcomed the announcement that NUZOLVENCE® (zoliflodacin), a first-in-class antibiotic for the treatment of uncomplicated urogenital gonorrhoea, has been nominated for the *Best Pharmaceutical Product* as part of the 2026 Prix Galien USA Award, widely regarded as one of the highest honours in biomedical innovation. The award recognizes outstanding achievements in scientific innovation that improve the human condition through drug development.

Zoliflodacin was developed as part of a public-private research and development (R&D) partnership between GARDP and Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc., who was responsible for filing the New Drug Application (NDA) with the US Food and Drug Administration (FDA) and is the marketing authorization holder in the United States. Recognition for this much-needed new treatment for gonorrhoea comes at a time when antimicrobial resistance (AMR) is making the sexually transmitted infection increasingly difficult to treat.

Approved by the US FDA in December 2025 and subsequently by the Thailand FDA in June 2026, zoliflodacin is the first new antibiotic developed solely for gonorrhoea, and one of the first new treatments for this disease in decades. It is also the first to be developed using a novel not-for-profit approach to antibiotic R&D aimed at tackling the rise and spread of AMR.

“Being nominated for a Prix Galien award is a tremendous honour and recognition not only of zoliflodacin itself, but of the power of partnership in addressing some of the world’s most urgent public health challenges,” said Peter Beyer, Deputy Executive Director of GARDP. “At a time when antimicrobial resistance is outpacing antibiotic development, this achievement demonstrates that a public health-driven approach can deliver innovation while also working to ensure access for the people who need it most.”

An estimated 82 million new gonorrhoea infections occur globally every year. The bacterium that causes gonorrhoea has developed resistance to almost every antibiotic used against it, with resistance now emerging even to ceftriaxone, the last remaining recommended treatment. Without new treatment options, gonorrhoea risks becoming increasingly difficult, and in some cases impossible, to treat.

Zoliflodacin belongs to a new class of antibiotics known as spiropyrimidinetriones and works through a novel mechanism of action with activity against multidrug-resistant isolates of *Neisseria gonorrhoeae*, including isolates resistant to current antibiotics.

Zoliflodacin's approval follows a pivotal phase 3 clinical trial, that was sponsored and led by GARDP, 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](#). Also, in parallel microbiology studies, zoliflodacin has been shown to be active against all multidrug-resistant strains of *N. gonorrhoeae* tested, with no cross-resistance with other antibiotics.

The development of zoliflodacin also represents an important proof of concept for a new approach to antibiotic research and development. Unlike traditional commercial models, the GARDP partnership model is designed around public health need, combining innovation with plans for stewardship and access from the outset. GARDP has rights to support registration and access across more than three-quarters of countries worldwide, including all low-income countries and most middle-income countries.

The rapid approval of zoliflodacin in Thailand, just six months after its first approval in the United States, has already challenged the traditional model in which new antibiotics often take many years to reach low- and middle-income countries (LMICs).

“Zoliflodacin shows what is possible when governments, researchers, industry, funders and public health organizations work together around a shared objective,” said Pierre Daram, Associate Director of the STI Portfolio at GARDP. “But it is also a reminder that the fight against AMR is far from over. We need a sustainable pipeline of new antibiotics and a continued commitment to ensuring they are available and used appropriately around the world.”

GARDP is continuing to work with partners to expand access to zoliflodacin in its territories, pursue additional regulatory approvals, generate evidence to support its optimal use, and advance the next generation of medicines for drug-resistant infections.

About zoliflodacin

Zoliflodacin is a first-in-class, single-dose oral antibiotic for the treatment of uncomplicated urogenital gonorrhoea. It is the first new antibiotic developed solely for gonorrhoea and one of the first new treatments against gonorrhoea in decades.

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.

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