FDA Grants Priority Review for Zoliflodacin New Drug Application for the Treatment of Uncomplicated Gonorrhea and Assigns Target PDUFA Date of December 15, 2025

June 12, 2025

FDA is expected to notify Innoviva Specialty Therapeutics regarding its decision to conduct an Advisory Committee Meeting in the Day 74 letter

If approved, zoliflodacin would be the first new antibiotic for treating gonorrhea in decades

WALTHAM, Mass. & GENEVA--(BUSINESS WIRE)--Jun. 12, 2025-- Innoviva Specialty Therapeutics, Inc., a subsidiary of Innoviva, Inc. (NASDAQ: INVA), in collaboration with the Global Antibiotic Research & Development Partnership (GARDP), today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the New Drug Application (NDA) for zoliflodacin, an investigational first-in-class, single dose, spiropyrimidinetrione oral antibiotic for the treatment of uncomplicated gonorrhea in adults and pediatric patients 12 years and older. The FDA assigned a target action date of December 15, 2025 under the Prescription Drug User-Fee Act (PDUFA). It is expected the FDA will notify Innoviva Specialty Therapeutics regarding the FDA's decision to conduct an Advisory Committee Meeting in the Day 74 letter. If approved, zoliflodacin would be the first new antibiotic for treating gonorrhea in decades.

The U.S. FDA has granted zoliflodacin a Qualified Infectious Disease Product (QIDP) designation. This designation allows it to benefit from FDA Priority Review, and Extended Market Exclusivity.

Entasis Therapeutics, Inc., the legal NDA holder and affiliate of Innoviva Specialty Therapeutics, Inc., retains the commercial rights for zoliflodacin in the major markets in North America, Europe, and Asia-Pacific. GARDP retains the right to register and commercialize the product in more than three-quarters of the world's countries, including all low-income countries, most middle-income countries, and several high-income countries. GARDP is committed to working with its partners and local health authorities in markets where zoliflodacin receives regulatory approval to help remove access barriers to ensure treatment is available to address unmet medical needs while ensuring appropriate and sustainable use.

About Uncomplicated Gonorrhea

With more than 82 million new gonorrhea infections occurring globally each year, gonorrhea is the second most common bacterial sexually transmitted infection (STI), affecting both men and women, which, if left untreated, can result in serious and permanent health consequences.

With the rise and spread of drug-resistant infections, the World Health Organization (WHO) has identified antimicrobial resistance (AMR) as one of the ten most critical global threats to public health. The bacterium *Neisseria gonorrhoeae,* which causes gonorrhea, has progressively developed resistance to most classes of antibiotics used to treat these infections, including ceftriaxone, a widely used intramuscular injection that was first made available in 1984.

About Zoliflodacin

Zoliflodacin is an investigational first-in-class antibacterial that is administered in a single oral dose for the treatment of uncomplicated gonorrhea. The oral route of administration simplifies treatment by providing a convenient option for patients unable to receive an intramuscular injection. Zoliflodacin has a unique mechanism of action, inhibiting a crucial bacterial enzyme called type II topoisomerase, which is essential for bacterial function and reproduction. In *in vitro* studies, zoliflodacin demonstrated activity against multidrug-resistant strains of *Neisseria gonorrhoeae*, including those resistant to ceftriaxone and azithromycin, with no cross-resistance to other antibiotics. In a pivotal Phase 3 clinical trial, zoliflodacin demonstrated non-inferiority in achieving microbiological cure at the urogenital site of infection with a single oral dose of zoliflodacin compared to a treatment regimen of a single intramuscular injection of 500mg ceftriaxone followed by 1g of oral azithromycin. The Phase 3 study found that zoliflodacin was generally well-tolerated, with no serious adverse events or deaths reported during the trial.

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.

About Innoviva

Innoviva is a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics ("IST"), and a portfolio of strategic investments in healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"). Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva's other innovative healthcare assets include infectious disease and critical care assets stemming from acquisitions of Entasis Therapeutics, including XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use approved for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex and the investigational zoliflodacin currently being developed for the treatment of uncomplicated gonorrhea, and La Jolla Pharmaceutical Company, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Innoviva also markets ZEVTERA® (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the U.S. through an exclusive license from Basilea Pharmaceutica International Ltd, Allschwil. For more information about Innoviva, go to www.inva.com. For information about Innoviva Specialty Therapeutics, go to www.innovivaSpecialtytherapeutics.com.

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Source: Innoviva Specialty Therapeutics, Inc.