Innoviva Specialty Therapeutics Receives FDA New Drug Application Acceptance for Zoliflodacin, a First-in-Class Oral Antibiotic for Uncomplicated Gonorrhea in Adults

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- In laboratory studies, zoliflodacin has been shown to be active against *Neisseria gonorrhoeae* including multidrug-resistant strains.
- If approved, zoliflodacin could become the first new antibiotic treatment for gonorrhea in decades.

WALTHAM, Mass. & GENEVA, Switzerland--(BUSINESS WIRE)--Jun. 10, 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 accepted its New Drug Application (NDA) for zoliflodacin, the investigational first-in-class, single dose, spiropyrimidinetrione oral antibiotic for the treatment of uncomplicated gonorrhea in adults and pediatric patients 12 years and older. If approved, zoliflodacin would be the first new antibiotic for treating gonorrhea in decades.

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 and the World Health Organization (WHO) identifying antimicrobial resistance (AMR) as one of the ten most critical global threats to public health, the bacterium *Neisseria gonorrhoeae* has progressively developed resistance to many classes of antibiotics used to treat these infections, including ceftriaxone, a widely used intramuscular injection that was first made available in 1984.

"Today's acceptance of the zoliflodacin NDA marks significant progress toward delivering health care providers with a potential new oral treatment option for uncomplicated gonorrhea, including infections caused by drug-resistant strains," said David Altarac, M.D., Chief Medical Officer, Innoviva Specialty Therapeutics. "We look forward to working closely with the FDA during its review and, if approved, we are committed to expediting the availability of zoliflodacin to patients in the U.S."

Recent reports (The Lancet Infectious Diseases) of emergent ceftriaxone-resistant infections have heightened the urgency for new antibiotics. Effective treatment options are essential to reducing the burden of disease for individuals and preventing the spread of highly drug-resistant gonorrhea globally. If left untreated, gonorrhea can also cause infertility in women, life-threatening ectopic pregnancies, and pelvic inflammatory disease.[2]

The FDA's acceptance of the zoliflodacin NDA is based on the totality of data collected from several clinical trials as part of an innovative public-private partnership with GARDP. These trials include a pivotal Phase 3 clinical trial which demonstrated non-inferiority in achieving microbiological cure at the urogenital site of infection of a single oral dose of zoliflodacin compared to a treatment regimen of a single intramuscular injection of 500 mg ceftriaxone followed by 1 g 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.

"This important milestone demonstrates the crucial role that public-private partnerships can play in tackling the escalating global antimicrobial resistance crisis," said Dr. Manica Balasegaram, Executive Director, Global Antibiotic Research Development Partnership (GARDP). "If zoliflodacin is approved, this collaboration paves the way for millions of people across the world to get access to a potentially powerful new drug to treat multidrug-resistant gonorrhea."

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 vitro* studies have demonstrated its activity against multidrug-resistant strains of *Neisseria gonorrhoeae*, including those resistant to ceftriaxone and azithromycin, with no cross-resistance to other antibiotics. This investigational antibacterial is administered in a single, oral dose, simplifying treatment by providing a convenient option for patients unable to receive an intramuscular injection.

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. Innoviva Specialty Therapeutics, Inc., anticipates that the NDA review will proceed according to the standard process for drugs with this designation.

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 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. On December 14, 2024, Innoviva entered into an exclusive distribution and license agreement with Basilea Pharmaceutica Ltd, Allschwil for the commercialization of ZEVTERA® (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the U.S. 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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