Innoviva Specialty Therapeutics Announces Publication in The Lancet of Positive Zoliflodacin Phase 3 Data for the Treatment of Uncomplicated Urogenital Gonorrhea

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- Phase 3 findings show oral zoliflodacin to be non-inferior to the combination of ceftriaxone and azithromycin for the treatment of uncomplicated urogenital gonorrhea.
- Positive study results are a significant milestone in the development of a first-in-class single-dose, oral antibiotic against gonorrhea, including infections caused by drug-resistant *Neisseria gonorrhoeae*, an urgent public health threat and high-priority pathogen.
- Gonorrhea is the second most reported bacterial STI in the United States, with resistance to first-line treatment emerging.[1,2]

WALTHAM, Mass.--(BUSINESS WIRE)--Dec. 11, 2025-- Innoviva Specialty Therapeutics, Inc., a subsidiary of Innoviva, Inc. (NASDAQ: INVA), today announced the publication of positive results from a pivotal Phase 3 trial evaluating its investigational single-dose, oral antibiotic zoliflodacin for the treatment of uncomplicated urogenital gonorrhea in ***The Lancet***. The trial was sponsored and led by the Company's not-for-profit partner, the Global Antibiotic Research & Development Partnership (GARDP).

"Gonorrhea 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 findings published today in *The Lancet* provide important evidence supporting the potential role of zoliflodacin as a novel, single-dose oral therapy for uncomplicated gonorrhea. These results represent a meaningful step forward in addressing the evolving landscape of gonococcal treatment."

More than 82 million new gonorrhea infections occur globally each year, which, if left untreated, can result in serious and permanent health consequences.[3] The emergence and spread of drug-resistant infections have led the World Health Organization to identify antimicrobial resistance as one of the ten most critical global health threats.[4] The bacterium *Neisseria gonorrhoeae* has developed resistance to most classes of antibiotics used to treat these infections, including cephalosporins such as ceftriaxone, an injectable treatment, which is the only recommended antimicrobial class for treating uncomplicated gonorrhea.

"Our study demonstrated the non-inferior efficacy of zoliflodacin in uncomplicated urogenital gonorrhea compared to a very potent, two-drug regimen," said study co-author Stephanie N. Taylor, MD, Professor of Medicine, Section of Infectious Diseases, Louisiana State University Health Sciences Center and Medical Director, LSU STD Research laboratory. "Microbiological cure rates at extragenital (pharyngeal and rectal) sites were also comparable between the two arms and both exhibited a similar safety profile."

Zoliflodacin study endpoints met the prespecified criteria for non-inferiority when compared to ceftriaxone and azithromycin (difference of 5.31% (95% CI 1.38%, 8.65%)) for the treatment of uncomplicated urogenital gonorrhea. Zoliflodacin was generally well tolerated and adverse events were comparable between treatment groups. No serious adverse events were reported.

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., received notification from the FDA in June 2025 that the agency accepted its New Drug Application (NDA) for review and has assigned a target action date of December 15, 2025, under the Prescription Drug User-Fee Act (PDUFA).

"Currently, there is only one first-line treatment option available for patients with uncomplicated urogenital gonorrhea. As clinicians, we are eagerly awaiting new treatments that can effectively overcome resistance and provide a single oral dosing option," said Patrik Hornak, MD, Associate Program Director of the ID Fellowship Program and Clinical Director of the AIDS Education & Training Center Program at the University of Texas Medical Branch. "I am encouraged that these data will lead to a new option that supports early intervention, which is especially important for the health of communities at higher risk of infection and transmission of the disease."

About the Phase 3 Trial
In a pivotal Phase 3, multinational, randomized, controlled, open-label, non-inferiority trial, zoliflodacin demonstrated non-inferiority compared to the dual therapy of ceftriaxone plus azithromycin for the treatment of uncomplicated urogenital gonorrhea, with both treatment groups showing comparable safety profiles. The study enrolled 930 adolescent and adult participants to evaluate the efficacy and safety of a single 3g oral dose of zoliflodacin versus a single dose of 500mg intramuscular injection of ceftriaxone plus 1g oral azithromycin for the treatment of uncomplicated gonorrhea. This trial was the largest clinical trial ever conducted for a new treatment against *Neisseria gonorrhoeae* infection, with 16 trial sites in regions with a high prevalence of gonorrhea across five countries, including Belgium, the Netherlands, South Africa, Thailand, and the U.S.

The Phase 3 trial was supported with funding from the governments of Germany (BMFTR), UK (GAMRIF, part of DHSC, and DFID), Japan (MHLW), the Netherlands (Ministries of VWS and BZ), Switzerland (FOPH), The Grand Duchy of Luxembourg, the Canton of Geneva, the South African Medical Research Council (SAMRC), and the Leo Model Foundation.

About Zoliflodacin
Zoliflodacin is an investigational, first-in-class oral antibiotic from the spiropyrimidinetrione class, currently in development as a single-dose treatment for uncomplicated gonorrhea, including strains resistant to current first-line therapies. Zoliflodacin inhibits bacterial DNA gyrase, an essential enzyme for bacterial survival. Zoliflodacin mechanism of action is distinct from that of currently approved antibiotics and has demonstrated activity against drug-resistant *Neisseria gonorrhoeae*.

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

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.

[1] STI Surveillance Report 2023: Centers for Disease Control and Prevention; https://www.cdc.gov/sti-statistics/media/pdfs/2025/09/2023_STI_Surveillance_Report_FINAL_508.pdf
[2] Drug Resistant Gonorrhea; Centers for Disease Control and Prevention 2024; https://www.cdc.gov/gonorrhea/hcp/drug-resistant/?utm_source
[3] Gonorrhea Infections Fact Sheet 2024; World Health Organization; https://www.who.int/news-room/fact-sheets/detail/gonorrhoea-%28neisseria-gonorrhoeae-infection%29/?utm_source
[4] Antimicrobial Resistance Collaborators. (2022): Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. The Lancet; 399(10325): P629-655. DOI: https://doi.org/10.1016/S0140-6736(21)02724-0

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