Innoviva Specialty Therapeutics Announces Oral Presentation Featuring New Analyses from the Zoliflodacin Pivotal Phase 3 Trial at IDWeek 2025

October 20, 2025

Zoliflodacin, an investigational single-dose oral antibiotic for uncomplicated gonorrhea, to be featured in oral presentation with key subset analyses from pivotal global Phase 3 trial

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 20, 2025-- Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (NASDAQ: INVA), will share new data on zoliflodacin during the Infectious Disease Society of America's IDWeek 2025 annual meeting in Atlanta, GA, October 19-22, 2025. Zoliflodacin is a first-in-class oral antibiotic being developed for the treatment of uncomplicated gonorrhea. Three sets of data will be presented, including an oral presentation and two poster presentations:

Poster Presentation P-1206

Date:	Tuesday, October 21, 2025
Time:	12:15 PM - 1:30 PM ET
Location:	Poster Hall B4-B5
Title:	Association of Sex Assigned at Birth and Sexual Orientation with Antimicrobial Susceptibility of Baseline *Neisseria gonorrhoeae* Isolates from Participants Recruited in the Global Zoliflodacin Phase 3 Randomized Controlled Trial

Poster Presentation P-1207

Date:	Tuesday, October 21, 2025
Time:	12:15 PM - 1:30 PM ET
Location:	Poster Hall B4-B5
Title:	In Vitro Activity of Zoliflodacin against *Neisseria gonorrhoeae* Isolates Collected in 2022 from The United States

Oral Presentation

Date:	Wednesday, October 22, 2025
Time:	1:45-3:00
Location:	B211-B212
Title:	Subgroup Analyses of Microbiological Cure Rates by Baseline Zoliflodacin MIC and Susceptibility to Ciprofloxacin in Participants from the Global Zoliflodacin Phase 3 Randomize Controlled Trial

The oral presentation on Wednesday, October 22, describes key subgroup findings from the pivotal Phase 3 trial, including observation of high microbiological cure rates across urogenital, rectal, and pharyngeal sites in infection caused by *Neisseria gonorrhoeae* with a zoliflodacin MIC of ≤0.25 µg/mL. Among participants with urogenital infections who received zoliflodacin, ciprofloxacin-resistant strains had a cure rate of 96.6% (346/358; 95% CI: 94.2–98.3) and ciprofloxacin-susceptible strains had a cure rate of 97.4% (113/116; 95% CI: 92.6–99.5). High cure rates were consistent regardless of infection site.

In poster P-1206 to be presented on Tuesday October 21, a demographic analysis of baseline isolates from the zoliflodacin Phase 3 trial found that while azithromycin resistance was higher in isolates from men who have sex with men (MSM), zoliflodacin MIC values were comparable across all patient groups, including females, MSM and heterosexual men (HSM). These findings underscore the in vitro activity of zoliflodacin across antibiotic-resistant *N. gonorrhoeae* from a broad range of sources and support the continued development of zoliflodacin as a single, oral dose treatment for uncomplicated gonorrhea.

"Findings from our analyses reinforce our initial conclusions and support the development of zoliflodacin as a potentially transformative treatment for gonorrhea, including infections caused by resistant strains," stated Dr. David Altarac, Chief Medical Officer of Innoviva Specialty Therapeutics. "Achieving high and consistent cure rates across urogenital and extra-genital sites, resistance profiles, and patient demographics represents a significant opportunity to address the growing global threat of antibiotic-resistant *Neisseria gonorrhoeae*."

Complementary analyses presented in poster P-1207 further support the potential of zoliflodacin as a broadly effective treatment for gonorrhea. In vitro susceptibility testing of *Neisseria gonorrhoeae* clinical isolates collected in the U.S. during 2022 confirmed that zoliflodacin potency remained consistent compared to prior surveillance years (2020–2021), including against antibiotic-resistant strains and isolates from both male and female patients.

"The results from all three presentations show that zoliflodacin mechanism of action is differentiated from fluoroquinolones with cure rates remaining high in the face of antibiotic resistance," said Dr. Sarah McLeod, Senior Director, Innoviva Specialty Therapeutics.

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*.

Non-inferiority was demonstrated in the global Phase 3 trial (NCT03959527) where a single oral dose of zoliflodacin was compared to ceftriaxone plus azithromycin for uncomplicated urogenital gonorrhea. This trial was sponsored by the Global Antibiotic Research and Development Partnership

(GARDP).

The U.S. FDA has granted zoliflodacin a Qualified Infectious Disease Product (QIDP) designation. This designation allows 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.

About Innoviva Specialty Therapeutics

Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc., is focused on delivering innovative therapies in critical care and infectious disease. Innoviva Specialty Therapeutics' products, through its affiliate, La Jolla Pharmaceutical Company, include 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 Specialty Therapeutics' products, through its affiliate, Entasis Therapeutics Inc., include 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 (*Acinetobacter*). ZEVTERA® (ceftobiprole) is an FDA-approved cephalosporin specifically designed to treat adult patients with acute bacterial skin and skin structure infections (ABSSSI), adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) including those with right-sided infective endocarditis, and adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP). The Company's clinical pipeline includes zoliflodacin, an investigational antibiotic for uncomplicated gonorrhea, which is being developed in collaboration with the Global Antibiotic Research and Development Partnership (GARDP), and is currently under review by the U.S. Food and Drug Administration.

For more information about Innoviva Specialty Therapeutics, please visit here.

Forward-Looking Statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, and future events. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. The words "anticipate", "expect", "goal", "intend", "objective", "opportunity", "plan", "potential", "target" and similar expressions are intended to identify such forward-looking statements. Such forward-looking statements involve substantial risks, uncertainties, and assumptions. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to known and unknown risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: expected cost savings; lower than expected future royalty revenue from respiratory products partnered with GSK; the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, formerly, TRELEGY® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of Innoviva (including Innoviva's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, and amount of potential capital returns to shareholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; and projections of revenue, expenses and other financial items; the impact of the novel coronavirus (COVID-19). Other risks affecting Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Reports on Form 10-Q, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The information in this press release is provided only as of the date hereof, and Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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