Zoliflodacin (NUZOLVENCE®) Receives WHO Recommendation as Alternative Treatment for Uncomplicated Urogenital Gonorrhea

November 25, 2026

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 25, 2026-- Innoviva Specialty Therapeutics (IST), a subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced a milestone in the global fight against drug-resistant gonorrhea: a World Health Organization (WHO) Joint Steering Committee Guideline Development Group issued its recommendation today, supporting zoliflodacin (NUZOLVENCE®) as an alternative to ceftriaxone for the treatment of uncomplicated urogenital gonorrhea, where available and appropriate. NUZOLVENCE is now the only oral alternative to ceftriaxone recommended by WHO for the treatment of uncomplicated urogenital gonorrhea.

An estimated 82 million new gonorrhea infections occur worldwide each year, according to the WHO. In the United States, the Centers for Disease Control and Prevention (CDC) estimates that nearly a half million cases are reported each year and over one million incident cases occur annually. The rise and spread of drug-resistant gonorrhea infections is a compounding factor in this trend. *Neisseria gonorrhoeae* has progressively developed resistance to every class of antibiotics used to treat these infections, including ceftriaxone, a widely used intramuscular injection that was first made available in 1984 and the most recently recommended treatment. Without effective new antibiotics, gonorrhea risks becoming one of the first infectious diseases to become untreatable due to antimicrobial resistance.

“The WHO recommendation gives clinicians around the world a framework for considering zoliflodacin as an effective oral alternative for appropriate patients — a disease where new treatment options have been urgently needed for decades. This guidance validates the Phase 3 evidence and marks a meaningful step toward broader global access to NUZOLVENCE®,” said David Altarac, M.D., Chief Medical Officer of Innoviva Specialty Therapeutics.

Already approved in the U.S. and Thailand under the brand name NUZOLVENCE, zoliflodacin is a first-in-class, single-dose oral antibiotic, and was co-developed through the longstanding partnership between IST and GARDP, as well as public-private partnerships with the National Institute of Allergy and Infectious Diseases (NIAID), bringing together public, nonprofit, and commercial partners to advance an innovative treatment and support access across high-income and low-income markets. NUZOLVENCE® is commercially available in the U.S.

About NUZOLVENCE® (zoliflodacin) for oral suspension

NUZOLVENCE® is the first approved antibiotic in the spiropyrimidinetrione class and is given as a single oral dose. In December 2025, the U.S. Food and Drug Administration (FDA), and then six months later the Thai FDA, approved NUZOLVENCE® for the treatment of uncomplicated urogenital gonorrhea caused by *Neisseria gonorrhoeae* in patients aged 12 years or older who weigh at least 35 kg.

Important Safety Information (ISI)

Please see the full U.S. Prescribing Information, including the Medication Guide.

Indication and Usage

Indication. NUZOLVENCE® is a spiropyrimidinetrione bacterial type II topoisomerase inhibitor indicated for the treatment of uncomplicated urogenital gonorrhea due to *Neisseria gonorrhoeae* in adults and pediatric patients 12 years of age and older, weighing at least 35 kg.

Usage to Reduce Development of Drug-Resistant Bacteria: To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZOLVENCE and other antibacterial drugs, NUZOLVENCE should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Contraindications

Known history of hypersensitivity to NUZOLVENCE.

Concomitant use with moderate or strong CYP3A4 inducers because this is predicted to result in decreased plasma concentrations of zoliflodacin and may reduce the NUZOLVENCE efficacy.

Warnings and Precautions

Embryo-Fetal Toxicity: Potential Risk for Pregnant Females. Based on data from animal studies, NUZOLVENCE may cause fetal harm when administered to a pregnant female at clinically relevant doses. Avoid use during pregnancy. Advise pregnant females about the potential risk to the fetus with maternal exposure to NUZOLVENCE. Obtain a pregnancy test prior to initiation in persons of reproductive potential.

Embryo-Fetal Toxicity: Potential Risk Related to Males with Female Partners of Reproductive Potential. Based on data from an animal toxicity study, the risk of early pregnancy loss may be increased in female partners of males treated with NUZOLVENCE. Advise males with female partners of reproductive potential to use effective contraception for at least 3 months after NUZOLVENCE administration.

Testicular Toxicity and Risks to Male Fertility. Based on findings from animal studies, NUZOLVENCE may cause testicular toxicity and impair male fertility. An assessment of spermatogenesis has not been conducted in humans. Advise males that NUZOLVENCE may cause testicular toxicity and impair male fertility.

Hypersensitivity Reactions. Hypersensitivity reactions, including rash and pruritus, have been reported in patients receiving NUZOLVENCE. Before therapy with NUZOLVENCE is instituted, carefully inquire about previous hypersensitivity reactions to NUZOLVENCE. If an allergic reaction to NUZOLVENCE occurs, discontinue NUZOLVENCE and institute appropriate supportive measures.

Clostridioides difficile Infection (CDI). CDI has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Development of Drug-Resistant Bacteria. Prescribing NUZOLVENCE in the absence of a proven or strongly suspected bacterial infection or prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions (≥2%) are headache, dizziness, nausea, and diarrhea. Laboratory abnormalities (neutropenia, leukopenia) were also observed.

Drug Interactions

Concomitant use with moderate or strong CYP3A4 inducers is contraindicated.

Use in Specific Populations

Pregnancy: Based on findings from animal studies, NUZOLVENCE may cause fetal malformations or increased embryo-fetal loss when administered to a pregnant female. A postmarketing descriptive pregnancy safety study is available for NUZOLVENCE. If exposure occurs during pregnancy, pregnant females or their healthcare providers should report the pregnancy to Entasis Therapeutics at 1-800-651-3861.

Lactation: There are no data on the presence of zoliflodacin in either human or animal milk, effects on the breastfed infant, or effects on milk production. If NUZOLVENCE is present in breast milk, intestinal flora alteration in the breastfed infant could occur.

Females and Males of Reproductive Potential: Based on animal studies, NUZOLVENCE may cause fetal malformations when administered to a pregnant female at clinically relevant doses. Additionally, based on data from an animal study, the risk of early pregnancy loss may be increased in partners of males treated with NUZOLVENCE.

Pregnancy Testing: Obtain a pregnancy test in females of reproductive potential prior to initiating treatment with NUZOLVENCE.

Contraception: Advise males with female partners of reproductive potential to use effective contraception for at least 3 months after their single-dose treatment of NUZOLVENCE.

Infertility: Based on data from repeat-dose animal toxicity and fertility studies, NUZOLVENCE may cause testicular toxicity and impair male fertility.

Pediatric Use: The safety and effectiveness of NUZOLVENCE in pediatric patients younger than 12 years of age or weighing less than 35 kg have not been established.

Geriatric Use: Clinical studies of NUZOLVENCE did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger patients.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. To report SUSPECTED ADVERSE REACTIONS, please contact:

Innoviva Specialty Therapeutics™ | 1-800-651-3861 |medinfo@istx.com

U.S. Food and Drug Administration | 1-800-FDA-1088 | www.fda.gov/medwatch

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 affiliates, include GIAPREZA ® (angiotensin II), XERAVA® (eravacycline), XACDURO® (sulbactam for injection; durlobactam for injection), and NUZOLVENCE® (zoliflodacin). Innoviva Specialty Therapeutics 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 Specialty Therapeutics, please visit www.innovivaspecialtytherapeutics.com.

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®, GIAPREZA®, XERAVA®, XACDURO®, ZEVTERA® and NUZOLVENCE® 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); the timing, manner, and amount of potential capital returns to shareholders; the development of the LYNX® platform; 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 timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy.

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, 2025 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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