Innoviva Specialty Therapeutics' Positive Phase 3 Oral Zoliflodacin Data for the Treatment of Uncomplicated Gonorrhea Announced at ESCMID Global 2024

April 24, 2024

- *Single-dose, oral zoliflodacin achieved 90.9% microbiological cure rate, demonstrating statistical non-inferiority compared to current global standard of care*
- *Pivotal Phase 3 data to be presented by the Global Antibiotic Research & Development Partnership (GARDP) in a Scientific Sessions Oral Presentation*
- *First collaborative study between industry and a non-profit to address a World Health Organization high priority pathogen and U.S. Centers for Disease Control urgent threat*

WALTHAM, Mass.--(BUSINESS WIRE)--Apr. 24, 2024-- Innoviva Specialty Therapeutics, Inc., a subsidiary of Innoviva, Inc. (NASDAQ: INVA), today announced that positive results from the Phase 3 oral zoliflodacin trial will be highlighted in an oral presentation given by the Global Antibiotic Research & Development Partnership (GARDP) at the European Society of Clinical Microbiology and Infectious Disease Global Congress (ESCMID Global 2024) taking place April 27-30, 2024, in Barcelona, Spain. Zoliflodacin is a first-in-class spiropyrimidinetrione, single dose, oral antibiotic that is being developed in partnership with GARDP for the treatment of uncomplicated gonorrhea.

"As a single dose, oral antibiotic, zoliflodacin, if approved, could have a profound effect on how physicians across the globe approach the treatment of gonorrhea infections, potentially improving patient access and compliance while helping to reduce the spread of antibiotic-resistant strains of gonorrhea," said David Altarac, M.D., Chief Medical Officer of Innoviva Specialty Therapeutics. "The presentation of these data for this innovative investigational therapy is an important step in advancing our clinical pipeline strategy, as we now turn our focus on regulatory filing requirements in the U.S."

"Presenting these findings to the scientific community for the first time is a significant milestone in the journey of this important antibiotic in the fight against *Neisseria gonorrhoeae*, a World Health Organization priority pathogen," said Dr. Alison Luckey, Senior Medical Lead for GARDP's Sexually Transmitted Infections programme. "These positive findings not only represent a step forward in the treatment of gonorrhoea if approved, but also demonstrate the pivotal role that this public-private partnership between GARDP and Innoviva Specialty Therapeutics has in addressing the public health failure at the heart of the global antimicrobial resistance (AMR) crisis."

In November 2023, the two organizations announced that the Phase 3 zoliflodacin trial met its primary endpoint, demonstrating statistical non-inferiority of microbiological cure at the urogenital site when compared to treatment with intramuscular injection of ceftriaxone and oral azithromycin, currently the only remaining global standard of care regimen for the treatment of uncomplicated gonorrhea.

In addition to the Phase 3 topline data, GARDP will also be presenting three additional posters highlighting details of zoliflodacin's safety profile and additional microbiological data from the Phase 3 trial, as well as data from a drug-drug interaction pharmacokinetic trial. GARDP and Innoviva Specialty Therapeutics plan to submit the Phase 3 zoliflodacin data for future publication in a medical journal.

Beyond the zoliflodacin posters, Innoviva Specialty Therapeutics will also be presenting three additional posters at the meeting that feature new data for XERAVA® and XACDURO®.

Results from the Phase 3 Zoliflodacin Trial

The Phase 3 non-inferiority trial analyzed a total of 930 patients with uncomplicated gonorrhea, including women, adolescents and people living with HIV, making it the largest clinical trial ever conducted for a new treatment against gonorrhea 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 trial compared a single oral 3g dose of zoliflodacin to a globally recognized standard of care regimen (500mg ceftriaxone intramuscular [IM] plus 1g oral azithromycin). The primary efficacy endpoint was microbiological response at the urogenital site (cure or failure) at the Test-of-Cure (ToC) visit 6+/-2 days after treatment. Secondary analyses included microbiological cure at rectal or pharyngeal sites and safety.

The trial met its primary efficacy endpoint, with zoliflodacin (oral, 3g dose) demonstrating non-inferiority to ceftriaxone (IM, 500mg) plus azithromycin (oral, 1g). In the micro-intent-to-treat (micro-ITT) population (n=744), zoliflodacin achieved a microbiological cure rate of 90.9%, a 5.3% difference compared to ceftriaxone and azithromycin which achieved a 96.2% cure rate (95% CI: 1.4%, 8.7%). Microbiological cure rates at extragenital sites were comparable between treatment arms (secondary endpoints).

Oral zoliflodacin 3g was generally well tolerated and emergent adverse events were comparable between treatment arms (46.2% vs 46.4%). No deaths or other serious adverse events were reported.

Details for the ESCMID Global 2024 presentations are as follows:

Oral presentation

Title: Oral zoliflodacin is non-inferior to a combination of ceftriaxone and azithromycin for treatment of uncomplicated urogenital gonorrhoea: results of a large global Phase 3 randomized controlled trial
Presenter/Author: Alison Luckey
Oral session #: 246
Session: 05. New antibacterial agents, PK/PD & Stewardship – Therapeutic expedition: mining old and new drugs and dosing strategies

Date and time: Tuesday, April 30, 2024; 8:30-10:30 CEST
Location: Hall H

Poster presentations

Title: Safety profile of oral zoliflodacin for uncomplicated gonorrhoea in a Phase 3 trial
Author: Gabrielle Kornman, et al.
Poster #: 2724
Session: 5e. Safety, hypersensitivity, and adverse effects of treatment
Date and time: Sunday, April 28, 2024; 12:00 CEST
Location: Poster Area, Sector A, Row 23, Position 2

Title: Pharmacokinetics of zoliflodacin in healthy participants in the presence of itraconazole suggest no clinically meaningful CYP3A4-mediated drug-drug interactions
Author: Alison Luckey, et al.
Poster #: 2424
Session: 5b. Pharmacokinetics/pharmacodynamics of antibacterial drugs & therapeutic drug monitoring (incl lab methods, models, in vitro and in vivo studies)
Date and time: Sunday, April 28, 2024; 12:00 CEST
Location: Poster Area, Sector B, Row 16, Position 26

Title: Antimicrobial susceptibility of baseline *Neisseria gonorrhoeae* isolates from participants recruited in the global zoliflodacin Phase 3 randomised controlled trial
Author: Alison Luckey, et al.
Poster #: 2527
Session: 5c. New or repurposed antibacterial agents: clinical studies and randomised trials
Date and time: Sunday, April 28, 2024; 12:00 CEST
Location: Poster Area, Sector B, Row 18, Position 17

Title: Eravacycline susceptibility against Gram-positive pathogens, collected in Europe during 2022
Author: Stephen Hawser, et al.
Poster #: 1281
Session: 3a. Resistance surveillance & epidemiology: MRSA, VRE & other Gram-positives
Date and time: Monday, April 29, 2024; 12:00 CEST
Location: Poster Area, Sector B, Row 1, Position 8

Title: In vitro activity of eravacycline against Enterobacterales and non-fermenter clinical isolates, including resistant isolates, collected in Europe during 2022
Author: Stephen Hawser, et al.
Poster #: 1421
Session: 3b. Resistance surveillance & epidemiology: Gram-negatives
Date and time: Monday, April 29, 2024; 12:00 CEST
Location: Poster Area, Sector A, Row 4, Position 12

Click here for full XERAVA safety and prescribing information or go to www.xerava.com.

Title: In vitro activity of sulbactam/durlobactam in combination with cefepime against Gram-negative bacterial isolates from a recent Phase 3 clinical trial
Author: Sarah McLeod, et al.
Poster #: 1816
Session: 3f. Clinical outcome of resistant infections (retrospective and prospective studies, excl clinical trials of new drugs)
Date and time: Monday, April 29, 2024; 12:00 CEST
Location: Poster Area, Sector B, Row 12, Position 3

Click here for full XACDURO safety and prescribing information or go to www.xacduro.com.

The oral presentation and posters will be available on the "Events & Presentations" page of the Investors Relations section of Innoviva's website following their presentation at ESCMID Global 2024.

About Oral Zoliflodacin

Zoliflodacin is a potential first-in-class, orally administered, single dose antibiotic with a novel mechanism of action that is currently in development for the treatment of uncomplicated gonorrhea. In a Phase 3 clinical trial, zoliflodacin met the primary efficacy endpoint by demonstrating non-inferiority compared to a globally recognized standard of care regimen (500mg ceftriaxone intramuscular [IM] plus 1g oral azithromycin). Zoliflodacin was found to be generally well tolerated with the overall rate of adverse events comparable between the two arms, and the majority of adverse events were mild to moderate. *In vitro* studies have shown that it is active against multidrug-resistant strains of *Neisseria gonorrhoeae*, including those resistant to ceftriaxone, and azithromycin, with no cross-resistance with other antibiotics.

About Gonorrhea

Gonorrhea is widely prevalent worldwide, with the World Health Organization estimating 82 million new cases worldwide in 2020[1], making it the second most prevalent sexually transmitted bacterial infection worldwide after *Chlamydia trachomatis*. In the U.S., gonorrhea is the second most prevalent sexually transmitted bacterial infection, with an estimated 1.6 million new infections each year.[2] The bacterium *Neisseria gonorrhoeae* has gradually developed resistance to many classes of antibiotics used to treat these infections and as a result, ceftriaxone, given as a single intramuscular injection, has become the last available recommended treatment for gonorrhea globally.

About GARDP

The Global Antibiotic Research & Development Partnership (GARDP) is a not-for-profit organization that develops new antibiotic treatments for drug-resistant bacterial infections that pose the greatest threat to human health, and makes them accessible to the people who need them. It puts public health needs at the centre of antibiotic drug development to address the immediate crisis of antimicrobial resistance (AMR). Its work is funded by the governments of Australia, Germany, Japan, Monaco, the Netherlands, the Public Health Agency of Canada, South Africa, Switzerland, the United Kingdom, the Canton of Geneva, the European Union (via the Health Emergency Preparedness and Response Authority), as well as the RIGHT Foundation, Wellcome and other private foundations. GARDP was created by the World Health Organization and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally registered as the GARDP Foundation in Geneva, Switzerland in 2018. www.gardp.org.

http://www.gardp.org

About Innoviva Specialty Therapeutics, Inc.

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). Our Phase 3 development pipeline includes zoliflodacin, a novel treatment for uncomplicated gonorrhea in adults. For more information about Innoviva Specialty Therapeutics, please visit here and follow us on X (formerly Twitter) and LinkedIn.

About Innoviva, Inc.

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.

For more information about Innoviva, please visit here and follow us on LinkedIn.

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® and XACDURO® 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 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); 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, 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.

References

1. https://www.who.int/news-room/fact-sheets/detail/multi-drug-resistant-gonorrhoea#:~:text=Antimicrobial%20resistance%20in%20gonorrhoea%20has,are%20aged%2015%E2%80%9349%20years
2. https://www.cdc.gov/std/gonorrhea/arg/public-health-threat/public-health-threat-text-only.htm#:~:text=Gonorrhea%20is%20the%20second%20most,to%20at%20least%20one%20antibiotic

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