GARDP and Innoviva Specialty Therapeutics announce completion of patient recruitment for registrational phase 3 gonorrhoea treatment trial

- Gonorrhoea is among the three most common sexually transmitted infections, affecting men and women worldwide.
- Global infection rates of gonorrhoea are increasing, with 82 million new cases estimated each year and limited treatment options due to antimicrobial resistance.

Geneva (Switzerland) and Waltham, MA (USA), 23 May 2023 – The Global Antibiotic Research & Development Partnership (GARDP) and Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced the completion of recruitment for their global phase 3 pivotal registration trial of oral zoliflodacin, an investigational, first-in-class antibiotic being developed for the treatment of uncomplicated gonorrhoea infection in patients.

“Completing the recruitment for the zoliflodacin phase 3 trial marks a significant milestone for us as it is the first antibiotic trial fully funded and sponsored by a non-profit like the Global Antibiotic Research & Development Partnership,” said Dr Manica Balasegaram, GARDP’s Executive Director. “It brings us one step closer to developing a new treatment for gonorrhoea, which is rapidly becoming resistant to existing antibiotics.”

In 2017, GARDP partnered with Entasis Therapeutics Limited, now a subsidiary of Innoviva Specialty Therapeutics, to carry out the phase 3 trial at 16 sites across 5 countries (Belgium, the Netherlands, South Africa, Thailand and the US), comparing zoliflodacin to a globally recognized regimen (500mg ceftriaxone plus 1g azithromycin) for the treatment of uncomplicated gonorrhoea. The first patient was recruited in the US in November 2019, and the trial continued, despite obstacles, throughout the COVID-19 pandemic. A total of 958 patients were recruited, making it the largest clinical trial ever conducted for a new treatment against gonorrhoea infection.

The top-line results of the phase 3 registrational trial are expected in Q4 this year.

"The successful completion of recruitment in the phase 3 trial underscores Innoviva's commitment, and our collaborative efforts with GARDP, to develop an oral therapy addressing an urgent, unmet patient need," said David Altarac, MD, Chief Medical Officer, Innoviva Specialty Therapeutics. "We are proud of this remarkable accomplishment, and we look forward to working with GARDP on the next stages of the zoliflodacin clinical development program."

Under the collaboration agreement with Entasis, GARDP has the rights to register and commercialize zoliflodacin upon approval in more than 3/4 of countries worldwide, including all low-income countries, most middle-income countries, and a number of high-income countries. Innoviva retains commercial rights for zoliflodacin in the major markets in North America, Europe, Asia-Pacific, and Latin America.

“Completion of study enrollment allows us to move forward to better understand how zoliflodacin may work to address the ongoing threat of progressive gonococcal antimicrobial resistance in patients,” said Dr. Edward W. Hook III, Emeritus Professor of Infectious

Disease at the University of Alabama at Birmingham, and Global Protocol Chair for the zoliflodacin trial. “It is our hope this novel approach will yield an oral alternative to currently recommended therapy, which can only be administered by injection.”

Gonorrhoea is among the three most common sexually transmitted infections, and it affects men and women, particularly ages 15-24 years old. Globally, the infection rate of gonorrhoea is increasing, with 82 million new cases estimated each year and very limited treatment options due to antimicrobial resistance. Recent outbreaks of extensively drug-resistant gonorrhoea to the last-line treatment option have been reported in the US and the UK.

If left untreated, gonorrhoea can have serious and permanent consequences, particularly for women, including infertility, life-threatening ectopic pregnancies and pelvic inflammatory disease.

Gonorrhoea is caused by the bacterium *Neisseria gonorrhoeae*, which has progressively developed resistance to globally recommended treatments and has been identified by the World Health Organization as a “priority pathogen” posing one of the greatest threats to global health.

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About GARDP

The Global Antibiotic Research and Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally founded in 2018 to ensure that everyone who needs antibiotics receives effective and affordable treatment. GARDP 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, as well as the European Union, Wellcome Trust and private foundations. GARDP is registered under the legal name GARDP Foundation. www.gardp.org

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. In addition, through its affiliate, Entasis Therapeutics Inc., sulbactam-durlobactam is an investigational, targeted antibiotic in late-stage development for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus complex* (*Acinetobacter*). For more information about Innoviva Specialty Therapeutics, please visit here.

About Innoviva

Innoviva, Inc., is a diversified holding company with a portfolio of royalties and other healthcare assets, including Innoviva Specialty Therapeutics, a subsidiary focused on delivering innovative therapies in critical care and infectious disease. Innoviva’s royalty portfolio includes respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, FF/VI) and ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, UMEC/VI). Under the Long-Acting Beta2 Agonist (LABA) Collaboration

Agreement, Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. ANORO®, RELVAR® and BREO® are trademarks of the GSK group of companies. For more information on Innoviva, please visit here.