GARDP to present positive phase 3 trial results for zoliflodacin at ESCMID Global 2024

- Top-line study results represent a significant milestone in the development of a novel antibiotic against drug-resistant *Neisseria gonorrhoea,* a high priority pathogen.
- ESCMID Global 2024 will be the first time GARDP has presented these results at a scientific conference.
- Groundbreaking antibiotic research & development partnership model paves the way for development of other antibiotics to address antimicrobial resistance (AMR).

Geneva (Switzerland), 24 April 2024 – The positive topline phase 3 results for zoliflodacin, a novel first-in-class oral antibiotic for the treatment of uncomplicated gonorrhoea, will be presented for the first time by the Global Antibiotic Research & Development Partnership (GARDP) at this week's 34th Annual European Society of Clinical Microbiology and Infectious Diseases Congress (ESCMID Global 2024) in Barcelona, Spain. The positive findings offer hope for patients with gonorrhoea, particularly in the face of rising antibiotic resistance to current regimens. If approved, zoliflodacin could become the first new antibiotic for treating gonorrhoea in decades.

Previous *in vitro* studies have shown that zoliflodacin is active against multidrug-resistant strains of *Neisseria gonorrhoeae,* including those resistant to ceftriaxone and azithromycin, with no cross-resistance with other antibiotics. The phase 3 trial was carried out by GARDP as part of a collaboration agreement with Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (Nasdaq: INVA) to develop zoliflodacin for the treatment of gonorrhoea infection. It is the first trial to be sponsored and led by a non-profit organization to address a World Health Organization (WHO) priority pathogen. The success of this publicly-funded trial paves the way for a new research and development model in the fight against the escalating global antimicrobial resistance (AMR) crisis.

"These findings represent a significant step forward in the treatment of gonorrhoea, and demonstrate that GARDP's public-private partnership model has a crucial role to play in helping to fix the public health failure at the heart of the escalating global AMR crisis," said Manica Balasegaram, Executive Director of GARDP. "This zoliflodacin programme demonstrates that it is possible to develop antibiotic treatments targeting multidrug-resistant bacteria that pose the greatest public health threat, and which may not otherwise get developed. The trial also proves that this innovative model has the potential to deliver first-in-class treatments in a way that is cost-effective and a responsible use of donor funds."

With more than 82 million new gonorrhoea infections occurring globally each year, gonorrhoea is the second most common bacterial sexually transmitted infection (STI), affecting both men and women in ways that can result in serious and permanent health consequences. 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 gonorrhoea globally.

The phase 3 trial enrolled a total of 930 patients with uncomplicated gonorrhoea, including women, adolescents and people living with HIV, making it the largest clinical trial ever conducted for a new treatment against gonorrhoea infection. The trial included 16 trial sites in regions with a high prevalence of gonorrhoea across five countries, including Belgium, the Netherlands, South Africa, Thailand, and the US. It compared a single oral suspension 3g dose of zoliflodacin to a globally recognized standard of care regimen (500mg ceftriaxone IM plus 1g oral azithromycin) for the treatment of uncomplicated gonorrhoea.

ESCMID Global is the premier congress in the field of infectious disease, bringing together more than 15,000 experts from all over the world. In addition to presenting these topline results at the event, GARDP will also present several additional posters and oral presentations demonstrating the progress of the GARDP portfolio, including scientific and clinical data on the development of and access to zoliflodacin, cefiderocol and treatments for neonatal sepsis. Dr Balasegaram will also chair a session entitled "Introduction of newer antibiotics in LMICs," with Jennifer Cohn, GARDP's Global Access Director, as part of the panel.

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 Canada, Germany, Japan, Monaco, the Netherlands, South Africa, Switzerland, the United Kingdom, the Canton of Geneva, the European Union (via the European Commission's Health Emergency Preparedness and Response Authority (HERA)), as well as Global Health EDCTP3, 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

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