



The RIGHT Foundation invests in new treatments for neonatal sepsis

Geneva, Switzerland, 20 November 2023 – In a boost to efforts to counter antibiotic resistance, the Research Investment for Global Health Technology (RIGHT) Foundation has awarded the Global Antibiotic Research & Development Partnership (GARDP) 4 billion South Korean Won (~€2.8 million) to improve antibiotic regimens for neonatal sepsis. This life-threatening infection affects over 3 million newborns each year, the vast majority in low- and middle-income countries (LMICs).

Funds from the RIGHT Foundation will support “NeoSep1,” an international clinical trial by GARDP and partners to evaluate three novel antibiotic regimens for neonatal sepsis. The regimens include combinations of fosfomycin, amikacin and flomoxef, three off-patent antibiotics with approved dosing for neonates. The NeoSep1 trial tests the efficacy and safety of these regimens against recommended treatments for neonatal sepsis in the context of rising antibiotic resistance. The trial is underway in Kenya and South Africa, and will be expanded to additional countries from 2024.

“Doctors and nurses in different parts of the world are running out of treatment options for neonatal sepsis,” said Manica Balasegaram, Executive Director at GARDP. “We are deeply thankful to the RIGHT Foundation for supporting our efforts to improve and provide access to effective treatment regimens for every newborn in need.”

In parallel to the trial, GARDP is developing an access strategy for quality-assured and affordable supply of the antibiotics in the combination regimens. Funding from the RIGHT Foundation will enable collaboration between GARDP and South Korean industry partner Jeil Pharma to explore options to optimize the manufacturing processes of the active pharmaceutical ingredient (API) in flomoxef. If this process can be optimized, GARDP and Jeil Pharma will look into options to transfer the technology to a manufacturer in an LMIC, likely based in Sub-Saharan Africa, with the goal of making the API for flomoxef at an affordable price and stabilizing supply.

“We are eager to foster public-private partnerships that engage in research and development for the benefit of global public health,” said Hani Kim, Executive Director of the RIGHT Foundation. “We welcome the collaboration between GARDP and Jeil Pharma and all partners involved in this project to improve care for newborn babies around the world.”

“Jeil Pharma is glad to be part of this project to improve antibiotic manufacturing for consistent, reliable supply at affordable prices for patients and health systems,” said Soomee Kim, Senior Director of the Global Business Department at Jeil Pharma. “We look forward to working with GARDP on this much-needed project.”

Funds from the RIGHT Foundation will further support activities to facilitate registration for flomoxef and fosfomycin. (The third antibiotic, amikacin, is already widely available from several generic antibiotic companies.) In the event of positive results in the NeoSep1 trial, GARDP will work with manufacturers to submit dossiers for flomoxef API, fosfomycin, and the product finished dosage form to World Health Organization (WHO) Pre-Qualification (PQ). WHO PQ status assures the quality of the product manufactured at a certain facility and makes it possible for participating countries to use the WHO PQ Collaborative Procedure for Accelerated Registration, which helps reduce the time for national regulatory approvals to 90 days in participating countries.

The NeoSep1 trial corresponds to Priority 19 in the [WHO Global research agenda for antimicrobial resistance in human health](#), which lists the top 40 research topics for evidence generation to inform policy by 2030. This trial works toward United Nations [Sustainable Development Goal 3.2](#) to end preventable death of newborns and children under 5 years of age by 2030, and it is in line with



research priorities recently identified by WHO and partners in the first-ever [“Paediatric Drug Optimization” \(PADO\) exercise for antibiotics](#).

About GARDP

The Global Antibiotic Research & 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, the RIGHT Foundation, Wellcome Trust and private foundations. GARDP is registered under the legal name GARDP Foundation. www.gardp.org

About the RIGHT Foundation

The RIGHT Foundation is a Korean funding agency dedicated to support global health R&D, established in 2018 by the Ministry of Health and Welfare of South Korea (MOHW) the Bill & Melinda Gates Foundation, and Korean life science companies with the mission of alleviating the disproportionate burden of infectious diseases in the low-middle income countries (LMICs). Since its establishment, the RIGHT Foundation has committed 72.6 billion KRW to support 55 projects. <https://rightfoundation.kr/en/>

About Jeil Pharma

Jeil Pharma is a Korean pharmaceutical company established in 1959. The company develops, manufactures and distributes pharmaceutical products, including active pharmaceutical ingredients and finished products, mainly in South Korea. It provides products in the areas of antibiotic, gastrointestinal, cardiovascular, neuropsychiatry, oncology, endocrinology, urology, antiviral, and antihistamine. The company also exports its products to approximately 40 countries in Europe, ASEAN, Central and South America, and Africa.

The company has recently succeeded in an NDA application to the Korean Ministry of Food and Drug Safety (MFDS) for its first innovative drug developed by a wholly owned company (Onconic Therapeutics) for the treatment of gastroesophageal reflux disease (GERD), and it expects to get marketing approval in the first half of 2024. www.jeilpharm.co.kr