GARDP's portfolio of antibiotic treatments

WHO and the Drugs for Neglected Diseases initiative (DNDi) created GARDP in 2016 in response to the Global Action Plan on AMR, which highlighted the lack of new antibiotics. Since then, GARDP has become an established R&D and access organization. With a significant portfolio of antibiotic treatments targeting WHO priority pathogens and priority infections—particularly those affecting underserved, high-burden populations and countries—we are progressing towards our goal of developing 5 new treatments by 2025. We are also working on securing agreements with manufacturers and distributors to provide access to these antibiotics in resource-limited settings.

DISEASE AREA	GARDP PROGRAMME AREA	TREATMENT	TARGET PATHOGENS* (WHO PRIORITY PATHOGENS)	DESCRIPTION	OBJECTIVE	GARDP'S 2022 HIGHLIGHTS
SEPSIS		**TREATMENT 1: neonatal sepsis treatment regimen** Partners: Shionogi & Co., Ltd, and InfectoPharm	ESBL	Treatment for sepsis in newborns using existing antibiotics: • fosfomycin-amikacin • flomoxef-amikacin • fosfomycin-flomoxef	• Provide a new standard for the treatment of sepsis in newborns and change the treatment guidelines • Ensure that new combinations are accessible	• **LAID** groundwork for a clinical trial to validate the doses of two antibiotics for use in newborns and to compare patient outcomes involving these new treatments with existing regimens
		**TREATMENT 2: cefiderocol** Partner: Shionogi & Co., Ltd.	CRE CRPA CRAB	Treatment for hospital- and community-acquired bacterial infections in: • adults • children • newboms	• Provide affordable and sustainable access to cefiderocol for patients in need while preserving this antibiotic's efficacy through appropriate use and good stewardship • Support the ongoing development of this drug for children and newborns	• **SIGNED** license and collaboration agreements with Shionogi and CHAI to treat bacterial infections by expanding access to the antibiotic cefiderocol in 135 countries
		**TREATMENT 3: cefepime-taniborbactam** Partner: Venatorx Pharmaceuticals, Inc.	CRE CRPA	Treatment for hospital- and community-acquired bacterial infections in: • adults • children • newborns	• Obtain FDA** and EMA** registration for a new antibiotic treatment for serious bacterial infections in adults • Support the development of a paediatric indication • GARDP's partnership with Venatorx includes a license agreement supporting access in 66 LMICs	• **WELCOMED** positive results in Venatorx's pivotal phase 3 clinical trial for cefepime-taniborbactam • **BEGAN** an observational study to assess standards for diagnostics and clinical management as well as patient outcomes for infections caused by carbapenem-resistant bacteria in high-burden settings
SEXUALLY TRANSMITTED INFECTIONS		**TREATMENT 4: zoliflodacin** Partner: Entasis Therapeutics Limited	*Neisseria gonorrhoeae*	Oral treatment for uncomplicated gonorrhoea	• Obtain FDA** and EMA** registration for an innovative oral antibiotic for gonorrhoea • GARDP's partnership with Entasis includes a license agreement supporting access in all LMICs	• **INCREASED** recruitment of participants for a phase 3 trial of zoliflodacin, setting this trial on track for completion in 2023. All 16 trial sites across 5 countries are now active and all participants have been recruited

* ESBL: extended spectrum beta-lactamases – producing Enterobacteriales; CRE: carbapenem-resistant *Enterobacteriaceae*; CRPA: carbapenem-resistant *Pseudomonas aeruginosa*; CRAB: carbapenem-resistant *Acinetobacter baumannii*.

** FDA: US Food and Drug Administration; EMA: European Medicines Agency.