

ACTIVITY REPORT 2020

Global Antibiotic
Research & Development
Partnership



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MESSAGE

FROM THE EXECUTIVE DIRECTOR & BOARD CHAIR

2020 was an extremely challenging year for all of us. COVID-19 has brought tragic loss, suffering and disruption to every corner of the world. And it will do so until we finally contain this virus.

We want to begin this report by thanking our partners, supporters and colleagues for their unwavering commitment to **GARDP** and its vital work against this extraordinary backdrop of adversity. Thanks to their courage and enthusiasm 2020 was a year in which we were able to make remarkable progress despite the many challenges.

In July, following a minimal pandemic-related delay, we locked the database on one of the largest global observational studies on the care of newborns with sepsis. This study, which involved newborns at 19 sites across 11 countries, will provide the evidence we need to fill knowledge gaps, improve treatments and save lives, and inform

a clinical trial—slated for a 2022 start—that will evaluate the potential of three antibiotic combinations in treating neonatal sepsis.

Unfortunately, the COVID-19 pandemic has made for an extremely challenging research environment this past year. Our work on a novel antibiotic

*“Antibiotic research and development needs an urgent boost now more than ever, and **GARDP** is part of the solution. As a **GARDP** Board Observer, I am honoured to support **GARDP** in its efforts to ensure that new and effective treatments against drug-resistant infections are made accessible to all.”*

PROFESSOR HANAN H. BALKHY

ASSISTANT DIRECTOR-GENERAL FOR ANTIMICROBIAL RESISTANCE
WORLD HEALTH ORGANIZATION

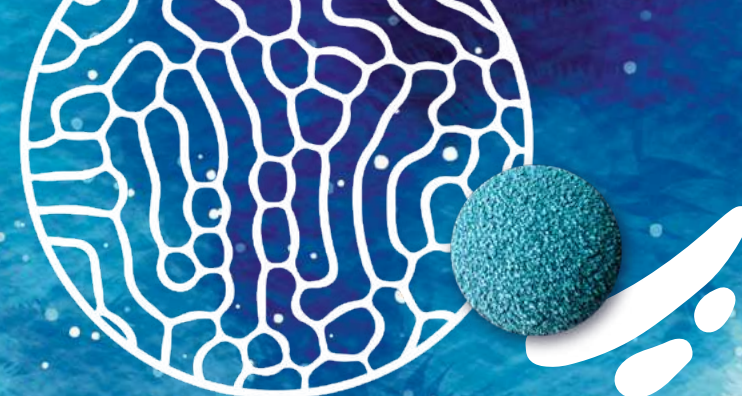
cefepime-taniborbactam did not escape the effects of this sweeping crisis, with both the initial phase 3 clinical trial and an observational study, investigating resistant infections, being delayed. Nevertheless, crucial preparatory and mitigating steps on both fronts have been undertaken and the partnership is on track to both complete the phase 3 study and start the observational study in 2021. The first clinical trial to develop this antibiotic combination for children will start in 2022. Cefepime-taniborbactam has the potential to address significant unmet need as a new treatment for antibiotic-resistant infections in adults and children, and we will work closely with our partner Venatorx to make it available to everyone who needs it, wherever they live.

In September 2019, **GARDP**'s Sexually Transmitted Infections programme initiated its phase 3 trial of zoliflodacin, a novel antibiotic to treat gonorrhoea, with the activation of sites in the US. However, as the pandemic unfolded, it became clear we would be required to place the trial on hold. Recruitment in the US was temporarily paused in March, as our focus turned to creating a strategy that would enable us to safely re-launch the study. Thanks to that hard work, we were able to resume patient recruitment in the US and enroll our first patients at sites in The Netherlands.

As the pandemic unfolded, our extensive experience in running virtual events enabled us to quickly and seamlessly move all of our con-

ferences and webinars online. This move did not hinder the ongoing success of our Scientific Affairs programme, whose activities are hosted on the REVIVE website, and promote the retention and sharing of knowledge among the antimicrobial R&D community. We are delighted to have reached over 3,800 people from over 100 countries through 17 webinars last year, with the REVIVE website content accessed by users in 182 countries. Another highlight was our new online Antimicrobial Encyclopaedia, which Scientific Affairs launched last October in time for World Antimicrobial Awareness Week.

If 2020 reminded us of one crucial fact, it is that infectious diseases have no regard for national borders.



Ideally, neither should drugs or vaccines. The only way to contain COVID-19 and ensure we are more prepared for future pandemics will be through a coordinated global effort—no country nor sector will succeed by going at it alone. And just as pandemic preparedness has become a priority for countries, so awareness has grown of the need to tackle the silent pandemic of antibiotic resistance.

Recognizing the critical role of antibiotics in pandemic readiness and modern medicine more generally, the German government announced in September that it would provide additional funding of EUR 5 million for **GARDP**. Also in 2020, Japan made its first

contribution of 200 million yen (US\$1.8 million) to **GARDP**, as part of a broader 1 billion yen pledge. Towards the end of year **GARDP** received an additional GBP 1.5 million from the UK to develop a new treatment for drug-resistant gonorrhoea.

As consciousness of antimicrobial resistance remains high, what we urgently need is more financial investments to tackle this silent pandemic. We are seeking €500 million to develop five new treatments by 2025 for drug-resistant infections that pose the greatest threat to health and ensure their responsible use and sustainable access.

We at **GARDP**, together with our partners from the public and private sectors, will redouble our efforts to ensure that antibiotic resistance never paralyzes the world as the COVID-19 pandemic has this past year. As we begin to look forward to life beyond this global health crisis, we and the whole team are looking forward to the next chapter of our work in tackling another great health challenge of our time.

DR. MANICA BALASEGARAM
GARDP EXECUTIVE DIRECTOR

& PROF. RAMANAN LAXMINARAYAN
GARDP BOARD CHAIR



Prof. Ramanan Laxminarayan
GARDP BOARD CHAIR



Dr. Manica Balasegaram
GARDP EXECUTIVE DIRECTOR

*“The COVID-19 pandemic has brought into sharp focus the impact of pandemics and the importance of preparedness. It has demonstrated that addressing the silent pandemic of drug-resistant infections can only be achieved through greater international cooperation and investment. As host country, Switzerland recognizes the major role **GARDP** plays at the global level in the fight against antibiotic resistance.”*

ALAIN BERSET
FEDERAL COUNCILLOR, HEAD OF THE FEDERAL DEPARTMENT
OF HOME AFFAIRS (FDHA), SWITZERLAND

CRISIS

COVID-19 AND THE SILENT PANDEMIC OF DRUG-RESISTANT INFECTIONS

In 2020, a novel coronavirus brought suffering, disruption and economic hardship to virtually every corner of the globe. With the COVID-19 pandemic all but certain to define a decade, what can it tell us about the silent pandemic that continues to grow?

With over 2.5 million people dead¹, trillions of dollars in economic damage, billions of lives disrupted and work on the UN's Sustainable Development Goals held back, the COVID-19 crisis has revealed the potential effects of a global pandemic with excruciating clarity.

In a November 2020 report², **GARDP** called on governments around the world to work with both the public and private sectors on bringing the lessons of COVID-19 to bear on drug-resistant infections. This silent pandemic existed before and will endure beyond the crisis that stopped the world in 2020—and may yet turn out to be even more devastating.

LEARNING THE LESSONS OF COVID-19

With drug-resistant infections killing around 700,000 people each year³, this silent pandemic already matches the COVID-19 death toll (as of May 2021) every 4.5 years. And unless we successfully tackle the spread of antibiotic resistance, even common infections will become significantly more difficult to treat. In other words, the death rate of the silent pandemic will only continue to rise until we can realize the level of collective will, knowledge and action we need to turn the tide.

Drug-resistant infections spread rapidly through international travel and migration, and their impact is felt

more quickly in low- and middle-income countries with poorly resourced healthcare systems that tend to have lower-quality infection prevention and control measures. Here, far more hospitalized patients—10% of all patients, compared with 7% in high-income countries⁴—will contract a bacterial infection. And, due to higher levels of antibiotic resistance and fewer available treatment options, the infections are more likely to be difficult to treat. Better access to the right antibiotics will, therefore, be vital in ensuring that we are prepared for future pandemics and in tackling the silent pandemic of drug-resistant infections.

According to recent data from India, the percentage of secondary infections among COVID-19 patients remains relatively low, but mortality is very high. In ten hospitals, 56.7% of COVID-19 patients with secondary infections died compared to an overall mortality of 10.6% in total admitted COVID-19 patients⁵.

While the COVID-19 pandemic has highlighted antibiotics as a crucial component of pandemic readiness, it has also underscored the potential for widespread antibiotic misuse. Consequently, the COVID-19 pandemic could have a long-term impact on the availability of these valuable drugs and even accelerate the growth of antibiotic resistance.

HOW TO STRENGTHEN THE INTERNATIONAL RESPONSE TO ANTIMICROBIAL RESISTANCE

We have a valuable opportunity to use the lessons of this crisis to better prepare ourselves for future pandemics. In particular, this includes the silent pandemic of drug-resistant infections—a growing crisis whose overall impact may yet eclipse that of COVID-19.

To that end, our report included five recommendations for concrete measures to strengthen domestic and global responses to antimicrobial resistance.

1. RECOGNIZE AND URGENTLY ADDRESS THE SILENT PANDEMIC OF DRUG-RESISTANT INFECTIONS.

¹ WHO. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>

² GARDP. 'Learning from COVID-19 to Tackle Antibiotic Resistance'. 2020

³ WHO. 'No Time to Wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations'. 2019.

⁴ WHO. 'Report on the Burden of Endemic Health Care-Associated Infection Worldwide'. 2011.

⁵ K. Walia. 'Secondary Infections in COVID-19 Patients: Indian Experience'. Infection and Drug Resistance 2021: 1893-1903, 27 May 2021

2. INVEST IN THE DEVELOPMENT OF MEDICAL COUNTERMEASURES AS A CRITICAL ELEMENT OF PANDEMIC PREPAREDNESS.



3. ENSURE THAT ACCESS TO DIAGNOSTICS, TREATMENTS AND VACCINES FOR ALL IS A CORNERSTONE OF PANDEMIC PREPAREDNESS AND RESPONSE.

4. EXPAND GLOBAL COOPERATION ACROSS GEOGRAPHIES AND SECTORS AND WITHIN A ONE HEALTH FRAMEWORK.

5. ENSURE LOW- AND MIDDLE-INCOME COUNTRIES ARE EQUAL PARTNERS IN A COMPREHENSIVE GLOBAL RESPONSE. SOLUTIONS THAT HAVE BEEN PIONEERED BY COUNTRIES SHOULD BE RECOGNIZED AND INTEGRATED INTO PANDEMIC PREPAREDNESS AND RESPONSE.



SUCCEED TOGETHER, FAIL ALONE

Over a year into the COVID-19 crisis, one lesson stands out above all: we can only achieve pandemic preparedness through a global, coordinated effort. Although, like COVID-19, the silent pandemic of drug-resistant infections has the potential to severely impact the world, it is different in that we know in advance what it will take to prevent such a disaster.

We call on governments to ramp up their response to antimicrobial resistance. For it is what we do now that will determine whether the silent pandemic of drug-resistant infections will be a century-defining crisis, or an exemplar of what we can achieve when we work together.

GOAL

TACKLING THE ANTIBIOTIC RESISTANCE CRISIS

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. We were created to ensure that everyone who needs antibiotics receives effective and affordable treatment, no matter where they live.

GARDP was established in 2016 by the World Health Organization (WHO) and Drugs for Neglected Diseases *initiative* (DNDi) to deliver on the Global Action Plan on Antimicrobial Resistance. After five years in operation, GARDP has already built a pipeline to tackle sexually transmitted infections as well as infections in hospitalized adults and children, including newborns with sepsis (a bloodstream infection). We have

formed over 60 partnerships in 22 countries that span governments, the biomedical and pharmaceutical industries, research institutions, non-profits, and civil society.

GARDP bridges the gap between innovation and access by focusing on developing candidates in late-stage clinical development. This requires identifying the barriers to access and finding innovative ways to overcome them. We are also

exploring ways to ensure there is a viable market and sustainable supply of treatments in the long-term.

To tackle the growing antibiotic resistance crisis, GARDP has set the 5 BY 25 goal, which seeks to deliver five new treatments by 2025 for drug-resistant infections that pose the greatest threat to health and economic security.

OUR VISION

All infections are treatable for everyone, everywhere.

OUR MISSION

We bring together the public and private sectors to develop new treatments for bacterial infections. We ensure responsible and sustainable access, addressing the public health impact of antibiotic resistance.

OUR FOCUS

- Bacteria on the WHO priority pathogen list
- Diseases and populations disproportionately affected by drug resistance
- Late-stage clinical development and access

HIGHLIGHTS

2020 MILESTONES

We are proud of the progress we made in 2020 towards building an antibiotic portfolio and achieving our 5 BY 25 goal: to deliver five new treatments to tackle drug-resistant infections that pose the greatest threat to health by 2025.

2020 MILESTONES

1. Completed a landmark observational study on neonatal sepsis and finalised a clinical study report on the pharmacokinetic clinical trial assessing the safety and dosing of fosfomycin in newborns.
2. Successfully identified one potential antibiotic combination of fosfomycin-amikacin to treat neonatal sepsis.
3. Signed first agreement of GARDP's Serious Bacterial Infections programme and started the first project to bring a new drug to market.
4. Continued patient enrolment, including a new site in The Netherlands, as part of our phase 3 trial of a new treatment for gonorrhoea.
5. Organized 17 REVIVE webinars and launched a new online Antimicrobial Encyclopaedia.
6. Screened over 24,000 compounds from five different partners. Daiichi Sankyo joined the GARDP-led Antimicrobial Resistance Screening Consortium alongside Eisai and Takeda.

HIGHLIGHTS

2020 HIGHLIGHTS

MARCH

GARDP enrolled 3204 babies into one of the largest ever observational studies on neonatal sepsis, which was conducted across 19 sites in 11 countries. This groundbreaking study will inform the design of future clinical trials on new drug combinations for treating neonatal sepsis, including GARDP's upcoming strategic public health clinical trial of three new antibiotic combinations.

GARDP paused recruitment in the global phase 3 pivotal trial of zoliflodacin, a novel oral antibiotic being developed to treat uncomplicated gonorrhoea, ensuring patient and site staff safety as the COVID-19 pandemic emerged. The trial will enrol approximately 1,000 adults with urogenital gonorrhoea from clinical trial sites in The Netherlands, South Africa, Thailand and the United States.

GARDP announced an agreement with Daiichi Sankyo to access and screen its chemical library, with the goal of discovering novel antibacterial compounds. Daiichi Sankyo also joined Eisai and Takeda as members of the Antimicrobial Resistance (AMR) Screening Consortium, which aims to accelerate GARDP's efforts to identify compounds for development into treatments for drug-resistant infections.

APRIL

Venatorx Pharmaceuticals and GARDP partnered to accelerate the development of and access to cefepime-taniborbactam, an investigational combination that employs the beta-lactamase inhibitor taniborbactam to restore the antibiotic cefepime's activity against carbapenem-resistant bacteria. The collaboration will include a phase 3 trial on complicated urinary tract infections, additional clinical trials in adults with multidrug-resistant infections, and clinical development activities and trials to enable cefepime-taniborbactam to be used in children and newborns.

GARDP launched a collaboration with international yoga star Tara Stiles to raise funds to fight drug-resistant infections in the midst of the COVID-19 pandemic.

MAY

GARDP and the University of Queensland expanded their partnership to tackle the growing global threat of serious bacterial infections by evaluating new and existing antibiotic treatments. The move builds on GARDP's collaboration with the Community for Open Antimicrobial Drug Discovery, which has been screening compound libraries at the University of Queensland in search of new treatments for WHO's priority drug-resistant infections.

GARDP partnered with Swiss biopharmaceutical company BioVersys to explore opportunities to accelerate the research and development of antibiotics for serious bacterial infections.

JUNE

GARDP was able to resume recruitment in the global phase 3 pivotal trial of zoliflodacin by working with sites on procedures to protect patients and staff and maintain data integrity. Subsequently patient enrolment restarted in the US, the first patient was enrolled in The Netherlands, and the plan to start the clinical trial in South Africa and Thailand resumed.

JULY

GARDP completed the data cleaning process and locked the database for its pioneering global neonatal sepsis observational study.

GARDP and Venatorx submitted a paediatric investigation plan for cefepime-taniborbactam to the European Medicines Association's (EMA) Paediatric Committee.

The Government of Japan contributed approximately 200 million yen (USD 1.8 million) to GARDP to accelerate the research and development of treatments for WHO's drug-resistant 'priority pathogens'. The funding will also support work to ensure these treatments are used responsibly and made accessible to every person who needs them. The contribution was the first of Japan's overall funding commitment of 1 billion yen (USD 9 million).

AUGUST

GARDP and Bugworks Research Inc. partnered to accelerate the development and availability of lifesaving new treatments for antibiotic-resistant infections. This includes working together to prepare regulatory strategies, in particular for clinical development programmes and post-approval studies.

GARDP co-organized a session at the fourth annual BIOCOM AMR conference. The conference is a platform for small- and medium-sized enterprises (SMEs), start-ups, big pharma, academia, investors and public institutions to discuss strategies and the specific challenges SMEs face in bringing new antimicrobial treatments and diagnostics to the market.

The United States Food and Drug Administration (FDA) approved GARDP and Venatorx's paediatric study plan for cefepime-taniborbactam.

SEPTEMBER

Germany contributed an additional EUR 5 million to GARDP. This contribution, announced during May 2020's Coronavirus Global Response international pledging conference, recognizes effective antibiotics as the foundation of healthcare systems and critical for long-term pandemic preparedness, including the treatment of secondary bacterial infections during viral pandemics.

GARDP established an India Advisory Group for research and development to maximize Indian knowledge and capacity in support of GARDP's work. This will include the development of networks and defining strategic priorities for R&D and access in India and internationally.

GARDP co-developed two 'Bootcamps' for the American Society for Microbiology (ASM) and European Society for Clinical Microbiology and Infectious Diseases (ESCMID) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. Following the conference's cancellation due to the COVID-19 pandemic, these Bootcamps were delivered as REVIVE webinars by GARDP.

OCTOBER

GARDP launched the Antimicrobial Encyclopaedia to share definitions of key terms in the antimicrobial field. The encyclopaedia initially included 70 written definitions and eight videos by GARDP experts and external contributors, with more added since.

GARDP delivered a session entitled 'Developing Antibiotics for Children to Achieve SDG3' at the World Health Summit.

NOVEMBER

GARDP, the Foundation for Innovative New Diagnostics (FIND) and WHO joined forces to explore joint initiatives to improve sustainable access to antibiotics and protect them against the emergence of antimicrobial resistance. The organizations will initially focus on sexually transmitted infections (STIs) by working to strengthen STI case management, evaluate public health needs for new tests and treatments for gonorrhoea, and define strategies to monitor and delay the emergence of resistance to gonorrhoea treatments.

The European Medicines Association's (EMA) Paediatric Committee approved GARDP and Venatorx's paediatric investigation plan for cefepime-taniborbactam, paving the way to regulatory approval for use of the drug in children and newborns.

DECEMBER

GARDP, Dr. Reddy's Laboratories Ltd. and Aurigene Pharmaceutical Services Limited (APSL) partnered to explore joint opportunities to make zoliflodacin, a new treatment for gonorrhoea, accessible in low- and middle-income countries. The MOU commits GARDP, Dr. Reddy's and APSL to collaborating to determine zoliflodacin's market potential and therapeutic value, and to explore future manufacturing and supply agreements.

Scientific Affairs made all its publications—including webinars, viewpoints and conference recordings—available on the REVIVE website, including an Antimicrobial Library that offers a wide selection of materials relevant to antimicrobial R&D. The Library also contains all Antimicrobial Encyclopaedia entries and an advanced search function.

GARDP received an additional GBP 1.5 million from the UK to develop a new treatment for gonorrhoea. This investment is on top of GBP 3.5 million committed in 2019.

CHILDREN'S ANTIBIOTICS

A MILESTONE IN THE FIGHT AGAINST NEONATAL SEPSIS

Each year, millions of newborns are diagnosed with neonatal sepsis, a life-threatening bloodstream infection that is becoming more dangerous due to the slow-moving pandemic of drug-resistant infections. In 2020, GARDP completed a study that represents a crucial milestone in its mission to give more newborns a fighting chance of survival.

With their immune systems having not yet developed, newborns are particularly susceptible to bacterial infections. In 2017, there were over 5 million cases of neonatal sepsis globally, with the most common reason for sepsis-related deaths in under-5s being neonatal disorders, which resulted in over 800,000 deaths⁶. The burden of neonatal sepsis is, therefore, more significant than was previously thought, with the highest impact occurring in low- and middle-income countries (LMICs), which are the least equipped to prevent, identify and treat sepsis. This problem is made even worse by the growing challenge of antimicrobial resistance. Today, up to 40% of bacterial antibiotic resistance in hospitalized babies are resistant to standard treatments⁷; a figure that is headed in the wrong direction.

We desperately need new treatments for infections in newborns that have become resistant to those in our existing pipeline. As part of its Children's Antibiotics programme, GARDP aims to address this crucial development gap by evaluating combinations of existing antibiotics that could be used to treat neonatal sepsis.

REPURPOSING EXISTING ANTIBIOTICS

GARDP's neonatal sepsis activities aim to develop new combinations of existing antibiotics that can be used to replace ampicillin and gentamicin. Although this combination remains the WHO standard of care for neonatal sepsis in most settings, many hospitals are increasingly unable to use it as their first-line treatment due to growing antibiotic resistance.

In collaboration with our partners, GARDP has undertaken research that will help establish a safe dose of the antibiotic fosfomycin to be used with other treatments to treat newborns with sepsis.

In 2020, we finalised a clinical study report on the pharmacokinetic clinical trial in Kenya assessing the safety and dosing of fosfomycin in newborns, which completed enrolment in 2019. The results, to be published in 2021, will inform the dosing of future work to develop effective treatments for neonatal sepsis.

GARDP has successfully identified three existing antibiotics – fosfomycin, flomoxef and amikacin – as potential alternative treatments to ampicillin-gentamicin. Together with partners we have completed the assessment of fosfomycin-amikacin and fosfomycin-flomoxef combinations using a hollow fibre infection model to assess the pharmacokinetic and pharmacodynamic properties of the combinations as well as their ability to prevent the emergence of resistance. This work is ongoing for the third combination of flomoxef and amikacin.

A GROUNDBREAKING STUDY

In February 2020, GARDP and its partners completed enrolment in one of the largest ever prospective observational studies on neonatal sepsis (NeoAMR Observational Study - NeoOBS). The study enrolled 3,204 babies (under 60 days old) with clinically diagnosed neonatal sepsis across 19 sites in 11 countries, most of which are LMICs: Bangladesh, Brazil, China, Greece, India, Italy, Kenya, South Africa, Thailand, Uganda and Vietnam. The study recorded, along with other information, daily clinical observations of the babies and which antibiotics they received. The data obtained from this vital study will inform the design of future clinical trials on new combinations of existing drugs for treating neonatal sepsis. This includes GARDP's upcoming clinical trial of the three aforementioned new combination treatments slated to begin in the first half of 2022.

Over **5 million** babies are diagnosed with neonatal sepsis annually⁶

Over **800,000** babies died of neonatal sepsis in 2017⁶

Up to **40% of** bacterial infections in hospitalized babies are resistant to standard treatments⁷

RESULTS OF NEONATAL SEPSIS STUDY

- 3204 babies with clinically diagnosed sepsis enrolled from 19 sites in 11 countries in 19 months
- Wide variety of antibiotics were prescribed to treat infants including carbapenems
- Approximately 18% of babies had a positive blood culture with *Klebsiella pneumoniae*, the most common pathogen identified

Apart from an additional month required to collect and clean data, the COVID-19 pandemic had a minimal impact on this observational study. Having locked the database in July, preliminary results were presented to investigators in October 2020. GARDP and its partners will publish the study once the analysis is complete. These preliminary results have informed the design of next year's clinical trial, demonstrating the immense value of undertaking this study.

⁶ Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR et al. 'Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study'. The Lancet. 2020;395(10219):200–211.
⁷ WHO. <https://www.who.int/mediacentre/commentaries/antibiotic-resistant-bacteria/en/>

NEONATAL SEPSIS

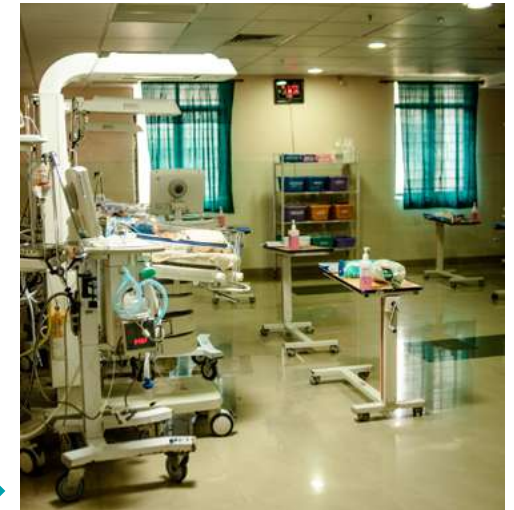
TRANSFORMING CARE OF BABIES IN INDIA WITH LIFE-THREATENING SEPSIS

GARDP partnered with Penta and St George's University of London to run one of the largest ever studies on the care of babies with sepsis, one that encompasses 11 countries. One of those countries is India, where sites in Mumbai, New Delhi and Puducherry are among the countries taking part.

Saba holds her daughter, Laiba, in a neonatal nursery, part of the Department of Neonatology at the Lady Hardinge Medical College, New Delhi. Laiba, who weighed only 970 grams when she was born and had underdeveloped lungs, was diagnosed and treated for neonatal sepsis.



Nandini, from Thirumanikuzhi village in Southern India, feeds her daughter Navika, who was treated for sepsis in Puducherry's Jawaharlal Institute of Postgraduate Medical Education and Research Hospital (JIPMER).



The JIPMER Women and Children's Hospital includes a neonatal ward, as well as an emergency and paediatric intensive care unit.



A newborn, diagnosed with sepsis, is monitored in the JIPMER neonatal intensive care unit.

CHILDREN'S ANTIBIOTICS

ACCELERATING CHILDREN'S ANTIBIOTIC DEVELOPMENT

Infectious diseases—including serious bacterial infections, such as pneumonia and sepsis—are a leading cause of child mortality, with more than three million deaths reported in 2013⁸. And yet, as of 2017, only two out of 37 new antibiotics being developed in adults were being studied in children⁹. This is the challenge that GARDP's paediatric development work aims to address.

GARDP's paediatric development activities focus on antibiotics that are either in late-stage clinical development or have already been approved for use in adults. The aim is to accelerate development of these antibi-

otics for use against serious bacterial infections in children for which there are currently limited or no treatment options. This will be achieved by confirming the safety of, and establishing the correct doses for, such



3 million children died of infectious diseases — including serious bacterial infections — in 2013⁸

antibiotics in children of all ages by completing paediatric development plans agreed with regulatory agencies in the US and Europe.

Following the agreement signed between GARDP and Venatorx Pharmaceuticals, (see 'Serious Bacterial Infections'), one of the first compounds we are examining is cefepime-taniborbactam, which is currently undergoing a phase 3 trial for use in adults. GARDP will seek regulatory approval for the use of cefepime-taniborbactam in children and newborns.

With the support of GARDP, Venatorx has led the creation of paediatric development plans for cefepime-taniborbactam, which were agreed with the European Medicines Association (EMA) and the US Food and Drug Administration (FDA) in 2020. We will begin implementing these paediatric development plans this year, with a view to beginning the first paediatric clinical trial of cefepime-taniborbactam in 2022 (pending the outcome of the phase 3 trial in adults).

GARDP also continued to evaluate the potential of a partnership to support a paediatric development programme for polymyxin B. This existing antibiotic shows activity against multidrug-resistant infections in adults, but there are currently limited data around its safe and effective use in children and newborns.

Only two out of 37 new antibiotics being developed in adults were being studied in children as of 2017⁹

⁸ Fleischmann-Struzek C, Goldfarb D M, Schlattmann P, Schlapbach L J, Reinhart K, Kissoon N. 'The global burden of paediatric and neonatal sepsis: a systematic review'. *The Lancet*. 2018;6(3):223–230.
⁹ Thompson G, Barker C I, Folgori L, Bielicki J A, Bradley J S, Lutsar I et al. 'Global shortage of neonatal and paediatric antibiotic trials: rapid review'. *BMJ Open*. 2017;7(10).

SEXUALLY TRANSMITTED INFECTIONS

DEVELOPING A NEW TREATMENT FOR GONORRHOEA DURING A GLOBAL PANDEMIC

With 87 million new infections globally each year, gonorrhoea is one of the most common of all sexually transmitted infections (STIs)—and growing antibiotic resistance is making the disease increasingly difficult to treat. To address this challenge, GARDP is working to develop a new drug that could re-enable effective treatment of gonorrhoea resistant to current antibiotics. And we have been doing so despite the significant challenges caused by the COVID-19 pandemic.

Like all STIs, gonorrhoea is becoming more common, particularly among 15-to-24-year olds. The disease disproportionately affects women, in whom it can cause infertility, pelvic inflammatory disease and life-threatening ectopic pregnancies. Gonorrhoea is also a risk to developing babies—alongside the possibility of the infection being transmitted from mother to child, gonorrhoea can also cause prematurity, low birth weight and even death.

Worse, gonorrhoea is now significantly less treatable than it used to be, having slowly become resistant to many antibiotics that were once highly effective treatments. And if we don't act now, the problem will continue to get worse.

To address this challenge, GARDP has partnered with US biotech company Entasis Therapeutics to develop

zolidodacin, a new antibiotic being developed specifically to treat resistant strains of gonorrhoea.

PATIENT ENROLMENT PAUSED

To gain regulatory approval for zolidodacin, GARDP and Entasis Therapeutics agreed a joint development plan that includes a phase 3 clinical trial across 12 sites in the Netherlands, South Africa, Thailand and the US. By early 2020, all US sites were actively recruiting participants and preparations to activate sites in the Netherlands, South Africa and Thailand were well underway.

Unfortunately, 2020 was not destined to be a normal year. Soon, it became clear that the unfolding COVID-19 pandemic would have a significant impact on the conduct of the study. The GARDP study team's initial approach was to work with all sites on evaluating the impact of the pandemic to establish whether it would be possible to continue the study while prioritizing patient and staff safety. We concluded that COVID-19 restrictions would make it impossible for sites to operate due to low staff availability and patients not seeking health-care. Moreover, subsequent travel restrictions would also pose a challenge for both new site set-ups and existing sites' training and monitoring visits.

As a result, following close consultations with all sites, GARDP decided to pause all patient enrolment in the US (notifying ethics committees and the FDA) and site activations in all other countries on 19 March.

WORKING THROUGH THE CRISIS

By June, we had begun working closely with our sites on a re-launch strategy, which we based on an ongoing evaluation of how to conduct the study safely while continuing to collect high-quality data. Although the steps taken will vary between sites depending on local context and guidance, all sites agreed a procedure with GARDP as sponsor before resuming patient enrolment. The measures implemented may include pre-screening patients for respiratory symptoms and recent exposure to SARS-CoV-2 prior to clinic visits, remote consultations where possible, and physical distancing and protective equipment where in-person interaction is required.

As the pandemic progressed throughout 2020, this re-launch and new site activation strategy was subject to repeated site closures, the pandemic's significant impact on clinic diagnostic supplies, and the requisitioning of laboratory and clinic resources for COVID-19 testing and research. Nevertheless, we have maintained our focus on supporting safe patient enrolment in existing sites and remote new site activations.

Unavoidably, the delays have had a significant impact on patient recruitment. Therefore, we will explore the option of adding new sites to support enrolment targets and continue meeting the overall quality standards required.



10,000 people are infected with gonorrhoea every hour¹⁰



87 million new cases of gonorrhoea are diagnosed each year¹⁰

FORGING AHEAD

The COVID-19 pandemic has posed tremendous difficulties not only for our study but also for researchers worldwide. Nevertheless, we must not allow such challenges to prevent us from tackling the slower-moving—though equally critical—pandemic of drug-resistant infections and its impact on the treatment of priority STIs like gonorrhoea.

To that end, in November 2020, **GARDP** announced its MOU with the Foundation for Innovative New Diagnostics (FIND) and the WHO. It commits us to working with FIND and WHO to explore joint initiatives, with an initial priority focus on STIs, that could improve sustainable access to antibiotics and protect them against the emergence of antimicrobial resistance. We will work

on a joint project to roll out and scale up the use of a point-of care test along with zoliflodacin treatment for improved clinical management, stewardship and public health value. This will generate the evidence required to strengthen national and international treatment guidelines and implementation strategies.

By adapting to a changing world, we will continue working to ensure that developing effective treatments for gonorrhoea remains a global health priority.

SEXUALLY TRANSMITTED INFECTIONS

SOUTH AFRICA ON THE FRONTLINE OF DEVELOPING A GONORRHOEA TREATMENT

South Africa is one of four countries where GARDP is engaged in a phase 3 trial to develop a treatment for gonorrhoea, which affects millions of people across the world every year.

“Because of the high prevalence of gonorrhoea in South Africa, particularly in young women, South Africa is an ideal country in which to conduct this trial. South Africa also has a large population of people living with HIV. This is an important group to include in the study, as we also need to understand the efficacy and pharmacokinetics of zoliflodacin in people who are HIV-positive,” said Jeanne Omony, a research doctor at the Wits Repro-

ductive Health and HIV Institute (Wits RHI) in Hillbrow, Johannesburg, and one of the investigators on the zoliflodacin study.

Edward Mukwaya, **GARDP**’s clinical trial manager, said South Africa’s research experience holds it in good stead. *“Among the countries with a high prevalence of gonorrhoea, South Africa also has a robust health research infrastructure, with highly*

qualified and experienced researchers as well as other amenities crucial to health research, such as well-equipped laboratories.”

The first site in South Africa was activated in late January 2021. Three sites are taking part in the study: the Wits Reproductive Health and HIV Institute (Wits RHI) based at the Hillbrow Health Precinct in Johannesburg, and two



South African Medical Research Council (SAMRC) sites at Tongaat and Botha's Hill in South Africa's Kwazulu-Natal province.

The Sexually Transmitted Infections Section Centre at the National Institute for Communicable Diseases is playing a leading role in testing and collating microbiological samples from the South Afri-

can study sites, for quality control and shipment to the central lab in the USA.

For Dr Omony, the trial is a very positive move in its quest to improve testing and treatment for gonorrhoea, as well as breaking down stigma around STIs. "Our clinic focuses on empowering young women to play active roles in their relation-

ships and to advocate for themselves, negotiating safe sex practices, including partner treatment of STIs. We also do a lot of education surrounding causes, spread, symptoms and complications of STIs and encourage our participants to bring their partners in for treatment."

GARDP has shown great progress in driving forward global health goals in such a challenging year. The UK is proud to partner with them in leading the fight against antimicrobial resistance.

LORD BETHELL
UK MINISTER FOR INNOVATION

SERIOUS BACTERIAL INFECTIONS

ADDRESSING DIFFICULT TO TREAT INFECTIONS IN HOSPITALS

With hospital infections resulting in around 37,000 deaths every year in Europe alone¹¹, we are in desperate need of new tools to combat the growing problem of antibiotic resistance. As the fight against this silent pandemic grows more urgent, GARDP is helping to develop a new antibiotic that could treat serious bacterial infections.

In high-income countries, around 7% of hospitalized patients will contract a bacterial infection, with that proportion rising to 1 in 3 in intensive care units (ICUs)¹². The elderly and immunocompromised are particularly vulnerable, with 1 in 10 cancer deaths being due to severe sepsis rather than the cancer itself¹³.

Although the data show that a low percentage of COVID-19 patients develop serious bacterial infections—around 3–5%, according to the most recent studies¹⁴—this is a complex problem that depends largely on the quality of the infection prevention and control measures hospitals have in place. That quality tends to be lower in LMICs, where far more hospitalized patients—10% of all patients and one in two ICU patients¹²—will contract a bacterial infection than in high-income countries.

Moreover, despite the relatively low rates of serious hospital-acquired bacterial infections in COVID-19 patients, the same studies show that around 80% of all hospitalized COVID-19 patients receive prophylactic antibiotic treatments¹⁵. As a result of these unnecessary antibiotic prescriptions, the pandemic could end up contributing to a rise in drug-resistant infections.

A GROWING PROBLEM

Antimicrobial resistance is making serious hospital infections much more difficult to treat. Hospitals generally reserve the carbapenem class of antibiotics for those patients whose infections are caused by bacteria resistant to cephalosporins and other beta-lactam antibiotics. However, increasing use of carbapenems has resulted in emerging resistance in key members of the *Enterobacterales* family of bacteria and some strains of *Pseudomonas aeruginosa* and *Acinetobacter baumannii*. These bacteria can enter the body through

¹¹ WHO. 'Report on the Burden of Endemic Health Care-Associated Infection Worldwide'. 2011.

¹² WHO Healthcare-associated infections factsheet. https://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf.

¹³ The PEW Charitable Trusts. <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/broken-antibiotics-market-puts-cancer-treatments-at-risk>.

¹⁴ Contagion. <https://www.contagionlive.com/view/bacterial-co-infections-among-us-patients-with-coronavirus-disease-2019>.

wounds, surgery incisions, ventilators and catheters, which could lead to lung, urinary tract, abdominal and bloodstream infections. To combat the unique resistance mechanisms that are making carbapenems less effective at treating certain strains of these bacteria, we urgently need to develop new drugs.

In many South African hospitals, for instance, 95% of *A. baumannii* are now carbapenem-resistant¹⁶. And the problem is getting worse.

MOUNTING A RESPONSE

To address this challenge, the objective of **GARDP**'s Serious Bacterial Infections (SBI) programme is to identify, review and evaluate both recovered assets and new chemical entities in development that show activity against WHO's priority pathogens.

Last year, in the first of several anticipated partnerships for the SBI programme, **GARDP** signed an agreement with Venatorx Pharmaceuticals to accelerate the development of and access to cefepime-taniborbactam, a new compound that could show activity against infections caused by two of the three WHO priority pathogens: carbapenem-resistant *Enterobacterales* and *Pseudomonas*. Taniborbactam blocks the activity of enzymes produced by these two pathogens that makes them resistant to carbapenems so that its companion antibiotic, cefepime, can go to work. As a result, cefepime-taniborbactam has the potential to become a safe and effective treatment for adults and children with serious bacterial infections, including those caused by bacteria that are resistant to last-line antibiotics.

PUSHING SAFELY THROUGH THE PANDEMIC

Our collaboration with Venatorx includes an observational study that will examine the frequency, treatment methods and outcomes in patients with carbapenem-resistant bacterial infections. Since such infections are particularly prevalent in India and South Africa, the sites involved in the observational study will be located in these two countries and are likely to participate in a future interventional trial of cefepime-taniborbactam in serious carbapenem-resistant bacterial infections. An additional objective of the observational study is knowledge exchange in regards to clinical trials for regulatory purposes, with the potential for creating clinical trial networks in India and South Africa that other programmes can use for future antibiotic studies.

We are also supporting a phase 3 Venatorx-sponsored trial to test the efficacy and safety of cefepime-taniborbactam in patients with complicated urinary tract infections (cUTI). This pivotal trial will pave the way for the initial new drug registration and eventual approval of cefepime-taniborbactam by the FDA and EMA. In addition, we will conduct trials to enable cefepime-taniborbactam to be used in children and newborns (see 'Children's Antibiotics'). Once approved for clinical use, Venatorx has granted **GARDP** exclusive rights to license and distribute cefepime-taniborbactam throughout most LMICs.

Unfortunately, the COVID-19 pandemic has hampered our progress on these fronts. With researchers unable to visit sites due to travel restrictions and ICU

workers focusing on caring for COVID-19 patients, both the start of the observational study and the cUTI clinical trial have suffered delays. Despite these issues, **GARDP** and Venatorx have completed some important preliminary steps for the observational study. We have agreed the protocol for the observational study,

while all countries have now re-opened for enrolment in the cUTI trial and are actively recruiting patients. We aim to complete enrolment for the cUTI study in 2021 and begin recruiting for the observational study in early 2022.



“Our partnership with **GARDP** is vital for advancing cefepime-taniborbactam through phase 3 clinical trials and affording access to patients, including children, who are more susceptible to hard-to-treat bacterial infections.”

CHRISTOPHER J. BURNS, Ph.D.

PRESIDENT AND CEO OF VENATORX PHARMACEUTICALS

¹⁶ Langford BJ, So M, Folgori L, Raybardhan S, Leung V, Soucy JR et al. 'Antibiotic prescribing in patients with COVID-19: rapid review and meta-analysis'. *Clinical Microbiology and Infection*. 2021;27(4).

¹⁶ National Institute for Communicable Diseases of South Africa. <https://www.nicd.ac.za>

SERIOUS BACTERIAL INFECTIONS

A YOUNG DOCTOR FACES CHALLENGE OF ANTIBIOTIC RESISTANCE DURING COVID-19

For young South African doctor Chelsea Kruger, working in a COVID-19 ward at the height of the first wave of the pandemic was compounded by the frightening reality of an outbreak of an antibiotic-resistant bacterial infection. *Klebsiella pneumoniae*, a Gram-negative bacteria that can cause pneumonia and bloodstream infections in hospitalized patients, spread through the COVID-19 intensive care unit (ICU) in a Johannesburg hospital where she was working.

“We were already facing an uphill battle with COVID-19. Not only were patients battling with the virus, they then had to face a secondary infection on top of it, which could often not be treated because of antibiotic resistance,” described Kruger.

“It took COVID-19 to make me realize how crucial it is to have effective antibiotics. After you have depleted all the drugs you have available, and you are on an antibiotic of last resort, you find your patient is resistant to it. That makes you feel so helpless. You have the knowledge and the skills, but not the resources.”

The textbook theory about antimicrobial resistance she had acquired as a university student only a few years earlier suddenly became very tangible. “Although some patients responded very well to the antibiotics that were available, there were some that were very resistant,” said Kruger.

“During that time, more patients were dying than we were discharging. It was often the bacterial infections, rather than COVID, that caused them to fight for their lives, and sadly some didn’t make it,” said Kruger.

Describing the challenge of facing a situation when a couple was admitted to the same COVID-19 ICU ward, Kruger said, “The husband was doing really well and his wife seemed to be recovering too. But, all of a sudden,

she deteriorated very rapidly. She died from an overwhelming sepsis, which was very resistant to the antibiotics we had available. We didn’t have anything to treat her with. It was devastating to tell her husband.”

Dr. Chelsea Kruger preparing for work in the COVID-19 intensive care unit. Every day, she meticulously changed into full personal protective equipment (PPE). It’s one crucial way to both stop the spread of COVID-19 and keep frontline workers safe. The COVID-19 pandemic has highlighted the importance of measures to prevent and control the spread of infection. It’s also shone a spotlight on the importance of addressing the pandemic of antibiotic resistance.



In high-income countries, **7% of all hospitalized patients** will contract an infection, including one in three people in intensive care units¹²

IN EUROPE EACH YEAR, HOSPITAL INFECTIONS RESULT IN...



16 million additional days in hospital¹¹
37,000 deaths¹¹
A cost to the economy of €7 billion¹¹

“Antibiotic resistance is on the rise, and we urgently need new antibiotics to treat resistant infections. It is about time that we focus on the WHO priority pathogens, which pose such a great threat to public health. We need to keep bacterial infections treatable.”

Kruger says that developing new antibiotics to prevent deaths from hospital-acquired infections is vital. “Antibiotics save lives, but only if they are sensitive,” said Kruger. WHO has declared that AMR is one of the top 10 global public health threats facing humanity.

“I’m very excited to know that new antibiotics are in the pipeline,” Kruger said.

Kruger also said she has learned valuable lessons about antibiotic stewardship and the importance of resisting the temptation to prescribe antibiotics when they are not essential. “Often doctors feel the pressure to prescribe antibiotics, even when they know the patient doesn’t have a confirmed bacterial infection,” Kruger explained. “Patients have grown to expect doctors to prescribe antibiotics. But it can be a big mistake. We need to find

ways to ensure we are prescribing the right antibiotics, and only when absolutely necessary.”

Misuse and overuse of antimicrobials are the main drivers in the development of drug-resistant pathogens. Kruger sees a glimmer of hope from her COVID-19 experience, in that people across the world have realized they can play their part in preventing infection.

“Wearing a mask, sanitizing and washing your hands is actually a very selfless act,” said Kruger. “We want to protect other people from infection. In doing this, every individual realizes: ‘I can contribute to the solution. It’s in my hands to do it.’” Kruger hopes this kind of awareness can be used to prevent more bacterial infections in hospitals and in the community.

More than **2.8 million** antibiotic-resistant infections occur in the US each year, and more than **35,000 people** die as a result¹⁷

*“As a doctor, it makes me breathe a sigh of relief to know that there is ongoing work by **GARDP** to develop antibiotics to combat at least some of these drug-resistant infections and get them to the people who need them.”*



In LMICs, **10% of hospitalized patients** will develop an infection, including one in two people in intensive care units¹²

¹⁷ Centers for Disease Control and Prevention. <https://www.cdc.gov/drugresistance/biggest-threats.html>.

ADVANCING ANTIBIOTIC R&D

RESTORING OUR ANTIBIOTIC PIPELINE & KNOWLEDGE SHARING

GARDP's Advancing Antibiotic R&D activities include Asset Evaluation and Development, Discovery and Exploratory Research, and Scientific Affairs.

ASSET EVALUATION & DEVELOPMENT

Once identified and optimized, new compounds may enter pre-clinical development and feed into the global antibiotic pipeline and possibly be future candidates for GARDP's clinical programmes

focused on difficult-to-treat infections, high priority pathogens, and vulnerable populations. GARDP is also working to repurpose under-used or forgotten compounds alone or in combination.

In 2020, GARDP evaluated ten new assets by conducting systematic reviews and meta-analyses of antibiotic combinations used on carbapenem-resistant pathogens.

In April, GARDP and Venatorx Pharmaceuticals announced a collaboration for the co-development of cefepime-taniborbactam, an asset identified by the asset evaluation and development programme in 2019. We integrated this new compound

into our programme for the treatment of serious carbapenem-resistant infections (see 'Serious Bacterial Infections' to find out more).

With cefepime-taniborbactam active against two of WHO's three carbapenem-resistant priority pathogens, our current focus is on identifying compounds that complement the activity of cefepime-taniborbactam by having the potential to cover the third: carbapenem-resistant

Acinetobacter baumannii. In 2020, we evaluated four potential assets in clinical development and are having ongoing discussions with the companies that own these compounds.

The Asset Evaluation and Development team also began conducting non-clinical studies on an approved asset to determine whether it may also work as a potential treatment for STIs.



DISCOVERY & EXPLORATORY RESEARCH

GARDP's Discovery and Exploratory Research activities aim to build a portfolio of new chemical entities with activity against

drug-resistant Gram-negative bacterial infections that urgently require new treatments.

The Discovery and Exploratory Research (DER) activities currently focus on *Klebsiella pneumoniae* and *Acinetobacter baumannii*, two Gram-negative bacterial species on WHO's priority pathogen list. These species often cause difficult-to-treat hospital-acquired infections, including bloodstream infections. GARDP's approach to DER focuses on activities that no other organization is or has undertaken. This includes negotiating access to and screening synthetic and natural compound libraries that not been screened against these bacterial species.

In March, Daiichi Sankyo joined the GARDP-led AMR Screening Consortium alongside Eisai and Takeda. Daiichi Sankyo contributed a chemical library from their proprietary collection that the Institut Pasteur Korea screened in GARDP-designed antibacterial assays. We also identified and prioritized three compounds from the AMR Screening Consortium partner libraries with activity against the DER target bacterial species for further investigation and generation of analogues in 2021.

In 2020, GARDP screened over 24,000 compounds from five different partners, bringing the total number of compounds screened since inception to 65,045. To identify novel compounds for screening, GARDP and DNDi performed computer analyses of over 700,000 compounds from 25 natural product and/or natural product-like compound libraries with chemical properties associated with good activity for gram-negative bacteria. These analyses will inform the selection of libraries with a high percentage of novelty and/or diversity for screening against *Klebsiella pneumoniae* and/or *Acinetobacter baumannii*.

GARDP also carried out a project to identify promising early-phase Gram-negative anti-bacterial drug discovery projects in publicly available databases. These databases detail projects funded by the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) Member States, the Wellcome Trust, and the European Commission between 2007 and 2019. These projects were filtered based on GARDP's strategic priorities of

new chemical classes and/or bacterial targets that have the potential to deliver new antibiotic classes that are active against *Enterobacterales* and/or *A. baumannii*. We applied the same inclusion and exclusion criteria to the 2019 WHO open-access database that lists antibacterial agents in preclinical development. In 2021, GARDP will deliver a report summarizing the findings of this project, together with a list of projects that are of potential interest and could form the basis of a future GARDP project.

SCIENTIFIC AFFAIRS

GARDP's Scientific Affairs education and outreach activities aim to promote existing knowledge and expertise and share new discoveries

Throughout 2020, **GARDP's** Scientific Affairs team organized and broadcast 17 webinars to over 3,800 people from more than 100 countries. It also collaborated with external organizations to develop sessions at key conferences including the fourth annual BIO-COM AMR Conference, where **GARDP** co-organized the session 'Top 10 mistakes in antibacterial development'.

GARDP co-developed two 'Bootcamps' for the American Society for Microbiology (ASM) and European Society for Clinical Microbiology and Infectious Diseases (ESCMID) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. Following the conference's cancellation due to the COVID-19 pandemic, these Bootcamps were delivered as REVIVE webinars by **GARDP**.

and tools with the antibiotic R&D community, mainly through the online platform REVIVE.

Following the signing of **GARDP's** Memorandum of Understanding with the British Society for Antimicrobial Chemotherapy (BSAC) to establish a framework for collaborating on education, policy and advocacy activities, **GARDP** and BSAC worked together to organize the second Antimicrobial Chemotherapy Conference, to be held in February 2021.

Our Scientific Affairs activities include the REVIVE webinar series, as well as Antimicrobial Viewpoint articles written by international experts from fields including economics, antimicrobial stewardship and drug development. In 2020, **GARDP** published 17 new Antimicrobial Viewpoints.

In October 2020, **GARDP** launched a new Antimicrobial Encyclopaedia to provide definitions of key terms in the field. At launch, the Encyclopaedia included over

70 definitions and eight videos from external contributors and **GARDP** experts, with more to come. In addition, **GARDP** developed and launched a Resource Library to host all of its content in a single location and provide links to valuable external resources relevant to antimicrobial R&D. The Resource Library also includes an advanced search function. **GARDP's** materials have been accessed from the REVIVE website (revive.gardp.org) by users in 182 countries.

REVIVE is currently supported by 129 experts from 21 countries. In addition to the expert network, the Scientific Affairs team has also built relationships with over 70 scientific societies and partner organizations worldwide that support the dissemination of **GARDP's** materials to the global antimicrobial R&D community.

THREE AIMS OF REVIVE



ACCESS

WHY WE NEED A NEW ACCESS MODEL FOR ANTIBIOTICS

Every year, 5.7 million people lose their lives because they cannot access the antibiotics they need—eight times the number of deaths due to antibiotic resistance¹⁸. To address this tragic problem, we urgently need a new access model for new and existing antibiotics.

THE CHALLENGE OF ANTIBIOTIC ACCESS

Most new antibiotics are unavailable in much of the world, especially in LMICs. Of the 25 new chemical entities (NCEs) developed between 1999 and 2014, only 12 have registered sales in more than ten countries¹⁹. Furthermore, the development of new antibiotics faces several challenges which makes them less appealing to investors than other drugs. As a result, small and medium-sized enterprises (SMEs), the main drivers of antibiotic innovation, are unable to ensure global distribution of their products nor even, in many cases, to invest in their development.

Meanwhile, many of the antibiotics developed in the 20th century are still used as first-line treatments for

common infections. However, supply issues often limit patients' access to these vital drugs. And with the supply chains of existing antibiotics becoming increasingly fragmented, shortages are likely to become increasingly common.

IN SEARCH OF NEW SOLUTIONS

The global health threat of poor access to antibiotics urgently requires us to develop new concepts and mechanisms to improve the availability and affordability of these life-saving drugs. To that end, **GARDP** has developed an access strategy that focuses on four pillars - evidence generation, early introduction, regulatory, and sustainable manufacturing and commercialisation. **GARDP** is working with WHO and other international bodies on a new initiative called SECURE that

SECURE AIMS TO:

1. Provide member countries with sustainable access to a portfolio of essential new antibiotic treatments to address drug-resistant infections and existing antibiotics that suffer from frequent supply chain interruptions and shortages.
2. Align public health needs, local demand, supply and usage of antibiotics available through SECURE by interacting with member countries, originators, manufacturers and other stakeholders to address barriers and promote positive change.
3. Promote the appropriate use of these new antibiotic treatments by generating the evidence needed to implement these treatments.

will examine new access models for essential antibiotics, particularly for countries with a high burden of drug-resistant bacterial infections.

Besides helping countries fight drug-resistant infections, **GARDP** expects this endeavour to benefit the global

public health community by ensuring antibiotic security, a key component of pandemic preparedness.

Much remains to be done to ensure that antibiotics are available for everyone who needs them. And with millions of lives at stake each year, we have no time to lose.

¹⁸ Center For Disease Dynamics, Economics & Policy (CDDEP). <https://cddep.org/publications/access-barriers-to-antibiotics/>

¹⁹ Källberg C, Årdal C, Salvanes Blix H, Klein E, Martinez E M, Lindbæk M et al. Introduction and geographic availability of new antibiotics approved between 1999 and 2014'. *PLOS ONE*. 2018;13(10).

FINANCE

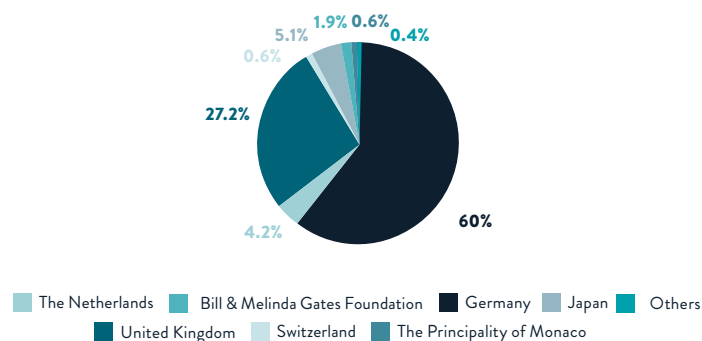
INCOME

NEW AND RENEWED FUNDING SHOWS COMMITMENT TO GARDP MISSION

GARDP's income grew by 27% between 2019 and 2020. Germany's Federal Ministry of Education and Research (BMBF) and the UK's Department of Health and Social Care (DHSC) increased their financial support to **GARDP** in 2020 by contributing a further EUR 5M and £2.5M respectively. The Leo Model Foundation also extended its support to **GARDP** with an additional USD 50,000. New funding of \$1.8M was received from the Japanese Ministry of Health, Labour and Welfare, with a pledge for a further \$7.2M over the next four years, bringing the total amount of funding in 2020 to EUR 24M. By the end of 2020, **GARDP** had secured a total of EUR 97M in commitments (91M) and pledges (6M).

FUNDER	%	IN M EUR
Germany (BMBF & BMG)	60 %	14.5 M
Netherlands (VWS)	4.2 %	1.0 M
United Kingdom (DFID, DHSC - GAMRIF and NIHR)	27.2 %	6.5 M
Switzerland (FOPH)	0.6 %	0.1 M
Japan (Ministry of Health, Labour & Welfare)	5.1 %	1.2 M
Bill and Melinda Gates Foundation	1.9 %	0.5 M
The Principality of Monaco	0.6 %	0.1 M
Others (South African MRC, Leo Model Foundation, Ministry of Health, Luxembourg)	0.4 %	0.1 M
Total		24 M

Total 2020 funding
EUR 24 M



FINANCE

EXPENDITURE

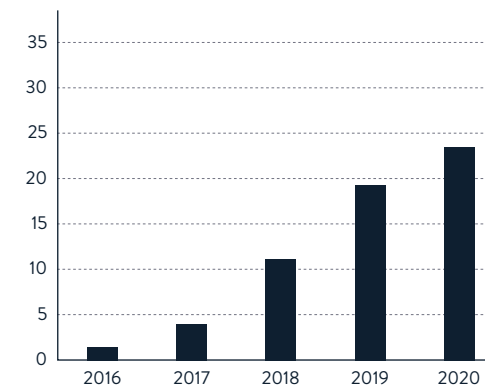
STEADY GROWTH IN SPENDING, CONCENTRATED ON R&D

Overall operational expenditure totalled 23.7M in 2020, an increase of 26% (+EUR 4.8M) over EUR 18.9M in 2019.

R&D expenditure totalled EUR 19.7M and spending on social mission equated to 89% of total expenditure.

Total **GARDP** expenditure since the start of its incubation within DNDi in 2016 totals EUR 59M.

Actual expenditure 2016-2020
(In million EUR)

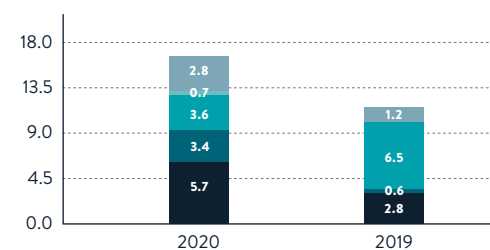


R&D EXPENDITURE

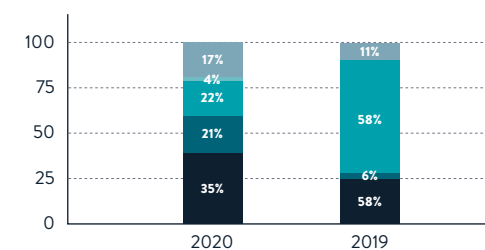
R&D spending per programme increased by EUR 5M in 2020 compared to 2019, with the largest proportion being spent within the Children's Antibiotics

programme - Neonatal Sepsis (EUR 5.7 M), followed by the Sexually Transmitted Infections programme (EUR 3.6 M).

R&D expenses per programme
(In million EUR)



R&D expenses per programme
(In %)



* - Previously called Antimicrobial Memory Recovery and Exploratory/Discovery & Exploratory in 2019 report

FINANCE

STATEMENT OF OPERATIONS

AT 31 DECEMBER 2020 WITH COMPARATIVE FIGURES

INCOME (EUR)	2020	2019
Total public institutional funding	23'440'130	17'402'268
Total private funding	493'027	1'515'832
Other income	75'239	6'412
TOTAL INCOME	24'008'397	18'924'512
SOCIAL MISSION EXPENDITURE (EUR)	2020	2019
Research & development expenditure:		
Research & development coordination and supervision	3'486'875	4'250'544
Children's Antibiotics - Neonatal Sepsis	5'682'538	2'801'705
Children's Antibiotics - Paediatric Development	3'440'195	640'190
Sexually Transmitted Infections	3'563'221	6'510'041
Serious Bacterial Infections	703'143	-
Advancing Antibiotic Research and Development*	2'801'504	1'236'462
Total research & development expenditure	19'677'476	15'438'942
International network expenditure	1'394'813	1'049'697
TOTAL SOCIAL MISSION EXPENDITURE	21'072'289	16'488'639
NON-SOCIAL MISSION EXPENDITURE (EUR)	2020	2019
Fundraising & General and Administration	2'642'344	2'386'869
Total non-social mission expenditure	2'642'344	2'386'869
TOTAL EXPENDITURE	23'714'634	18'875'508
Operating surplus / (loss)	293'763	49'004
OTHER INCOME (EXPENSES) (EUR)	2020	2019
Financial income, net	7'893	572
Exchange gain (loss), net	(293'764)	(49'002)
TOTAL OTHER INCOME (EXPENSES)	(285'871)	(49'002)
Net surplus for the year prior to allocations	7'892	2
Allocation to unrestricted operating funds	(7'892)	(2)
NET SURPLUS FOR THE YEAR AFTER ALLOCATIONS	-	-

* - Previously called Antimicrobial Memory Recovery and Exploratory/Discovery & Exploratory in 2019 report

Extracted from the unaudited "2020 Finance & Performance Report". The full report, audited by Deloitte, will be available in July 2021 on www.gardp.org

PARTNERS

INVESTORS IN THE FUTURE

A WORD OF THANKS

GARDP aims to build an antibiotic portfolio and deliver 5 new treatments by 2025 for drug-resistant infections that pose the greatest threat to health. **GARDP** is extremely grateful for the commitment of all its funders in helping us address the silent pandemic of drug-resistant infections. Thank you for your loyal support



*“**GARDP** brings together the public and private sectors to invest in public-health driven antibiotic R&D and access to develop critically needed treatments for drug-resistant infections. Japan is proud to support **GARDP**’s vision and mission as it strives to ensure that all bacterial infections are treatable to everyone, everywhere through appropriate use of antibiotics.”*

FUKUSHIMA YASUMASA
CHIEF MEDICAL AND GLOBAL HEALTH OFFICER,
MINISTRY OF HEALTH, LABOUR AND WELFARE, JAPAN

PARTNERS

HELPING GARDP MAKE A DIFFERENCE

Partnerships with governments, academia, research centres and industry are at the heart of GARDP's work. Without the support of partners, GARDP would not have been able to achieve its milestones so far:

AUSTRALIA

Australian Research Council Research Hub to Combat Antimicrobial Resistance
University of Queensland including the Community for Open Antimicrobial Drug Discovery
Kirby Institute
Melbourne Sexual Health Clinic

BELGIUM

University of Antwerp

BANGLADESH

Dhaka Shishu Hospital, Dhaka

BRAZIL

FCM da santa casa de Sao Paulo
Hospital das Clínicas de Ribeirão Preto

CHINA

Shenzhen Children's Hospital, Shenzhen
Beijing Children's Hospital
Beijing Women and Children's Hospital

DENMARK

REPAIR Impact Fund

EUROPEAN UNION

Joint Programming Initiative on Antimicrobial Resistance

GERMANY

InfectoPharm
Helmholtz-Institute for Pharmaceutical Research Saarland

GREECE

Hippokraton Hospital, Thessaloniki

INDIA

Bugworks
Dr. Reddy's Laboratories Ltd.
Aurigene Pharmaceutical Services Limited
All India Institute of Medical Sciences
Indian Council of Medical Research
Jawaharlal Institute of Postgraduate Medical Education and Research Hospital, Pondicherry, Tamil Nadu
King Edward Memorial Hospital, Mumbai
Lady Hardinge Medical College, New Delhi

ITALY

Penta Foundation
Bambino Gesù Hospital, Rome

JAPAN

Shionogi
Takeda
Eisai
Daiichi Sankyo

KENYA

Kenyan Medical Research Institute
Kilifi General Hospital, KEMRI-Wellcome Trust Research Programme
Kilifi County Hospital

KOREA

Institut Pasteur Korea

THE NETHERLANDS

The Public Health Services of Amsterdam

SOUTH AFRICA

National Institute for Communicable Diseases
South African Medical Research Council
Stellenbosch University
University of KwaZulu Natal
Wits Health Consortium
Wits Reproductive Health and HIV Institute
Chris Hani Baragwanath Academic Hospital, Johannesburg
Charlotte Maxeke Academic Hospital, Johannesburg
Tygerberg Children's Hospital, Cape Town

SWEDEN

WHO Collaborating Centre for gonorrhoea and other Sexually Transmitted Infections, Department of Laboratory Medicine, Örebro University Hospital

SWITZERLAND

BioVersys
World Health Organization
Drugs for Neglected Diseases initiative
European Society of Clinical Microbiology and Infectious Diseases
Foundation for Innovative New Diagnostics

Sandoz, the Novartis generics division

THAILAND

Bangrak STIs Center, Division of AIDS and STIs, Department of Disease Control, Ministry of Public Health
Silom Community Clinic at the Hospital for Tropical Diseases
Institute for HIV Research and Innovation Foundation
Thailand MoPH U.S. CDC Collaboration Laboratory
The Diagnostic Laboratory Unit, Hospital for Tropical Diseases, Mahidol University
Siriraj Institute of Clinical Research, Faculty of Medicine Siriraj Hospital, Mahidol University
Queen Sirikit National Institute of Child Health, Bangkok
Chiang Rai Prachanukroh Hospital

UGANDA

Mulago Hospital, Kampala

UNITED KINGDOM

British Society of Antimicrobial Chemotherapy
St George's, University of London
Medical Research Council – Clinical Trials Unit at University College – London
The University of Liverpool
Wellcome Trust
Oxford University

UNITED STATES

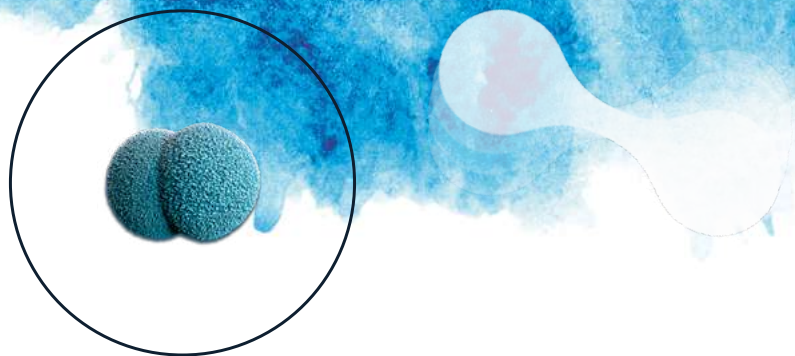
American Society of Microbiology
CARB-X
Entasis Therapeutics Ltd.
National Institutes of Health
National Institute of Allergy and Infectious Diseases

The Pew Charitable Trusts
University of Alabama at Birmingham
University of Florida
Venatorx Pharmaceuticals

VIETNAM

National Hospital of Pediatrics, Hanoi





EXECUTIVE STRUCTURE

GOVERNANCE & MANAGEMENT

BOARD OF DIRECTORS

GARDP's Board of Directors, which meets twice a year, is the ultimate policy and decision-making authority and includes leading international figures in global health. The Board, currently composed of seven members, determines **GARDP's** strategic goals and ensures the management works efficiently to meet them. It establishes the policies and principles followed by **GARDP** and appoints the Chair, Vice-chair, and Treasurer of the Board as well as the Executive Director.

BOARD MEMBERS

- Ramanan LAXMINARAYAN**
Chair, Center for Disease Dynamics, Economics and Policy, USA
- Marie-Paule KIENY**
Vice-chair, Institut national de la santé et de la recherche médicale, INSERM, France
- Frédéric VALLAT**
Treasurer, Ville de Genève, Switzerland
- Glenda GRAY**
South African Medical Research Council, South Africa
- Hiroki NAKATANI (new member)**
Global Research Institute, Keio University, Japan
- Mercedes TATAY**
Médecins Sans Frontières
- Veronika VON MESSLING**
Federal Ministry of Education and Research, Germany

OBSERVERS

- Hanan H. BALKHY (new observer)**
World Health Organization, Switzerland
- Prabhavathi FERNANDES**
Chair of the GARDP Scientific Advisory Committee
- Ambassador Nora KRONIG ROMERO (new observer)**
Chair of the GARDP Donor Partnership Advisory Committee
- Bernard PÉCOUL**
Drugs for Neglected Diseases initiative, Switzerland
- Manica BALASEGARAM**
Ex officio, GARDP

SCIENTIFIC ADVISORY COMMITTEE

GARDP's Scientific Advisory Committee (SAC) is made up of scientists with expertise in various disciplines within infectious diseases and microbiology. The SAC has a consultative function: its members advise and make recommendations to **GARDP's** Board of Directors in order to carry out **GARDP's** scientific objectives, assess its scientific strategy and projects and provide guidance and medical and scientific expertise to **GARDP's** programmes.

MEMBERS

- Prabhavathi FERNANDES**
Chair, USA
- Karl-Heinz ALTMANN**
Swiss Federal Institute of Technology, Switzerland
- Marc BONTEN**
University Medical Centre Utrecht, The Netherlands
- Anthony COATES**
St George's University, UK
- Mark J. GOLDBERGER**
Formerly AbbVie, USA
- William HOPE**
University of Liverpool, UK
- Kazuki HOSHINO**
Daiichi Sankyo, Japan (up to 30 April 2020)
- Rudo MATHIVHA**
Chris Hani Baragwanath Hospital, South Africa
- Marc MENDELSON**
University of Cape Town, South Africa
- Malcolm PAGE**
formerly Roche, Switzerland
- Andreas RUMMELT**
InterPharmaLink AG
- Kamini WALIA**
Indian Council of Medical Research, India
- Nicholas WHITE**
Mahidol University, Thailand

OBSERVERS

- Laurent FRAISSE**
Drugs for Neglected Diseases initiative, Switzerland
- Sarah PAULIN**
World Health Organization, Switzerland

DONOR PARTNERSHIP ADVISORY COMMITTEE

The Donor Partnership Advisory Committee (DPAC) ensures key funding partners are represented as stakeholders and partners in **GARDP**, allowing them to bring their insights to the Board. Importantly, it provides advice and funder perspectives that assist the Board in fulfilling its mission by reviewing the success of previous and ongoing donor investments made into **GARDP** and providing advice to the Board on how further funding can deliver the highest possible impact. It also provides advice to the Board on how **GARDP** can widen and better manage its partnerships with governments and other important global health funders. The Chair of the Committee represents the Committee at the Board meetings and ensures that key decisions of the Board are brought back to the full Committee.

MEMBERS

- Ambassador Nora KRONIG ROMERO**
Chair, Federal Office of Public Health, Switzerland
- Nireesh BHAGWANDIN**
South African Medical Research Council, South Africa
- Jasper CLAESSEN**
Ministry of Health, Netherlands
- Louise NORTON-SMITH**
Department of Health and Social Care, UK
- Dagmar REITENBACH**
Federal Ministry of Health, Germany
- Yasuyuki SAHARA**
Ministry of Health, Labor and Welfare, Japan

GARDP LEADERSHIP & PROGRAMMES

GARDP's leadership team and staff work to deliver on our vision by supporting the R&D ecosystem while developing and securing sustainable access to new treatments.

GARDP has a flexible R&D operating model that enables cross-functional project leadership integrating technical disciplines from across **GARDP** and our partners. At the core of the model is a collaborative project team focusing on the development of a drug and delivery of an antibiotic treatment. The collaborative project teams lead by **GARDP** project leaders follow development plans underpinned by target treatment/product profiles, with progress reviewed via **GARDP** R&D governance and a **GARDP** Board-appointed Scientific Advisory Committee.

GARDP DIRECTORS

Manica BALASEGARAM
Executive Director

Seamus O'BRIEN
Research & Development Director

Vincent CONSTANTIN
General Counsel

Pierre-Yves DELHEZ
Internal Operations Director

Jennifer KATZ
External Affairs Director

Jean-Pierre PACCAUD
Business Development and Corporate Strategy Director

Laura PIDDOCK
Scientific Affairs Director

Subasree SRINIVASAN
Consultant Medical Director

PROGRAMME LEADS

Emilie ALIROL
Sexually Transmitted Infections Project Leader (up to 30 September)

Seamus O'BRIEN
Sexually Transmitted Infections Interim Project Leader (as of 1 October)

Sally ELLIS
Children's Antibiotics Project Leader

François FRANCESCHI
Head of Asset Evaluation and Development and Serious Bacterial Infections Project Leader

Julie MIRALVES
R&D Portfolio and Planning Lead

GARDP WORLDWIDE

GARDP, through DNDi, has a global presence with regional offices in Africa, North America, Latin America and Southeast Asia, and country offices in Japan and India. In-country implementation of **GARDP's** programmes is supported by these offices and a joint DNDi-**GARDP** office for Southern Africa. **GARDP** also has representation in Australia.

GARDP's regional and country offices are critical in connecting us with partners and the people we serve. Staff in these offices oversee clinical trials and research, provide links to health ministries and national disease control programmes, patients, clinicians and researchers, and raise funds to make our work possible.

COLLABORATION

GARDP AND ITS FOUNDERS: A CLOSE COLLABORATION

Built on the shared missions of WHO and DNDi, **GARDP** draws its strength from WHO's mandate to drive the global response to AMR and set health priorities, and DNDi's expertise in harnessing partnerships with the public and private sectors and building a R&D pipeline focused on public health needs.

The idea for **GARDP** arose through consultations between WHO, DNDi and groups around the world working to address infectious diseases, with **GARDP** created in 2016 by WHO and DNDi. Hosted by DNDi for a three-year period, in 2019 **GARDP** became a fully independent organization.

GARDP continues to collaborate closely with WHO and DNDi, leveraging the organizations' knowledge and expertise in the global fight against antibiotic resistance.

This includes collaborating with WHO on developing strategies for regulatory approval and access and appropriate use. WHO also continues efforts to garner Member States support, and ensure effective liaison with WHO technical departments.

With DNDi, **GARDP** shares specialized R&D expertise and capacity, policy advocacy expertise, as well as infrastructure and support services to drive efficiencies. In-country implementation of **GARDP's** programmes are supported by DNDi's regional network and a joint DNDi-**GARDP** office for Southern Africa.

LOOKING AHEAD

2021 PRIORITIES

SEXUALLY TRANSMITTED INFECTIONS

In Q4 2020, GARDP initiated a consultation process with key experts around zoliflodacin, in order to identify the evidence necessary to understand public health need, optimize clinical management and support optimal use. We expect to finish the process by the end of 2021. Activities are already progressing to understand the prevalence of gonorrhoea in priority countries (including Kenya, South Africa and Thailand) and levels of antibiotic resistance in the relevant bacteria.

In early 2021, sites for the global phase 3 trial of zoliflodacin were activated in South Africa and Thailand, initiating the study in all participating countries.

CHILDREN'S ANTIBIOTICS

The main priority for GARDP's Children's Antibiotics programme is to use the information that was generated from its landmark observational study to design, obtain approvals and initiate an innovative strategic public health trial (phase IIIB) to evaluate new combinations of existing antibiotics to treat newborns with sepsis. This trial is slated to begin in 2022.

In collaboration with GARDP, in 2021 Venatorx will begin implementing paediatric development plans to obtain regulatory approval for the use of cefepime-taniborbactam in children and newborns following the completion of the adult phase 3 trial. We currently expect to begin a phase 3 paediatric trial of cefepime-taniborbactam in mid-2022.

GARDP aims to confirm a development asset that could address those difficult-to-treat resistant infections in children not covered by our current portfolio.

SERIOUS BACTERIAL INFECTIONS

In 2021 our partner Venatorx aims to complete one of the studies that form part of our agreement: the phase 3 interventional trial of cefepime-taniborbactam in cUTI

patients. We will complete all of the enabling activities for the observational study on carbapenem-resistant infections in 2021, and we expect enrolment to begin in early 2022.

ASSET EVALUATION & DEVELOPMENT

In 2021 we expect to finalize discussions with companies that own the four potential assets in clinical development which we evaluated in 2020. We will also continue exploration with several companies that are developing assets with the potential to address serious bacterial infections for which there are currently limited treatment options. This includes completing comprehensive due diligence as part of the asset evaluation process.

DISCOVERY & EXPLORATORY RESEARCH

We aim to complete our investigation into analogues of three series of novel chemical entities and will decide by the end of 2021 whether any are suitable to enter a hit-to-lead campaign. We will complete the horizon scanning activities, including reviews of efflux inhibitors as well as of potential targets for antibiotic discovery. We will also continue our cheminformatic activities that underpin the selection of new libraries for screening.

SCIENTIFIC AFFAIRS

In 2021, we will continue our successful REVIVE webinar program, conference participation and Antimicrobial Viewpoint series. The Antimicrobial Chemotherapy conference will be held in February 2021. New content will be added to the Antimicrobial Encyclopedia. To further extend our global engagement, we will add new REVIVE experts and collaborating and partner organizations. AMR Discussions, a new webinar series, will also be launched.

CONTACT

FOR MORE INFO

Global Antibiotic Research & Development Partnership (GARDP)

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