GARDP and Penta partner to accelerate the development of children's antibiotics to tackle AMR

Geneva /Padova, Monday 4 March 2019 – The Global Antibiotic Research & Development Partnership (GARDP) and Penta, the paediatric infectious diseases research network, have joined forces to tackle drug-resistant infections in children. The strategic collaboration aims to accelerate paediatric development of antibiotic treatments including: clinical trials designed to meet regulatory requirements; and trials with a focus on public health interventions to inform treatment guidelines.

Globally, more than three million childhood deaths result from infectious diseases, such as pneumonia and sepsis (1). Children are also particularly affected by antimicrobial resistance (AMR). In Europe, a recent study found that infants under one-year-old bear the highest burden of drug-resistant infections, with a major impact on health, economy and society (2). The impact is expected to be even more severe in many low and middle-income countries.

"Ending unnecessary childhood deaths is a global health priority" said Dr Manica Balasegaram, Executive Director, GARDP. *"Yet, severe lack of evidence is preventing the development of child-appropriate antibiotics for the treatment of drug-resistant infections. In response to this urgent global public health need, GARDP and Penta have embarked on a joint mission to develop and deliver accessible antibiotic treatments to tackle serious bacterial infections in children."*

Tackling AMR and its effects on children is critical to the attainment of the Sustainable Development Goals (SDGs), in particular the children's health targets under SDG 3, which aims to ensure healthy lives and promote wellbeing for all (3). Prioritising the development of child-friendly antibiotics is an essential component of this. Children, particularly babies and infants, need medicines that are adapted to their specific needs. Scarce evidence means child-friendly antibiotic treatment options are often limited, with paediatric evaluation of antibiotics only happening years after treatments are registered for use in adults.

GARDP and PENTA's partnership consolidates plans to help overcome this gap through the development of a global children's antibiotic platform. Building on Penta's international network of clinical trial sites and paediatric experts, the platform objectives include to: develop streamlined paediatric development plans acceptable to regulatory authorities; accelerate regulatory approval of treatments by ensuring children's trials are started as early as possible; and incorporate innovative designs to maximise the information that can be gained from each trial.

"*Clinical trials in children involve highly complex ethical, regulatory and study-design issues"* said Professor Carlo Giaquinto, President, Penta. "*This partnership consolidates existing efforts between GARDP and Penta, allowing us to maximise our expertise in the fields of paediatric treatments and AMR, including Penta's strong partnership with the Medical Research Council's Clinical Trial Unit in London. The knowledge created can help public health and industry partners to efficiently design and conduct their paediatric plans. This will speed-up access to antibiotics and facilitate the dissemination and routine implementation of global treatment guidelines".*

GARDP and Penta have established strong relationships with academic and/or government institutions from across Asia, Africa, Europe and South America. Partnerships with countries including Kenya, Greece, India, South Africa and Thailand underpin recent GARDP and Penta collaborations. These include a pharmacokinetic clinical trial in Kenya, to assess safety and dosing of the antibiotic fosfomycin in new-borns, which recently completed enrolment; and a large-scale global observational study on neonatal sepsis, collecting clinical information in up to 3,000 new-borns in 19 hospitals in 11 countries.

Such engagement from countries worldwide, will be critical to the success of the platform and its trial networks.

"*Country partnerships are critical for the children's antibiotic platform to flourish and reach its full potential" concluded Dr Balasegaram "GARDP and Penta call on governments worldwide, as well as academics, donors, maternal child health organizations, public institutions, the private sector, scientists and more, anyone with an interest in overcoming AMR in children – to join us."*

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Notes to Editors

A briefing note with further background on the need for children's antibiotics and the partnership is available here.

GARDP is a not-for-profit R&D organization that addresses global public health needs by developing and delivering new or improved antibiotic treatments, while endeavouring to ensure their sustainable access. Initiated by the WHO and the Drugs for Neglected Disease *initiative* (DND*i*), GARDP is an important element of WHO's Global Action Plan on Antimicrobial Resistance that calls for new public-private partnerships to encourage R&D of new antimicrobial agents and diagnostics. GARDP's programmes on sexually-transmitted infections, neonatal sepsis, paediatric antibiotics and antimicrobial memory recovery, evaluation and exploratory research are designed to address global public health priorities. Projects include the sponsoring of a phase III clinical trial for a novel, first-in-class oral antibiotic to treat drug-resistant gonorrhoea.

www.gardp.org

Penta, a leader in the evaluation of paediatric treatments since 1993 incorporates research centres and hospitals across the world, collaborating with more than 100 clinical centres in 18 countries, with strong training and educational programmes across the world. To date it has sponsored 22 clinical trials involving more than 3,000 children, as well as numerous immunological, pharmacokinetic, microbiological and other epidemiological studies. Penta is co-ordinating the new Innovative Medicine Initiative (IMI2) EU funded progamme, connect4children (c4c) to build a pan-European Paediatric Clinical Trial Network for medicine development and research. Penta is also involved with numerous other EU funded projects – including trials aimed at developing optimal dosing regimens for generic antibiotics in neonates.

www.penta-id.org

(1). Cassini, A. et al Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015 Lancet Infect Dis. 2019 Jan;19(1):56-66

(2). Sustainable Development Goals sustainabledevelopment.un.org/SDG3