News Release

AstraZeneca

INNOVATIVE PUBLIC-PRIVATE COLLABORATION LAUNCHES TO TACKLE ANTIBIOTIC RESEARCH

New €224m (£180m) funding to enable development of antibiotics for bacterial infections and drive unprecedented information sharing

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AstraZeneca and GlaxoSmithKline today welcomed the launch of a pioneering approach to antibiotic research in Europe that will see pharmaceutical and biotechnology companies working alongside public partners to tackle the rising threat from antibiotic resistance and address some of the key barriers to the development of effective antibiotics.

The objective of the proposed research programme is to improve the underlying scientific understanding of antibiotic resistance, design and implement efficient clinical trials and take novel drug candidates through clinical development. The programme is part of the European Commission's *Action Plan Against the Rising Threats from Antimicrobial Resistance*, launched in November last year.

Set against a backdrop of emerging resistant bacteria and with the pipeline of future antibiotics described by the World Health Organization (WHO) as "virtually dry", this innovative research programme, *NewDrugs4BadBugs*, intends to boost the currently faltering discovery and development of new antibiotics.

Supported by the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative, the research programme's first projects will be funded by a joint budget of up to €223.7 million – €109 million provided by IMI and €114.7 million in-kind contributions from the pharmaceutical and biotechnology companies involved. GlaxoSmithKline, AstraZeneca, Janssen, Sanofi and Basilea Pharmaceutica will work alongside public research organisations and scientific experts to address several aspects of resistance and stimulate new antibiotic research. Further projects within the programme, with additional funding, are expected to launch later in the year.

Antibiotic resistance is increasingly becoming a worldwide health threat. Many of the medical advances in recent years, such as chemotherapy for cancer treatment and organ transplantation, depend on effective antibiotics. Despite this need and the continued emergence of bacteria resistant to existing drugs, research has diminished over the past 15 years and few companies remain active in this area. This is due to the scientific difficulties in finding new agents that successfully target bacteria, regulatory complexities and a lack of the commercial incentives needed to encourage investment in this area and to fund future R&D.

Patrick Vallance, President, Pharmaceuticals R&D at GlaxoSmithKline, said: "The rise of infections such as MRSA is well known, but today marks a chance to reverse the threat. This announcement signals a new model of collaboration and a willingness to change and adapt to seek different solutions. GSK has a legacy in the development of new antibiotics going back 40 years and we remain active in this field of research. We can bring our

scientific innovation and expertise to this novel collaboration which, in combination with the different skills and resources provided by other partners, provides a real opportunity to address the needs of patients today and prepare for the potential threats of tomorrow."

Martin Mackay, President, R&D, at AstraZeneca, said: "The steady rise of drug-resistant bacteria is an imminent and urgent threat to public health, and without a reliable arsenal of effective antibiotics, modern medical care is not possible. Bacteria develop resistance as fast, or faster, than we can develop treatments and a combination of scientific, regulatory, and financial challenges have impeded new antibiotic development.

"It is time to tackle this issue in a different way, sharing information and expertise among public and private partners – collaboration of this type is critical if we are to speed up the discovery of these medicines to improve patient health."

The proposed research programme will initially focus on three key areas:

Progressing development of pipeline antibiotics

This funding will support new research that will progress potential antibiotics already under investigation through clinical trials and improve the design of future clinical trials.

GlaxoSmithKline's investigational antibiotic, GSK1322322, targeting multi-drug resistant respiratory and skin infections including MRSA (m*ethicillin resistant Staphylococcus aureus*) and currently in Phase II development, will be included in the research programme. Pending the results of ongoing work, these will be joined slightly later by AstraZeneca's MEDI4893, a novel investigational monoclonal antibody in early stage development that targets a toxin released by *Staphylococcus aureus* and AZD9773, an investigational treatment for severe sepsis and septic shock, conditions triggered by uncontrolled bacterial infection.

Information sharing

The collaboration will be underpinned by an unprecedented level of data and knowledge sharing. It is hoped that developing a platform to enable the sharing of knowledge and resources across multiple groups will improve the chances of success in developing the next generation of antibiotics.

A new information hub will allow the sharing of knowledge and data between participants and across the wider antibiotic research community to enable the field to learn from antibiotic development successes and failures and gain a shared and improved understanding of the science behind antibiotic resistance. This will minimise duplication of effort and reduce inefficiencies in future R&D, supporting antibiotic research through the life of the programme and beyond.

Participants will share information on the design of clinical trials and the data generated, to support development of novel trials in the future that will increase efficiency of antibiotic research. A clinical trial network will be established to evaluate antibiotics currently in development, enabling experts in clinical antibiotic research to work alongside the scientists developing future medicines.

Continuing research and discovering new antibiotics

Tackling infections caused by Gram-negative bacteria is a very difficult challenge, owing to the particular defence mechanisms they employ. There are few treatment options available and currently limited ongoing development activities in this area. This research programme aims to find more approaches to the design of antibiotics that could be effective against Gram-negative bacteria, increase understanding of their defence mechanisms and use this knowledge to support future drug discovery efforts.

Key to the success of *NewDrugs4BadBugs* will be the involvement of multiple public partners from across Europe. Public institutions and research organisations, clinical investigators and scientific experts are being encouraged to learn more about the proposed research programme through a series of events. Full details can be found at www.imi.europa.eu.

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NOTES TO EDITORS

About the Innovative Medicines Initiative (IMI)
The Innovative Medicines Initiative Joint Undertaking (IMI JU) is a unique pan-European public private partnership between the European Commission and EFPIA (European Federation of Pharmaceutical Industries and Associations) driving collaboration between all relevant stakeholders including large and small biopharmaceutical and healthcare companies, regulators, academia, and patients.

Three major areas have been identified by the Innovative Medicines Initiative as key barriers currently facing the development of new antibiotics:

- **Discovering** new antibiotics is inherently difficult and finding novel agents that successfully target bacteria is scientifically challenging.
- **Regulatory** complexities specific to antibiotics compound this scientific challenge. For example, late stage clinical trials investigating antibiotics against resistant infections require an excess number of trial participants, as not all of those enrolled will be infected with the resistant strain of bacteria being targeted. This significantly impacts the practicalities and cost of running large trials.
- **Low return on investment** relative to other medicines limits the feasibility of antibiotic development for manufacturers. New antibiotics are used as little as possible, only when patients have failed to respond to existing treatments. This significantly limits the commercial return that is needed to encourage investment in this area and to fund future R&D.

The aim of IMI is to propose a coordinated approach to overcome identified research bottlenecks in the drug development process, in order to accelerate the development of safe and more effective medicines for patients, by fostering collaboration between all stakeholders such as industry, public authorities (including regulators), organisations of patients, academia and clinical centres, and enhancing Europe's competitiveness. www.imi.europa.eu

About GlaxoSmithKline

One of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

CONTACTS

Media Enquiries

Esra Erkal-Paler	+44 20 7604 8030
Christopher Sampson	+44 20 7604 8279

Investor Enquiries AstraZeneca UK

James Ward-Lilley	+44 20 7604 8122	mob: +44 7785 432613
Karl Hård	+44 20 7604 8123	mob: +44 7789 654364
Nicklas Westerholm	+44 20 7604 8124	mob: +44 7585 404950

Investor Enquiries AstraZeneca US

Ed Seage	+1 302 886 4065	mob: +1 302 373 1361
Jorgen Winroth	+1 212 579 0506	mob: +1 917 612 4043