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PRESS RELEASE

NEW IMI PROJECTS TO REVITALISE ANTIBIOTIC DEVELOPMENT

- **New Drugs 4 Bad Bugs programme represents an unprecedented partnership between industry, academia and biotech organisations to combat antibiotic resistance in Europe.**
- **Antibiotic-resistant bacteria cause 25 000 deaths in EU every year and cost economy €1.5 billion.**
- **€194.6 million COMBACTE project aims to create a new comprehensive clinical research agenda to address antibacterial resistance.**
- **€29.3 million TRANSLOCATION project will investigate new pathways for getting antibiotics into bacteria.**

BRUSSELS, 11 February 2013 – Today the Innovative Medicines Initiative (IMI) is launching the first two projects under its antimicrobial resistance (AMR) research programme, 'New Drugs for Bad Bugs' (ND4BB). The new projects, COMBACTE (Combatting Bacterial Resistance in Europe) and TRANSLOCATION (Molecular basis of the bacterial cell wall permeability), are set to revitalise antibiotic development by promoting greater collaboration within the entire antibiotic development community, and by tackling key challenges to the development of new medicines.

Antimicrobial resistance (AMR) is a growing problem worldwide, and with few new drugs making it to the market, there is an urgent need for new medicines to treat resistant infections. Efforts to develop novel antibiotics are hampered by a number of scientific and regulatory hurdles that cannot be tackled by any individual organisation working alone.

If no action is taken to address these issues, we risk leaving society in a situation where doctors will have few, if any, options to treat bacterial infections. To avoid a public health emergency, the entire antibiotic research community must work together to reinvigorate research into new antibiotics. As a public-private partnership (PPP), IMI is the ideal platform to launch such an initiative.

Michel Goldman, IMI's Executive Director commented: *'Antimicrobial resistance represents a major threat to public health worldwide. Developing new antibiotics is challenging, but by bringing together experts from pharmaceutical industry, academia, and hospitals, these new projects will give a fresh impetus to the search for new weapons to fight the drug-resistant pathogens that have already killed so many in Europe and elsewhere.'*

The COMBACTE project is pioneering a new collaborative model which will hopefully result in a new model for the clinical research and development of antibiotics. This model will see academic investigators working hand in hand with industry scientists to combine knowledge and expertise, thereby increasing the probability of developing effective new medicines and addressing the public health threat of antimicrobial resistance.

A key outcome of the project will be a pan-European clinical trial network capable of recruiting patients and of conducting efficiently high quality multinational trials at all stages of development. Alongside this, the project will also establish a pan-European laboratory network to deliver epidemiological information and data from microbial surveillance work to guide the selection of clinical trial sites.

Crucially, the COMBACTE team aims to generate innovative trial designs to facilitate the registration of novel antibacterial agents. It will also design and validate tests to support the diagnosis of patients, identify the most appropriate treatments, and monitor the patient's response.

COMBACTE will test its novel clinical trial designs on drugs under development in the pharmaceutical companies involved in the project, starting with a novel antibiotic that appears to be effective in respiratory and skin infections caused by multi-drug resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA).

For its part, TRANSLOCATION will focus its efforts on identifying new ways of getting antibiotics into bacteria and preventing bacteria from expelling the drugs before they can take effect. It will work

primarily on Gram-negative pathogens such as *Escherichia coli* and *Klebsiella pneumoniae*. Drug resistant Gram-negative bacteria are responsible for two thirds of the 25 000 deaths resulting from antimicrobial resistance reported in Europe annually.

More information:

- COMBACTE project: <http://www.imi.europa.eu/content/combacte>
- TRANSLOCATION project: <http://www.imi.europa.eu/content/translocation>
- 6th Call for proposals: <http://www.imi.europa.eu/content/6th-call-2012>

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Facts & Figures on antimicrobial resistance (AMR)

AMR represents a serious and growing threat to human and animal health worldwide. Resistance can also spread from animals to humans through the food chain or direct contact. According to the World Health Organization (WHO), 'antibiotic resistance is becoming a public health emergency of yet unknown proportions'. In the EU, AMR is responsible for some 25 000 deaths every year, and the annual treatment and social costs have been estimated at some €1.5 billion ([ECDC/EMA joint technical report "The bacterial challenge: time to react", 2009](#)). Meanwhile, new forms of resistance continue to arise and spread, leaving clinicians with few weapons to bring infections under control. Yet despite the recognised need for new antibiotics, the reality is that only two new classes of antibiotics have been brought to the market in the last three decades.

The reasons for this are manifold. On the scientific front, there is an urgent need for a greater understanding of how antibiotics work, how bacteria develop resistance to them, and what molecular mechanisms could be exploited to get round bacterial defence mechanisms. Running clinical trials on new antibiotics is also problematic due to regulatory requirements and the large numbers of patients required – put simply, a lot of patients have to be recruited to the major studies of efficacy performed for each clinical indication sought in order to be sure of having enough patients with the resistant bacteria under investigation and to demonstrate that the new antibiotic is not inferior to comparable antibacterial drugs. These issues mean that the costs of carrying out a clinical trial on a new antibiotic are extremely high.

At the same time, because some antibiotics will only be used on a very small number of patients, the costs of development often exceed the potential return on investment. In other words, antibiotic development is simply no longer a financially viable option for pharmaceutical companies, and just a handful of pharmaceutical companies remain in the field.

In its [Action Plan against the rising threats from Antimicrobial Resistance](#) of November 2011, the European Commission called for 'unprecedented collaborate research and development efforts to bring new antibiotics to patients' by, among other things, launching an IMI programme 'for research on new antibiotics aimed at improving the efficiency of research and development of new antibiotics through unprecedented open sharing of knowledge'.

The result is the New Drugs for Bad Bugs (ND4BB) programme, the first two topics of which were launched as IMI's 6th Call for proposals in May 2012. COMBACTE and TRANSLOCATION are the result this Call. A third topic under ND4BB was launched as part of IMI's [8th Call for proposals](#) in December 2012.

Since the launch of ND4BB, the European Parliament has also weighed in on the issue. In December 2012 it adopted a [resolution](#) on the rising threat of AMR that highlights the important role of public-private partnerships in reinvigorating antimicrobial R&D.



Innovative Medicines Initiative

About IMI

IMI is the world's largest public-private partnership in health care. IMI is improving the environment for pharmaceutical innovation in Europe by engaging and supporting networks of industrial and academic experts in collaborative research projects. The European Union contributes €1 billion to the IMI research programme, which is matched by in kind contributions worth at least another €1 billion from the member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative currently supports 40 projects, many of which are already producing impressive results. The projects all address major bottlenecks which will lead to accelerate the development of safer and more effective treatments for patients.

More info: www.imi.europa.eu

