

PRESS RELEASE

PRESS RELEASEAugust 1, 2019 || Page 1 | 7

New IMI Project “GNA NOW” kicks off its battle against antimicrobial resistance

New partnership will advance three antibacterial programmes as part of the Innovative Medicines Initiative (IMI), a public-private European R&D consortium.

Hamburg, Germany and Utrecht, Netherlands, 01 August 2019: Evotec SE (Frankfurt Stock Exchange: EVT, MDAX/TecDAX, ISIN: DE0005664809) and Lygature announced their cooperation in a new initiative for the development of novel antibacterial agents today: Gram-Negative Antibacterials NOW (“GNA NOW”). The new GNA NOW project, led by Evotec SE, managed by Lygature and funded by the Innovative Medicines Initiative (IMI), will work on the development of novel antibacterial agents to battle antimicrobial resistance in gram-negative bacteria. The multi-stakeholder consortium includes nine other partners from academia, industry and SMEs: Nosopharm, BIO-ASTER, Helmholtz Centre for Infection Research, North Bristol National Health Service Trust, University of Liverpool, Inserm, Erasmus Medical Center, Medical University of Vienna, and Fraunhofer IME. Collectively, the GNA NOW members will progress three programmes in parallel with the goal of bringing one through completion of Phase I studies and one reaching Investigational New Drug (IND) stage and/or up to two programmes reaching clinical development candidate stage, by 2024.

GNA NOW is supported by the IMI, a joint initiative between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), of which Evotec is a member. The IMI, the world's largest public-private partnership (PPP) in life sciences, will match Evotec's in-kind contribution with a € 12 m grant over the next six years, to fund the activities of the consortium. This award will allow the eleven partners of this consortium to build European platforms of excellence around each step of the critical path for drug discovery and development. European experts will join forces to contribute to “mechanism of action elucidation”, “medicinal chemistry and design”, “in vitro profiling”, “pre-candidate efficacy studies”, “candidate PK/PD studies”, “safety and ADME”, “CMC”, as well as “clinical studies and modelling”.

Dr Cord Dohrmann, Chief Scientific Officer of Evotec, commented: “We are extremely glad to initiate GNA NOW with the backing of the European Commission and the EFPIA through the Innovative Medicines Initiative. Bacterial infections are a growing threat around the globe and are driving the need for innovative therapeutics with new mechanisms of action. GNA NOW gives us the opportunity to join forces with leading institutions of both the public and the private sector across Europe to develop new gram-negative antibacterial agents as quickly and as efficiently as possible.”

Redaktion

Dr. Mira Grättinger | Fraunhofer Institute for Molecular Biology and Applied Ecology IME, ScreeningPort |
TPhone + 49 40 303764-0 | Schnackenburgallee 114 | 22525 Hamburg | mira.graettinger@ime.fraunhofer.de | www.ime.fraunhofer.de

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Dr Kristina Orrling, program manager at Lygature and GNA NOW project coordinator, commented: “By joining forces we can fend off a grim future where a simple urinary infection can be fatal. Together, we’ll strengthen the antibacterial arsenal.”

PRESS RELEASE

August 1, 2019 || Page 2 | 7

About antibiotic-resistant bacteria and GNA NOW

Antibiotic-resistant bacteria were estimated to be responsible for 670,000 infections and 33,110 attributable deaths in the EU and the European Economic Area (EEA) in 2015. From a global perspective, antimicrobial resistance could kill up to ten million people every year by 2050, which could cost up to € 94 trillion (\$ 100 tn). In February 2017, the WHO published a list of priority pathogens for the development of new antibiotics. Carbapenem-resistant gram-negative bacteria (Enterobacteriaceae, *Pseudomonas aeruginosa*, *Acinetobacter baumannii*) were at the top of that list, with critical priority. GNA NOW is an Evotec-led joint initiative of eleven partners, project managed by Lygature, with the goal of developing novel antibacterial agents and bringing one of the three simultaneously developed compounds through completion of Phase I studies plus one compound reaching Investigational New Drug (IND) stage and/or up to two compounds reaching clinical development candidate stage, by 2024.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853979. The JU receives support from the European Union’s Horizon 2020 research and innovation programme and EFPIA.

ABOUT THE INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) is working to improve health by speeding up the development of, and patient access to, the next generation of medicines, particularly in areas where there is an unmet medical or social need. It does this by facilitating collaboration between the key players involved in healthcare research, including universities, pharmaceutical companies, and other companies active in healthcare research, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. This approach has proven highly successful, and IMI projects are delivering exciting results that are helping to advance the development of urgently-needed new treatments in diverse areas.

IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Through the IMI2 programme, IMI has a budget of €3.3 billion for the period 2014-2020. Half of this comes from the EU’s research and innovation programme, Horizon 2020. The other half comes from large companies, mostly from the pharmaceutical sector; these do not receive any EU funding, but contribute to the projects ‘in kind’, for example by donating their researchers’ time or providing access to research facilities or resources.



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ABOUT LYGATURE

Lygature, a not-for-profit foundation, acts as the independent coordinator of the GNA NOW consortium, providing governance in terms of progress, finance, collaboration and communication. Since 2006, Lygature has supported over a hundred public-private partnerships in the field of life sciences & health with a combined budget of well over 600 million euros.

Lygature media contacts and analysts (not for publication)

Anne Kwak
anne.kwak@lygature.org
Tel: +31 6 28 53 94 27
@Lygature

PRESS RELEASE

August 1, 2019 || Page 3 | 7

ABOUT NOSOPHARM

Nosopharm is a biotechnology company specialized in the research and development of new antimicrobial molecules. Nosopharm discovered and developed NOSO-502, a first-in-class antibiotic for the treatment of multidrug-resistant hospital-acquired infections. It has developed a unique expertise in the discovery of natural bioactive products stemming from the Xenorhabdus and Photorhabdus microbial genera and in the medicinal chemistry of Odilorhabdins, the new class of antibiotics to which NOSO-502 belongs. Founded in 2009, Nosopharm is based in Lyon, France, and has a staff of seven. To date, the company has raised a total of € 4.3 m (\$ 5.2 m) in private equity and received € 3.8 m (\$ 4.6 m) in grants from Bpifrance, IMI, DGA, Region Languedoc-Roussillon and FEDER.
www.nosopharm.com

Nosopharm media contacts and analysts

Andrew Lloyd & Associates
Agnes Stephens – Juliette dos Santos
agnes@ala.com - juliette@ala.com
Tel : +44 1273 675 100
@ALA_Group

ABOUT BIOASTER

BIOASTER is a Technology Research Institute, an independent non-for-profit research organization created in 2012. It conducts innovative technological research projects in applied microbiology: Composed of high-level scientists and engineers, BIOASTER teams use state-of-the-art technological equipment within their integrated 8 technology units located in their labs (BLS2-BLS3) in Lyon and Paris.

Bioaster media contacts and analysts

Olivier Charzat
Olivier.CHARZAT@bioaster.org
Emilie Bernard
Emilie.BERNARD@bioaster.org

FRAUNHOFER INSTITUTE FOR MOLECULAR BIOLOGY AND APPLIED ECOLOGY IME**ABOUT HZI**

Scientists at the Helmholtz Centre for Infection Research (HZI) in Braunschweig and its other sites in Germany, are engaged in the study of bacterial and viral infections and the body's defence mechanisms. They have a profound expertise in natural compound research and its exploitation as a valuable source for novel anti-infectives. As member of the Helmholtz Association and the German Center for Infection Research (DZIF) HZI performs translational research laying the ground for the development of effective new treatments and vaccines against infectious diseases. www.helmholtz-hzi.de/en

The Helmholtz Institute for Pharmaceutical Research Saarland (HIPS) in Saarbrücken belongs to the Helmholtz Centre for Infection Research (HZI) in Braunschweig and was established by the HZI and Saarland University in 2009. Its researchers are searching mainly for new agents against infectious diseases, optimise these agents for application in humans and research ways how these agents can be transported best through the body to the site of action. www.helmholtz-hzi.de/hips

HZI media contacts

Susanne Thiele, Press Spokesperson

susanne.thiele@helmholtz-hzi.de

Dr Andreas Fischer, Editor

andreas.fischer@helmholtz-hzi.de

Phone: +49 531 6181-1404

ABOUT NBT

The Microbiology Research Department at North Bristol National Health Services Trust (NBT) has over 25 years of experience in performing PK/PD in vitro experiments to aid drug development programmes. In GNA now, these PK/PD evaluations will be central to the programme success. NBT has experience in performing previous Quality Management studies in PK/PD programmes.

NBT will use their expertise to develop a Quality Management Template (QMT) to ensure all PK/PD experiments across the GNA Now drug programmes are completed to this same QMT. This will safeguard the output from these studies, give strength to the data and therefore give confidence to regulators that the pre-clinical dose determination is robust.

NBT has an established Patient and Public Involvement (PPI) group who have collaborated on a number of microbiology research projects. The group has contributed to the development of a Toolkit and Practical Guide to PPI in antimicrobial drug development and is looking forward to explore the potential for PPI in pre-clinical aspects of the antimicrobial medicines development cycle.

NBT media contacts and analysts

Connor Dicks – External Communications Manager

North Bristol NHS Trust

Connor.Dicks@nbt.nhs.uk

Tel: +44 117 4143841

PRESS RELEASE

August 1, 2019 || Page 4 | 7

FRAUNHOFER INSTITUTE FOR MOLECULAR BIOLOGY AND APPLIED ECOLOGY IME**ABOUT UNIVERSITY OF LIVERPOOL**

The Centre for Antimicrobial Pharmacodynamics (CAP) is based in the Department of Clinical and Molecular Pharmacology, Institute of Translational Medicine at the University of Liverpool. The CAP is one of relatively few academic laboratories in the world that can develop pharmacodynamic packages for new antimicrobial agents. CAP has extensive experience in providing preclinical pharmacokinetic-pharmacodynamic (PK/PD) evaluation of compounds and early phase clinical support to ensure new drugs are developed in a streamlined manner.

University of Liverpool media contacts and analysts
Nicola Frost – Media Relations Manager
Crown Street, University of Liverpool
Liverpool, United Kingdom
L69 3BX
nicola.frost@liverpool.ac.uk
T: +44 (0)151 795 9620
M: +44 (0)7341105442 nicola.frost@liverpool.ac.uk
Tel. +44 (0)151 795 9620
Mobil +44 (0)7341105442

PRESS RELEASE

August 1, 2019 || Page 5 | 7

ABOUT INSERM

Inserm U1070 “Pharmacology of Antimicrobial Agents”, is a Research Unit affiliated to the University of Poitiers and Inserm. It has been created in 2012 and comprises 20 permanent staff members (clinicians, pharmacist, scientific) and 13 students (PhD and master students). It is located on the University Campus of Poitiers (France). The objective of Inserm U1070 is to develop innovative PK/PD modelling approaches to select the best dosing regimen of antibiotics administered alone or in combination as well as the best route of administration and best formulation, in order to increase antimicrobial efficacy and limit bacterial resistance. Inserm U1070 conducts translational research, from cells culture models to patients, and integrating microbiology, analytical chemistry, drug formulation, and in vivo preclinical experiments. To date, Inserm U1070 received grants from Region Nouvelle Aquitaine, ANR, PHRC, JPIAMR, IMI, and CPER-FEDER and has established collaborations with ANSES and several Universities in France (Paris Sud, Paris Diderot) and abroad (Dublin, Erasmus MC, Uppsala, Hamburg, Catholic University of Louvain), as well as leading pharmaceutical companies.

For more information, please visit our web site: <http://phar.labo.univ-poitiers.fr/>

INSERM media contacts and analysts
Inserm Information and communication Nouvelle Aquitaine
Didier Dubrana
didier.dubrana@inserm.fr
Tel +33 5 57 57 36 54

FRAUNHOFER INSTITUTE FOR MOLECULAR BIOLOGY AND APPLIED ECOLOGY IME**ABOUT ERASMUS MEDICAL CENTER**

The Erasmus MC is one of the largest academic hospitals in Western Europe, employing more than 14,000 people, with researchers being involved in more than 221 EU-financed projects. With expertise in pharmacology and innovative PK/PD approaches, the department of Medical Microbiology and Infectious Diseases extensively researches the mechanisms of antimicrobial resistance, their detection and characterization. The department has more than 40 years of experience in animal models of infection, coupled to antimicrobial resistance and drug efficacy studies.

EMC media contacts and analysts

Dr. Will Goessens

w.goessens@erasmusmc.nl

@ErasmusMC

PRESS RELEASE

August 1, 2019 || Page 6 | 7

ABOUT THE MEDIZINISCHE UNIVERSITÄT WIEN

The Medical University of Vienna (MUW) is located in one of the largest hospitals in Europe. Within the university, the Department of Clinical Pharmacology is specialized on clinical studies with antimicrobial agents. They performed almost 1000 drug studies in the last 25 years and their spectrum includes the full range of Phase 1 studies from First-in-Man studies to special PK studies. Thereby the MUW will link the knowledge of the consortium to patients in the fastest possible way while being fully compliant with regulations for studies involving humans. The obtained data provide the basis to optimize dosing by PK/PD means to enhance efficacy while preventing side effects and development of bacterial resistance.

Medical University of Vienna media contacts and analysts

pr@meduniwien.ac.at

ABOUT Fraunhofer IME

Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V. (Fraunhofer), (<https://www.fraunhofer.de>), is the leading organization for applied research in Europe. Its research activities are conducted by 72 institutes and it employs a staff of 26,600, with an annual research budget of 2.6 billion euros. The Fraunhofer Institute for Molecular Biology and Applied Ecology IME, with over 520 employees at its six sites in Schmallenberg, Aachen, Gießen, Münster, Frankfurt/Main and Hamburg conducts research in the field of applied life sciences from a molecular level to entire ecosystems.

Fraunhofer IME ScreeningPort in Hamburg contributes with its expertise in drug discovery and life science informatics. Within GNA NOW it will be providing support to the project in three main areas:

Firstly, a data management plan will be formulated, including regular monitoring of the status of project data sets and annual audits of compliance to quality standards across the project team. Key to the data management plan will be systematic implementation of the IMI FAIRplus toolbox (where Fraunhofer IME is a work package leader) to FAIRify all data from the moment of generation all the way to archiving and eventual re-use of appropriate data sets.

Secondly, a project wide cloud based ELN as recommended by Pillar A (IMI-Combine), where Fraunhofer IME is in the lead for platform infrastructure, which will be used to support day-to-day experimental data generation within the projects.

FRAUNHOFER INSTITUTE FOR MOLECULAR BIOLOGY AND APPLIED ECOLOGY IME

Thirdly, provision of software tools to support aggregated discovery and handling of preclinical data sets, which will be based on the GRIT42 suite that was developed as part of the ND4BB InfoCentre in cooperation with Fraunhofer IME.

PRESS RELEASEAugust 1, 2019 || Page 7 | 7

Fraunhofer IME media contacts and analysts

Dr. Mira Grättinger | Fraunhofer Institute for Molecular Biology and Applied Ecology IME, ScreeningPort
Schnackenburgallee 114
22525 Hamburg
Tel. + 49 40 303764-0
mira.graettinger@ime.fraunhofer.de
www.ime.fraunhofer.de

ABOUT EVOTEC SE

Evotec is a drug discovery alliance and development partnership company focused on rapidly progressing innovative product approaches with leading pharmaceutical and biotechnology companies, academics, patient advocacy groups and venture capitalists. We operate worldwide and our more than 2,800 employees provide the highest quality stand-alone and integrated drug discovery and development solutions. We cover all activities from target-to-clinic to meet the industry's need for innovation and efficiency in drug discovery and development (EVT Execute). The Company has established a unique position by assembling top-class scientific experts and integrating state-of-the-art technologies as well as substantial experience and expertise in key therapeutic areas including neuronal diseases, diabetes and complications of diabetes, pain and inflammation, oncology, infectious diseases, respiratory diseases and fibrosis. On this basis, Evotec has built a broad and deep pipeline of approx. 100 co-owned product opportunities at clinical, pre-clinical and discovery stages (EVT Innovate). Evotec has established multiple long-term alliances with partners including Bayer, Boehringer Ingelheim, Celgene, CHDI, Novartis, Novo Nordisk, Pfizer, Sanofi, Takeda, UCB and others. For additional information please go to www.evotec.com and follow us on Twitter @Evotec.

FORWARD LOOKING STATEMENTS

Information set forth in this press release contains forward-looking statements, which involve a number of risks and uncertainties. The forward-looking statements contained herein represent the judgement of Evotec as of the date of this press release. Such forward-looking statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.

The **Fraunhofer-Gesellschaft** is the leading organization for applied research in Europe. Its research activities are conducted by 72 institutes and research units at locations throughout Germany. The Fraunhofer-Gesellschaft employs a staff of more than 26,600, who work with an annual research budget totaling 2.6 billion euros. Of this sum, almost 2.2 billion euros is generated through contract research. Around 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. International collaborations with excellent research partners and innovative companies around the world ensure direct access to regions of the greatest importance to present and future scientific progress and economic development.