



Session 4. Antimicrobial Resistance and New Antibiotics

Chair: **Domingo Gargallo, ABAC Therapeutics**

The so-called “silent pandemic” is one of most relevant Global Health challenges facing humanity in the 21st century. It is a priority issue for the WHO, but it is also a prominent part of the agenda of the United Nations, the G20 or the G7. There is unanimous concern and commitment about the need to take measures to stop the proliferation of multi-resistant pathogens, and the urgent need to discover new therapeutic options to deal with this serious health threat.

Currently, small and medium-sized enterprises (SMEs) are the main players in the fight against AMR, providing 80% of the approximately 400 active antimicrobial projects worldwide. In this session we would like to focus on reviewing the ongoing efforts and barriers to discover and develop new antibiotics to treat AMR:

- Product discovery and development pipeline including small molecules, but also new approaches and unconventional strategies that contribute to the therapeutic arsenal. Products that meet the innovation criteria described by the WHO, not cross-resistance with commercial products, new target, and new mechanism of action
- PUSH and PULL financial incentives will be discussed, which are imperative to ensure that the industry maintains its focus on developing innovative AMR solutions. Financial incentives are needed to help both the implementation of R&D actions (PUSH) and to restore a broken value chain and market of products focused on combating AMR (PULL).

SPEAKERS:

Domingo Gargallo-Viola
ABAC Therapeutics

Discovery and development of new antibiotics, the challenge to align efforts to incentivate the value chain

Rafael Cantón
Hospital Ramon y Cajal Madrid

New antimicrobials: have they met the expectation?

Concepción González-Bello
University of Santiago de Compostela

Exploring New Bacterial Niches for Facing the Silent Pandemic

Sergio Lociuero
Bioversys AG

Does “old” necessarily mean “obsolete”? Old antibiotic classes turned into novel drugs



Speaker 1: Domingo Gargallo-Viola, ABAC Therapeutics, Spain

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Discovery and development of new antibiotics, the challenge to align efforts to incentivate the value chain.

Infections by multidrug resistance bacteria is one of the most serious global health threats. The challenge demands a coordinated strategy from different approaches. Among them, the discovery and development of new antibiotics, with new targets and novel mechanisms of action, that avoid cross-resistance with marketed classes, are essential to combat this threat. The need to provide an urgent response to the lack of new antibiotics is widespread, and is part of the agenda of the WHO, UN, EC, G20 or G7, among other international organizations. However, developing new tools to combat antimicrobial resistance is hampered by market failure; antimicrobial products have costly R&D with low return on investment, due among other reasons to short treatments and low prices. A new paradigm to incentivize and encourage new products in the space is urgently needed, considering the vision of all key players in the AMR sphere, in particular SMEs. SMEs represent the largest research in this area, they collectively hold the largest portfolio of preventive, diagnostic and therapeutic products, but most of them struggle to survive due to lack of investment in this field. Solutions must be sought to address the market failure that is disrupting the smooth functioning of the entire AMR ecosystem. The Association for the Discovery of new antibiotics in Spain (AD-ES) and Biotech companies from Europe innovating in Anti-Microbial resistance research (BEAM Alliance) works to guarantee changes considering the reality of SMEs, which represent 80% of the global development pipeline of novel antimicrobials, thus being a very important stakeholder in preventing the silent pandemic of AMR.

CV:

Domingo Gargallo-Viola is founder and CEO-CSO at ABAC Therapeutics, a company focused on the discovery and development of first-in-class, novel mechanism of action, pathogen-specific, narrow spectrum antibiotics. ABAC prioritizes compounds for the treatment of severe and life-threatening infections due to multidrug-resistant organisms, Domingo has over 30 years' experience in the discovery and development of anti-infective drugs and has been a pioneer in promoting precision medicine for the treatment of infectious diseases. Before founding and taking responsibility for ABAC in 2014, he spends 6 years as Infectious Diseases Manager and Director of Pharmacology, Toxicology and Safety Pharmacology at Ferrer, and 18 years as Director of Drug Discovery Biology at GSK. While at GSK and Ferrer, he led several projects that led to the discovery of first-in-class drug candidates and products to market. Before joining GSK, he was at the Uniformed Services University of the Health Sciences, Department of Defense, Maryland, US, and Research Associate at the Faculty of Pharmacy at the University of Barcelona. Domingo is the intellectual author of the *PasNas* platform, a novel approach to addressing the screening of compound collections, that together with a novel algorithm allows for the identification and prioritization of high-quality weighted leads. Domingo has published over 90 peer-reviewed articles in international journals and has directed several doctoral theses. He is recipient of several distinctions including the Henri Warembourg Faculty of Medicine Medal, awarded by the University of Lille, Medicines for Malaria Venture Project of the Year Awards (2003, 2004 and 2015) and five GSK R&D Recognition Awards. He holds a PhD in sciences from the University of Barcelona, and several master's degrees in business management and executive development from IE and IESE. Domingo is currently President of the Association for the Discovery of New Antibiotics in Spain (AD-ES), Vice-President of the Spanish Network for the Development of Alternative Methods in Animal Experimentation (REMA), and is the National Representative in Spain of the Alliance Biotech companies from Europe innovating in Anti-Microbial resistance research (BEAM).



Speaker 2: Rafael Cantón, Hospital Ramon y Cajal, Madrid, Spain

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New antimicrobials: have they meet the expectation?



Since 2010, more than 20 “new antimicrobials” have been approved by the EMA and/or the FDA to address resistance problems in priority pathogens identified by the WHO. Except for the new beta-lactamase inhibitors and some cephalosporins, their mechanism of action is quite similar to those of their predecessors. Although from a clinical point of view they represent an advance over their predecessors and particularly solve resistance problems, there are resistance mechanisms described for all of them, which makes their long-term future uncertain.

CV:

Clinical Microbiologist, Head of the Clinical Microbiology Dept. at the University Hospital Ramón y Cajal and associated Professor of Clinical Microbiology at Complutense University in Madrid (Spain). His research activity is developed within the CIBER of Infectious Diseases (CIBERINFEC, <https://www.ciberinfec.es/>) and Institute Ramón y Cajal for Health Research (IRYCIS, <http://www.irydis.org>) in which he coordinates the Microbiology, Immunology and Infection Area. His research is focused on antimicrobial resistance mechanisms, susceptibility testing and surveillance, and chronic respiratory infections. He is the clinical data coordinator of the European Committee of Antimicrobial Susceptibility Testing (EUCAST) (former president) and has been President of the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC). He has participated in several EU funding projects (COBRA, TROCAR, R-GNOSIS, ENABLE, MON4SRAT, iABC BADGER, FAST-Bact, ...).



Speaker 3: Concepción González-Bello, University of Santiago de Compostela, Spain
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Exploring New Bacterial Niches for Facing the Silent Pandemic.

After many years of success in the battle against infectious diseases, we are now losing ground in this fight with the worldwide increasing appearance of “superbugs”, which are resistant to most antibiotics in clinical use. Hence, there is great interest in the identification of unexplored bacterial targets as well as compounds with a new mechanism of action. Our efforts to explore the therapeutic potential of new bacterial niches and to develop compounds targeting them will be discussed.

CV:

Concepción González-Bello is Professor of Organic Chemistry in the University of Santiago de Compostela (USC, Spain) and one of the principal investigators at CIQUS, Spain. She obtained her PhD in Chemistry from the USC in 1994. She carried out pre-doctoral stays in the University of Ghent (Belgium) with Prof. M. Vandewalle and in the Scripps Research Institute (La Jolla, USA) with Prof. K. C. Nicolaou and post-doctoral studies in the University of Cambridge (UK) with Prof. Chris Abell. She is author of about 100 scientific articles in peer-reviewed journals, 14 chapters in books, and 3 European patents. Since 2019, she is one of the managers of the Spanish State Research Agency (AEI).



Speaker 4: Sergio Lociuero, BioVersys AG, Basel, Switzerland
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Does “old” necessarily mean “obsolete”? Old antibiotic classes turned into novel drugs.

Known targets versus novel targets, known chemical classes versus new chemical classes, and natural products versus totally synthetic molecules are still burning topics that animate discussions in the research and development of new antibiotics. These topics will be briefly addressed to then focus on some interesting ongoing developments of existing antibiotic classes either to improve safety and/or resistance aspects within the typical clinical indications for which the class was/is used, or to generate potential new drugs with new clinical indications and improved properties.



CV:

Sergio Lociuro is CSO at BioVersys AG, a Swiss biotech company. He graduated in chemistry at the University of Rome (Italy) and at UNB (Canada). He has over 35 years' experience in drug discovery and development in the AMR field. In his career, he has held several positions in small, medium, and large pharma companies such as Lepetit (MMD), GSK, Polyphor, Arpida, Adenium and C10 Pharma where he contributed to the discovery and development of several products and NCEs from several chemical classes as for instance rifamycins, diaminopyrimidines, natural and synthetic peptides, and synthetic bacterial transcription regulator inhibitors. He is co-author in more than 60 publications and patents.

