Big bucks against resistant bugs

ANTIMICROBIAL RESISTANCE Since the withdrawal of Big Pharma in the late '80s, the antibiotic research market has dried up. Supported by public funds, European small and medium sized enterprises (SMEs) create new alliances to reanimate the market.



Despite the stern topic, the overall spirit at the 10th Berlin Conference on Life Sciences was optimistic. "It is not as scary as it looks," keynote speaker Egerton-Warburton said.

Health care payers see a growing need to fight emerging antimicrobial resistances (AMR) among different microbes. In February, the World Health Organization presented a top 12 list of bacteria resistant to current antibiotics for which new drugs are desperately needed. After years of stagnancy, policy makers world wide have made the topic a high priority - and set up a large number of funding initiatives, especially for SMEs involved in R&D. Christopher Egerton-Warburton, Chair of the expert advisory board of the UK's newly established Global AMR Innovation Fund (GAMRIF), argues for a multi-donor capital pool to address the estimated total funding need of €2bn. He lobbies for a ten-year perspective because drug developers "don't need all the money on day one." GAMRIF was set up by the British government with an initial capital base of £50m and is open for others to join. "Given my experience from the vaccine world, I strongly believe we should tame the bewildering and confusing AMR funding landscape and bundle all efforts into few strategic initiatives of high value instead of establishing too many stand-alone, fragmented funds," emphasises Egerton-Warburton. Being aware of the society's high hopes, he gives the AMR community some advice: "We need public money that behaves like privatesector venture capital. That would accelerate development."

Berlin Conference in jubilee year

Egerton-Waburton was the keynote speaker at the 10th Berlin Conference on Life Sciences in February. Attracted by this year's topic, "Novel Antimicrobials," the organisers, UK Department for International Trade and BIOCOM AG welcomed around 30 speakers and 130 attendees from European biotech and pharma companies. Drug developers, microbiologists, and investors discussed the growing need to efficiently combat AMR both at the speaker's reception at the China Club and at the conference at the British Embassy in Berlin. The presenters argued that science and technology are not the only fields that will need to adress the spread of resistant bacteria.Beyond that, questions regarding funding, patenting, and pricing of new drugs, as well as antibiotics regulation and stewardship, have to be considered.

"In the antimicrobials space, there is a clear imbalance between high investment costs and a low return on investment," said Ute Kilger, partner at IP expert Boehmert & Boehmert (GER), opening the panel discussion about the bottlenecks in antimicrobials R&D. Moderator Peter West from the Academy of Infection Management (UK) added that the public appreciation of antibiotics has to improve, and Andrew Ul-Imann, Head of Infectious Diseases at the University clinical centre Würzburg (GER), advised drug developers to talk with clinical experts: "Often scientists don't see the treasures they have in their pipeline until they discern the clinical context."

During the conference, Peter Jackson steering group chairman of UK's newly established AMR Centre – gave an update on the first two CARB-X cycles. The AMR Centre in Alderley Park (UK) is a partner of the international initiative CARB-X – Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator. The centre is one of two accelerators in the UK; the other two are US-based. CARB-X targets preclinical work, so most applicants will be SMEs. Over the first five years, the goal is to get a diverse range of 20 high-quality antibacterial products close to human testing. The US Biomedical Advanced Research Authority (BARDA) provides the CARB-X initiative up to US\$250m. The AMR Centre is expected to receive up to US\$100m in total. Adding its own financial resources, Jackson expects to be able to focus US\$200m on a range of R&D projects. According to him, CARB-X received so far more than 360 companies worldwide expressed interest requesting over US\$1bn in funding. "Currently, 11 projects are in triage at the AMR Centre. In March, we will announce the first selected projects," Jackson told the audience.

Funding schemes for SMEs

The high relevance of SMEs was emphasised by the dozen companies that presented their new technologies and drug candidates during the conference. Some of them, such as AntibioTx from Denmark, reported successful progress in their antibiotic pipeline. NovaBiotics from Aberdeen (UK) stressed the need for a multi-targeted approach to combat AMR, developing therapeutic peptides as well as technologies to address biofilm resistance. "We are a small company with high ambitions," CEO Deborah O'Neil said.

Both companies are members of the European consortium BEAM Alliance, which seeks to improve the regulatory, investment, and market viability of new products to fight antimicrobial resistance. Marie Petit, co-ordinator of the alliance, announced a new position paper by the European network: "In December, we es-



Sergio Lociuro (CSO Bioversys, CH), Rasmus Toft-Kehler (CEO AntibioTx, DK), Holger Reithinger (Partner Forbion Capital, GER/NL) and Olivier Litzka (Partner Edmond de Rothschild, F) discussed when an antimicrobial is considered a good business case.

tablished BEAM as an official association to more efficiently represent our more than 50 members. During 2017, we are going to precisely outline our recommendations." In addition to the high need of appropriate regulatory mechanisms for novel antimicrobials, the SMEs called for flexible funding schemes. Petit: "The majority of innovation is done by SMEs, and we welcome all new funding initiatives. However, we should take care that the schemes are manageable for small companies."

The VC side showed willingness to invest in one to two antimicrobials companies per fund. "Regulatory environment has stabilised a lot. However, we need a promising exit strategy which is realistic within a ten-year frame," said Olivier Litzka from Edmond de Rothschild (F).

The full range of entrepreneurial spirit and scientific excellence in the field became visible in the event's start-up competition. Against Auspherix (UK), Quretech Bio (SE), Immunethep (P), and Omnix Medical (Israel), the Swiss startup Juvabis stood out. The jury awarded Juvabis the first prize for its technology platform of next-generation aminoglycoside antibiotics that target the ribosome in Gram-positive and -negative bacteria.

> h.maerzhaeuser@biocom.eu, m.laqua@biocom.eu

Competence of the second second

YOU NEED FULL COMMITMENT FOR BEST RESULTS. IN EVERY PHASE.

- We offer the complete range of clinical development and consulting services
- We work for pharmaceutical, biotechnology and medical device companies
- We are present in Munich, Budapest, London, Prague & Warsaw

fgk-cro.com



Edgar J. Renzi +49 St 203 119-22 edgar.fanzliftigt-cro.com Martin Krauss +49 89 893 118-25 martin kraussift gir-cro.com

The Clinial Trial Optimizer

Heimenstrame 35 - 80239 Munich - Germany