



BEAM Alliance urges G20 support to fight deadly superbugs

At the Hamburg G20 summit, political leaders will speak about a growing global health threat - antibiotic resistance - which causes 50,000 deaths in Europe and the USA alone and more than 700,000 deaths worldwide annually. The BEAM Alliance, a coalition of small and medium-sized biopharmaceutical companies focused on the discovery and development of new antibacterial products, is calling attention to the urgency to fight against resistant bacteria asking political leaders to work together to implement now bold solutions to fight this deadly problem.

- G20 leaders to discuss growing global health threat – antibiotic resistance – in Hamburg this week
- Antibiotic resistance causes 50,000 deaths in Europe and the USA alone and more than 700,000 deaths worldwide annually
- Urgent need for political leaders to work together and urgently implement bold initiatives to fight this deadly global problem
- **BEAM Alliance (Biotech companies in Europe combating AntiMicrobial Resistance)**, a coalition of small and medium-sized biopharmaceutical companies focused on the discovery and development of innovative products tackling antimicrobial resistance.

[6th July, 2017] Traditionally, G20 summits focus on global economics. But over the next two days, world political leaders gathering in Hamburg will speak about a growing global health threat as well – antimicrobial resistance (AMR). The rapid growth of multidrug-resistant bacteria, known as superbugs, has become a very hot topic, driving an urgent need for new antibiotics. And it has become an economic topic as well: **“If nothing is done to thwart the progression of anti-microbial resistance, it will equate to a potential global economic burden of up to 100 trillion US dollars by 2050,”** Florence Séjourné, **president of the BEAM Alliance stated**, citing estimates from the 2016 O’Neill-report.

How did this desperate situation come about? In the second half of the twentieth century, many highly effective antibacterial agents from amoxicillin to vancomycin were developed by the pharmaceutical industry to fight common pathogens. These were so successful that bacterial infections were no longer considered to be an important area for new drug development and so little new research was conducted. Because these drugs were overused, the bacteria that cause these infections are steadily developing resistance to most and in some cases all available antibiotics. In the last twenty years, the world has been losing the fight against bacterial infections. This is especially – but not only – true in the hospital setting where resistance to several of the most efficacious antibacterial agents has been rising steadily.

The mission of the more than 30 member companies of the Beam Alliance is the development of life-saving cures for the treatment of severe bacterial infections to ensure effective antibacterial therapeutic options for the future. The companies’ innovative antibacterial pipelines comprise a large

number of discovery programs as well as late stage preclinical candidates targeting multi-resistant pathogens. Much more than big pharma has to offer.

Within the BEAM member programs there are more than 100 innovative antimicrobial products in our pipeline from those in early stage preclinical studies to those in clinical development phase, with one new antibiotic recently approved and available to patients. Most of the BEAM member companies are focusing on developing products to treat critical pathogens which are on the recently updated list from the World Health Organization (WHO): It sums up the critical pathogens, which have a high priority, because they cause the most severe problems worldwide.

Most important: A significant number of BEAM Alliance members are developing innovative compounds with completely new modes of action – drugs that are urgently needed to fight the rising number of multi-resistant microbes. For example:

- A compound with new mode of action against *Pseudomonas* – one of the top-priority bugs on WHO list.
- Substances that protect or strengthen the healthy and helpful microbiota in the gut to prevent life threatening infections such as *Clostridium difficile*.
- Molecules that act on bacterial transcription factors to manipulate resistances, biofilm-formation and virulence of bacteria so that existing antibiotics can successfully work again.
- So called phages to heal severe skin infections in burn patients.

Small and medium-sized entities (SMEs) comprising the BEAM Alliance, have a central position in the value chain since they focus on AMR, and are a rich source of innovation that will provide new molecules and technologies. Over the last ten years every new antibiotic reaching the market was under development by a small or medium sized company at a certain stage.

But given the fact that SMEs are not big pharma, the BEAM alliance members face a continual challenge to attract sufficient financial support. The BEAM Alliance therefore calls for immediate action to support their fight against multi-resistant bacteria. **“Numerous national and international reports have today suggested a range of different incentives policies to stimulate innovation in antimicrobial resistance. We urge the G20 leaders to take immediate action to mandate member states to implement concrete measures including push- and pull-mechanisms and to simplify the access to available funding in order to help revitalize the industry”, BEAM Alliance President Séjourné says: “- In this way we can thrive developing innovative products to combat antimicrobial resistance.”**

Bacteria are evolving resistance faster than policy makers are implementing actions. To revitalize and replenish antibacterial research and the development (R&D) pipeline the BEAM Alliance proposes short-term actions to be mandated immediately by the G20 leaders and a long-term strategy to tackle antimicrobial resistance now and in the future.

- **Action n°1** - Implement PULL incentives: Require robust market incentives to be implemented nationally (e.g., tax breaks, longer market exclusivity, revised pricing models) and as a key element, a globally co-ordinated Market-Entry-Reward (MER) system with the early-designation (similar to the Qualified Infectious Disease Product designation in the US) of eligible compounds which guarantees an appropriate return on investment. Implemented systems should be reviewed regularly and adjusted to ensure effectiveness, with a goal to evolve and harmonize globally.

- **Action n°2** - Implement PUSH incentives: Expand available funding to antibacterial R&D activities and significantly improve accessibility to SMEs. Currently available government funding, including EU funding, is geared towards the needs of big pharma requiring participation in a complex consortia and incurring significant administrative and managerial burden. The availability of substantial non-dilutive financing more tailor-made to suit the needs of small and medium-sized biopharmaceutical companies is required, with a focus on funding early-stage projects (discovery to clinical proof of concept).
- **Action n°3** - Further improve the regulatory pathways: Require national health authorities to define accelerated and simplified pathways to allow the development and approval of innovative products tackling antimicrobial resistance. Crucially national authorities should continue efforts with a goal to globally harmonize clear-cut regulatory guidelines to develop antibacterials which would include adaptive trial designs for novel innovative approaches (e.g. small molecules, biologics, prophylactic, diagnostic, immune-targeting, microbiome-based, phage-based therapies, anti-biofilm agents etc.) which many SMEs are developing.
- **Long-term strategy** - Recognize the societal value of antimicrobial medicines: All stakeholders especially the governments, regulators and payers must re-align on approaches which appropriately recognize and measure the societal value of antibiotics to combat AMR since this value surpasses the individual direct benefit. Such value should be reflected in any payment and incentives models. Complementing this dedicated and concerted actions must be implemented to nurture a vibrant R&D environment for new antimicrobials at all levels: a strong expertise at every stage of the antibacterial drug development should be preserved in Europe, especially since the industry has faced decreasing investments in the antibacterial field.

About the BEAM Alliance

BEAM (**B**iotech companies in **E**urope combating **Anti**Microbial Resistance) represents European small and medium-sized biopharmaceutical companies involved in developing innovative products to tackle antimicrobial resistance, including small molecule antibiotics, biologics, products with a prophylaxis indication, and new technologies that include microbiome-based and phage-based therapies, immune targeting therapies, and anti-biofilm agents. BEAM collaborates with the existing community of stakeholders dedicated to implementing tangible strategies. BEAM gives its members a unique voice to propose and support policies and incentives in antimicrobial research and development in Europe. BEAM recommends bold incentives that warrant action by policymakers to stimulate much needed innovation.

The current members of the BEAM Alliance are:

ABAC therapeutics – AiCuris Anti-infective Cures GmbH – ALAXIA – ALLECRA THERAPEUTICS – ANTABIO S.A.S – AntibioTx ApS - Arsanis, Inc. – Auspherix Ltd – Basilea Pharmaceutica International Ltd – BioFilm Pharma – BioVersys AG – Centauri Therapeutics Ltd – DA VOLTERRA – DEINOBOTICS – Destiny Pharma – Discuva Ltd – Eligo Bioscience – Helperby Therapeutics Ltd – Karveel Pharmaceuticals – MaaT Pharma – Mutabilis SAS – Nabriva Therapeutics AG – Neem Biotech Ltd – Northern Antibiotics Oy Ltd – NOSOPHARM – NovaBiotics Ltd – Pherecydes Pharma – Polyphor Ltd – QureTech Bio AB – Redx Anti-Infectives Ltd – SEPTEOS – SetLance srl – VIBIOSPHEN

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