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drug discovery
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JOINING FORCES FOR THE NEXT GENERATION OF ANTIBIOTICS

A conversation with **LLOYD PAYNE**, EVP Head of Anti Infective, Evotec



Antibiotics are one of the greatest achievements in medicine. Cheap and effective antibiotics are available for most bacterial infections. However, many are prescribed before the infectious agent is known. While this is often done for good reason, it has led to misuse and overuse of antibiotics across the world. Although resistant infections are still in the minority, they are an increasing problem and are projected to become a major burden to global health in the near future. Evotec understands the issues around multi-drug resistant bacteria and is supporting anti-infective drug discovery and development, from target identification through to clinical stage.

What are the challenges facing companies developing new antibiotics?

It's clear that we urgently need innovative antibiotics. However, there haven't been enough economic incentives for companies to develop new anti-infectives. The cost of getting a drug onto the market is high and, especially with antibiotics, there is no promise of investment return. Unlike other drugs, antibiotic treatments tend to be short courses of around 5 to 15 days, after which the patient is usually cured. Furthermore, any new drugs are likely to be used only for resistant infections. This means that sales can be initially low. Drug developers are moving out of the field. The current economic model needs to evolve.

Are there any new economic models to support development?

There is a growing number of new funding mechanisms that provide a 'push' for drug developers. Several funding organisations, including CARB-X, BARDA, Novo REPAIR Impact Fund, the Global Antibiotic Research & Development Partnership (GARDP), and the European Innovative Medicines Initiative (IMI), are all highly committed to antibiotic discovery and development. Global regulatory bodies, including the US Food and Drug

Administration and the European Medicines Agency, also provide a 'push' by improving the regulatory framework to allow submissions for approval based on smaller clinical trials. The agencies have also helped with trial planning and assessment of clinical value, which is making development easier, less costly, and faster without compromising on quality. All of this support is important, and has been effective in stimulating new discoveries. However, since 1962, only two new classes of antibiotics have been approved. We need new classes of antibiotics, new targets and new mechanisms of action.

Antibiotic development has 'pushes', what about the 'pulls'?

There is an urgent need to address the pull incentives. Several incentives have been introduced, such as the GAIN Act in the US and suggestions of transfers of exclusivity or financial rewards for companies successfully marketing a new antibiotic. Other proposed approaches involve disconnecting antibiotic volumes from sales, ensuring a return on investment without stimulating unnecessary prescriptions and overuse. Not all of these solutions have been implemented, but there are efforts to address them. Evotec is part of the global community

THE CURRENT ANTIBIOTICS ECONOMIC MODEL IS BROKEN.

working to make this happen. We feel confident that a solution will be found to bring much needed new therapies to the patient and provide a sustainable business model.

How can Evotec help?

There is a global trend to outsource R&D. This is particularly important in the infectious disease therapy area as a growing number of pharma and biotech companies need to access expertise to innovate and develop new antibiotics. Evotec takes a highly collaborative approach to anti-infective R&D, and has established an open innovation platform for time- and cost-efficient development of new anti-infectives. Most critically, we have in-depth knowledge across bacterial infections including drug-resistant tuberculosis. Our team and platform supports our partners from target identification through to IND-enabling studies and clinical stage development. We have the largest number of dedicated infectious-disease scientists in the private sector, developing new antibiotics with many partners as well as helping to retain critical expertise and train new scientists.

In addition to our integrated services offering, we also work in risk- and reward-sharing partnerships, where we co-own products, as well as developing our own.

What about very early projects?

Our BRIDGE model (Biomedical Research, Innovation & Development Generation Efficiency) is a link between academia and the pharmaceutical industry. BRIDGE partnerships serve as an incubator and help academic researchers produce important data, validate processes and financing experience that investors require.

We also have a new partnership with the Helmholtz Centre for Infection Research, based on work by Rolf Müller on a new class of broad spectrum gram-negative antibiotics. A second partnership with GARDP has the potential to become highly strategic and is set up to enable joint investment in understanding and fighting antimicrobial resistance.

At Evotec, we are constantly striving to promote change and we are proud to be at the forefront of anti-infectives R&D.



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ADVANCING THE DISCOVERY OF ANTI-INFECTIVES

Your partner for drug discovery and development-leading innovation for both small and large molecules from target to IND and high-end CMC

- ▶ World-leading expertise in bacterial, fungal, viral and parasitic diseases with an established global network
- ▶ Over 200 dedicated scientific minds working with you to develop new anti-infectives
- ▶ Deep understanding of funding and investment landscape including public-private partnerships



