

**FOR MEDICAL AND PHARMA TRADE MEDIA ONLY**

**SHIONOGI ADVOCATES INNOVATION IN ANTIBIOTIC DEVELOPMENT AND POLICY CHANGE TO ADDRESS THE GROWING THREAT OF ANTIMICROBIAL RESISTANCE**

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- Shionogi is pleased to announce sponsorship of a *Nature Outlook* supplement that addresses critical issues of antimicrobial resistance (AMR)<sup>1</sup>
- Although AMR is a slower moving threat, it is no less dangerous than COVID-19: every year, drug-resistant microbes are responsible for an estimated 700,000 deaths worldwide, and future projections for the impact of unresolved AMR are as high as 10 million deaths per year by 2050<sup>2</sup>
- Urgent action is needed to support the discovery, development and commercialization of novel antibiotics, and encourage the implementation of access models that reward innovation and appropriate use to address the growing threat of AMR

**OSAKA, Japan and AMSTERDAM, NL**, 26 October 2020 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Isao Teshirogi, Ph.D.) (hereafter "Shionogi") today announces the publication of a sponsored, editorially independent supplement in *Nature* called *Nature Outlook*, this supplement is focused on antimicrobial resistance (AMR) and highlights the need for continued innovation in antibiotic development and significant policy change. *Nature Outlook* editors chose this topic to bring better awareness to the continued threat posed by AMR. Shionogi believes that combatting AMR is an urgent issue and fully addressing it requires collaboration from all involved stakeholders including pharmaceutical companies in addition to major NGOs and governments around the world.

Antibiotics are crucial for every aspect of modern-day healthcare, from common surgeries to chemotherapy and organ transplantation. Every year, drug-resistant microbes are responsible for an estimated 700,000 deaths worldwide, and future projections for the impact of unresolved AMR are as high as 10 million deaths per year by 2050.<sup>2</sup> Unless we take immediate action, the world could face a future in which the lack of effective antibiotics makes routine medical procedures dangerous, makes more complex interventions and procedures impossible, and reduces our ability to respond to outbreaks of infectious diseases.

Tedros Adhanom Ghebreyesus, Director General at the World Health Organization (WHO) has called AMR a ‘*slow tsunami that threatens to undo a century of medical progress*’.

To address this growing threat from the rapid rise of antibiotic-resistant infections, innovative antibiotics are urgently needed. The *Nature Outlook* supplement describes a number of research advances in the development of novel antibiotics, including studies on the persistence of genes conferring resistance in bacteria, and how existing antibiotics might be reinvigorated to overcome bacterial defences. This supplement also covers for the need for new economic incentives to encourage a more robust antibiotic development pipeline.

Shionogi actively supports innovative antibiotic development and has recently brought cefiderocol to market. Cefiderocol is the first treatment to provide coverage against all Gram-negative pathogens considered a critical priority by the WHO – carbapenem -resistant *A. baumannii*, *P. aeruginosa*, and carbapenem-resistant, 3<sup>rd</sup> generation cephalosporin-resistant Enterobacteriaceae.<sup>3,4</sup>

To support research and development of innovative antibiotics by small biotech companies, Shionogi and more than 20 biopharmaceutical companies recently came together to launch an initiative known as the AMR Action Fund, with a \$1BN fund to support the development of 2 to 4 innovative antibiotics by 2030.

While developing antibiotics is a long, risky and costly process, commercialization is also challenging. Once launched, there is often a low frequency of use driven by the need for stewardship to prevent resistance development. Low use leads to limited revenues, which in turn restricts continued commercialisation and new product research. As a result of these economic challenges, many large pharmaceutical companies are no longer active in the development and commercialization of antibiotics.

To address the economic challenges associated with developing and commercializing new antibiotics, Shionogi strongly supports policy change, including the introduction of new post-market incentives, funding models and revised value assessment frameworks for reimbursement. These new approaches are urgently needed to restore a viable commercial market for antibiotics.

One country that is leading the way with new economic incentives is Sweden, which has started a pilot study on a new model that aims to ensure availability of new antibiotics that provide special medical value. Shionogi is proud to be one of four companies partnering with the Public Health Agency of Sweden to pilot this model.<sup>5</sup>

Further details of the policy changes needed to reinvigorate the antibiotic pipeline and market are available online in the Shionogi sponsored AMR feature in *Nature Outlook*:

<https://www.nature.com/articles/d42473-020-00446-9>

In addition, there are a number of other AMR-focused articles from *Nature* publications available at the following link: <https://www.nature.com/collections/decbfhfjib>.

### **Shionogi's commitment to fighting antimicrobial resistance**

Shionogi has a strong heritage in the field of anti-infectives and has been developing antimicrobial therapies for more than 60 years. Shionogi is proud to be one of the few large pharmaceutical companies that continues to focus on research and development in anti-infectives. The company invests the highest proportion of its pharmaceutical revenues in relevant anti-infectives R&D compared to other large pharmaceutical companies.<sup>6</sup>

For more information please refer to: <https://www.shionogi.com/global/en/sustainability/amr.html>

### **About Shionogi**

Shionogi & Co., Ltd. is a 142-year-old global, research driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders, cardiovascular diseases and gastroenterology. Shionogi's research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders.

For more information on Shionogi & Co., Ltd., please visit <https://www.shionogi.com/global/en/>

### ***Forward Looking Statement***

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with

respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also, for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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**References**

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<sup>1</sup> Antimicrobial Resistance, Nature Outlook, <https://www.nature.com/articles/d42473-020-00446-9>

<sup>2</sup> O'Neill, J. *et al.* Review on antimicrobial resistance. Tackling drug-resistant infections globally: final report and recommendations. 2016 [https://amr-review.org/sites/default/files/160518\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf) Last accessed October 2020

<sup>3</sup> World Health Organization. Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. February 27, 2017. Retrieved from <https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/>. Last accessed October 2020

<sup>4</sup> World Health Organization. 2019 Antibacterial Agents in Clinical Development. 2019. Retrieved from <https://apps.who.int/iris/bitstream/handle/10665/330420/9789240000193-eng.pdf> Last accessed October 2020

<sup>5</sup> Availability of Antibiotics: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/antibiotics-and-antimicrobial-resistance/availability-of-antibiotics/> Last accessed October 2020

<sup>6</sup> Antimicrobial Resistance Benchmark 2020.

[https://accessmedicinefoundation.org/media/uploads/downloads/5e270aa36821a\\_Antimicrobial\\_Resistance\\_Benchmark\\_2020.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5e270aa36821a_Antimicrobial_Resistance_Benchmark_2020.pdf) Last accessed October 2020