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## **Novartis and Biological E agree to deliver affordable vaccines for typhoid and paratyphoid A fevers to developing world**

- *License agreement advances a Novartis goal to deliver accessible and affordable vaccines that address unmet medical need in endemic regions*
- *More than 21 million cases of typhoid fever and five million cases of paratyphoid A fever are reported worldwide each year<sup>1</sup>*

**Basel, Switzerland, July 8, 2013** – Novartis today announced that it has entered into a development and licensing agreement with Biological E Limited (BioE), a biopharmaceutical company based in India, for two vaccines to protect against typhoid and paratyphoid fevers. The agreement advances the Novartis goal to deliver accessible and affordable vaccines that address unmet medical need in endemic regions.

In just five years, the Novartis Vaccines Institute for Global Health (NVGH), part of the Novartis Institutes for BioMedical Research, has developed a typhoid vaccine with funding by the Fondazione Monte dei Paschi di Siena and Regione Toscana through the Sclavo Vaccines Association (Italy). In addition, a dual-acting vaccine with components against both typhoid and paratyphoid fevers is being developed with on-going support from the Wellcome Trust. Both could reduce the burden of these diseases in endemic regions.

“NVGH uses its innovative know-how to tackle important problems in public health,” said Don Ganem, VP and Global Head of Infectious Diseases, Novartis Institutes for BioMedical Research. “BioE has a proven track record in vaccine manufacture, and capabilities to clinically develop and deliver WHO pre-qualified affordable vaccines to the developing world. We are pleased to be working with them to address this unmet need.”

More than 21 million cases of typhoid fever and five million cases of paratyphoid A fever are reported worldwide in a year<sup>1</sup>, especially in areas that lack appropriate sanitation and access to clean water. Many victims are children under the age of two for whom there is no widely available typhoid vaccine, while no vaccine is available for any age group against paratyphoid fever.

Under the license, NVGH will transfer technology to BioE, which will have financial and operational responsibility for manufacturing, further clinical development, approval and distribution in the developing world. The typhoid vaccine (Vi-CRM197) has achieved Proof of Concept, had successful Phase 2 results, and will be transferred to BioE. A combined typhoid-paratyphoid vaccine will be transferred once Proof of Concept is completed through early, small-scale studies in humans to determine safety and immunogenicity. The Wellcome Trust continues to support the development of the dual-acting vaccine through a Strategic Award that was awarded in 2009.

“Typhoid and paratyphoid are major causes of life-threatening disease worldwide and with the emergence of resistance to all of the commonly used antibiotics, they are becoming increasingly difficult to treat,” said Ted Bianco, Director of Technology Transfer

and Acting Director of the Wellcome Trust. “This licensing deal takes us a step closer to getting much-needed affordable vaccines into the communities that need them most.”

BioE is committed to achieving World Health Organization (WHO) pre-qualification and fulfill specific obligations to meet Novartis standards<sup>2</sup>. The agreement is worldwide except for developed countries, where Novartis will retain rights.

### **Information about typhoid and paratyphoid fevers**

The bacteria *Salmonella enterica* serovar Typhi (*S. Typhi*) causes typhoid fever and is a significant public health problem in developing countries where access to clean water and proper sanitation is limited and causes over 21 million cases and over 200,000 deaths per year worldwide<sup>1</sup>. *S. Paratyphi A* causes a clinically similar disease (paratyphoid fever) and is reported to cause five million cases in a year<sup>1</sup>. Given limitations of current typhoid vaccines and increasing antibiotic drug resistance of the bacteria, there is an urgent need for effective vaccines.

### **Disclaimer**

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### **About Novartis Vaccines Institute for Global Health**

The mission of the Novartis Vaccines Institute for Global Health is to develop effective and affordable vaccines for neglected infectious diseases of impoverished communities. In striving to achieve this mission, NVGH aims to substantially reduce development risks and cost of new vaccines so that manufacturers will be able to viably produce and distribute these vaccines to the public health sector of the developing world. NVGH's role is to undertake the translational research required to take a laboratory concept through development to the human Proof of Concept and then to transfer this knowledge to a manufacturer.

### **About Novartis**

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in all these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

### **References**

1. Bulletin of the World Health Organization 2004; 82:346-353 (<http://www.who.int/rpc/TFDisBurden.pdf>)
2. <http://www.novartis.com/downloads/corporate-responsibility/responsible-business-practices/10-principles.pdf>

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