



# Astellas and Affinivax Announce Worldwide Partnership for MAPS Vaccine targeting Pneumococcal Disease

Novel Vaccine to be developed based on Affinivax's MAPS Vaccine Technology Platform

**CAMBRIDGE, Mass. and TOKYO, February 28, 2017** -- <u>Affinivax, Inc.</u> ("Affinivax") and <u>Astellas Pharma Inc.</u> ("Astellas") today announced they have entered into an exclusive worldwide license agreement to develop and commercialize a vaccine targeting *Streptococcus pneumoniae* (pneumococcus). The partnership will utilize Affinivax's proprietary vaccine technology platform – Multiple Antigen Presenting System (MAPS) – to advance a novel MAPS vaccine targeted to prevent and reduce the spread of pneumococcal disease.

"I am pleased to enter into this agreement and partner with Affinivax to develop a pneumococcal vaccine using their novel MAPS technology." said Kenji Yasukawa, Ph.D., Senior Vice President and Chief Strategy Officer of Astellas. "Astellas expects to provide a new option to prevent pneumococcal disease with high unmet medical needs by developing innovative MAPS vaccine as part of our commitment to serve patients interests worldwide."

Astellas will lead and fully fund the development program and will obtain worldwide rights to commercialize the MAPS vaccine for pneumococcal disease. Affinivax will receive an initial upfront payment of \$10 million from Astellas and will be eligible to receive a range of development milestones and commercial milestones. In addition, Affinivax will receive tiered royalties on any future product sales.

The MAPS vaccine platform is designed to enable the high affinity binding of protective polysaccharides and proteins in a single vaccine, offering the potential to provide broader protection against invasive disease<sup>1)</sup> than currently available vaccines, as well as the potential to reduce nasopharyngeal colonization (the first step in disease transmission). To date, Affinivax has advanced its novel vaccine targeting pneumococcus through nonclinical proof-of-concept studies.

"We are very pleased that Astellas has recognized the significant potential of our MAPS pneumococcal vaccine," said Mr. Steven B. Brugger, CEO of Affinivax, Inc. "We are excited to join forces with Astellas to advance a vaccine which can offer such an important global benefit for pneumococcal disease and contribute to Astellas' impact with its global vaccine franchise"

There is no impact of this transaction on Astellas' financial results for the fiscal year ending March 31, 2017.

<sup>&</sup>lt;sup>1)</sup>Invasive disease: Invasive disease is defined as an infection confirmed by the isolation of bacteria from a normally sterile site (eg, blood or cerebrospinal fluid but not sputum).

# **About the Global Impact of Pneumococcal Disease**

Pneumococcus is a bacterium frequently found in the upper respiratory tract of healthy children and adults, and can cause serious infections ranging from pneumonia, meningitis, and sepsis, representing a major global health problem. The World Health Organization estimates that more than 1.6 million people, including more than 800,000 children under 5 years old, die every year from pneumococcal infections, with most of these deaths occurring in low-resource countries. The U.S. Centers for Disease Control and Prevention estimates that about 900,000 cases occur in the U.S. alone, resulting in up to 400,000 hospitalizations and 50,000 deaths annually.

# **About Multiple Antigen Presenting System (MAPS)**

MAPS uses proprietary chemistry that capitalizes on the highly specific and durable non-covalent, affinity binding between biotin and rhizavidin, a biotin-binding protein. The highly stable complex created by this affinity binding contributes to a simple, modular, and efficient approach to the development of MAPS vaccines. In stark contrast to the highly complex chemistry of conventional vaccine conjugation (which is optimized to induce protective antibody responses to only the polysaccharide antigen with the protein antigen serving primarily as a carrier), a MAPS vaccine presents both the polysaccharide antigen and the protein antigen to induce an immune response.

#### **About Affinivax**

Affinivax is advancing a next generation vaccine technology platform to enable the development of vaccines that provide the highest level of protection against challenging infectious diseases. Backed by an investment from the Bill & Melinda Gates Foundation, and working with world experts in vaccine discovery and development, Affinivax is focused on creating a pipeline of vaccines for children and adults in both the developed and developing worlds. The company's proprietary vaccine platform, called Multiple Antigen Presentation System (MAPS), enables the high affinity binding of protective polysaccharides and proteins in a single vaccine and uniquely induces a broad and protective immune response. The MAPS technology provides a highly stable, modular, and efficient approach to develop vaccines against a wide range of diseases. The company has achieved preliminary preclinical proof-of-concept for several MAPS vaccines and is currently advancing its lead vaccine candidate against Streptococcus pneumoniae. Affinivax initiated a collaboration with PATH in early 2015 to help support the advancement of its lead MAPS vaccine candidate for Streptococcus pneumoniae (pneumococcal disease), and since September 2015, Affinivax has collaborated with Astellas and its R&D partner, ClearPath Development Company to research and develop MAPS vaccines to prevent bacterial nosocomial infections. For more information, visit www.affinivax.com.

### **About Astellas**

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, visit <a href="https://www.astellas.com/en">www.astellas.com/en</a>.

## **Astellas Cautionary Notes**

The safety and efficacy of the agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for uses being investigated. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

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