



## **Affinivax Reacquires Rights from Astellas for ASP3772, a Novel 24-valent *Streptococcus pneumoniae* Vaccine Candidate from Affinivax's MAPS™ Platform**

**CAMBRIDGE, Mass, USA, and TOKYO, Japan, February 28, 2022** – Affinivax, Inc. (“Affinivax”) and Astellas Pharma Inc. (“Astellas”) today announced that they have entered into an agreement whereby Affinivax has reacquired the exclusive worldwide rights to ASP3772, a novel vaccine candidate targeting *Streptococcus pneumoniae*. In conjunction with the rights reacquisition by Affinivax, ASP3772 will be renamed AFX3772. Closing of the transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act, which is expected in March or April of 2022. Under the terms of the parties’ new agreement, Astellas will receive a \$65 million upfront payment and will be eligible to receive milestone payments and royalties tied to the clinical development and commercialization of ASP3772, as well as royalties tied to the commercialization of Affinivax’s next generation pneumococcal vaccine products designed to treat *Streptococcus pneumoniae*.

“We are excited to regain exclusive, worldwide rights to ASP3772, our MAPS vaccine candidate for *Streptococcus pneumoniae* that has achieved positive Phase 2 clinical trial results and received FDA Breakthrough Therapy designation. We believe ASP3772 has significant potential to address unmet needs in this important vaccine category. Following the closing of the transaction with Astellas, ASP3772 would become the most advanced vaccine candidate in Affinivax’s pipeline, along with other MAPS vaccine programs for bacterial pathogens, viral infections and cancer,” said Steven B. Brugger, CEO of Affinivax. “We are very appreciative of the trust that Astellas placed in Affinivax and our novel MAPS technology platform when we signed our original agreement in 2017, and their commitment to our partnership since then.”

“For Astellas, this decision is based on the strategic prioritization of our R&D pipeline to other core therapeutic areas and drug modalities,” said Naoki Okamura, Chief Strategy Officer and Chief Financial Officer, Chief Business Officer at Astellas. “Our work with Affinivax has been consistent with our vision of being a partner of choice for biotech companies advancing innovative technology platforms that can deliver promising new drugs to prevent and treat diseases and help patients worldwide. Our collaboration on the MAPS vaccine and technology platform has enabled the clinical validation and advancement of a promising new vaccine for *Streptococcus pneumoniae* for adults and infants that offers the potential to improve human health.”

Developed using Affinivax’s proprietary MAPS™ (Multiple Antigen-Presenting System) technology platform, ASP3772 is designed to elicit both B-cell (antibody) and T-cell immune protection against *Streptococcus pneumoniae*. ASP3772 includes 24 pneumococcal polysaccharides, as well as two conserved pneumococcal proteins. The results from the Phase 2 clinical trial demonstrated that ASP3772 was well

tolerated. ASP3772 also exhibited an antibody response to each of the 24 polysaccharides, as well as an additional antibody response to the conserved pneumococcal proteins.

The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for ASP3772 for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes included in ASP3772 in adults aged 50 years and older. The FDA decision is informed by the results of the Phase 2 clinical data. The FDA's Breakthrough Therapy process is designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition.

## **Global Impact and Management of Pneumococcal Disease**

*Streptococcus pneumoniae* remains one of the most frequent bacterial causes of morbidity and mortality worldwide, causing a range of diseases including invasive infections such as bacteremia with sepsis and meningitis, as well as the more common mucosal site infections such as pneumonia, otitis media, and sinusitis. The bacteria typically colonize the respiratory tract, sinuses, and nasal cavity, and spread by direct person-to-person contact via respiratory droplets. *Streptococcus pneumoniae* typically resides asymptomatically in healthy individuals; however, in individuals with weaker immune systems such as the elderly and young children, the bacterium may become pathogenic. Over 95 distinct pneumococcal serotypes have been identified based on their unique capsular polysaccharide structure, making broad spectrum vaccine protection based on polysaccharides alone a difficult task. The National Foundation for Infectious Disease estimates that approximately 1.3 million emergency department visits, 150,000 hospitalizations and 50,000 deaths are attributable to pneumonia<sup>1</sup>. In more than 30% of *Streptococcus pneumoniae* infections, the bacteria are resistant to one or more clinically relevant antibiotics.

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

The MAPS™ technology platform uses proprietary chemistry that capitalizes on the specific and durable non-covalent, affinity binding between biotin and rhizavidin, a biotin-binding protein. The MAPS™ complex created by this affinity binding contributes to a simple, modular, and efficient approach to the development of novel vaccines and immunotherapies. Conventional vaccine conjugation technology seeks to optimize the generation of protective antibody responses mainly to polysaccharide antigens, using the protein antigen as a carrier. In contrast, a MAPS™ vaccine can present both the polysaccharide and the protein antigens to the host immune system to induce both a B- and T-cell immune response. This unique capability of the MAPS™ technology allows for the tailored development of each MAPS™ vaccine or immunotherapy based on the specific type of immune response desired for each pathogen and disease.

## **About Affinivax, Inc.**

Affinivax is a clinical stage biopharmaceutical company pioneering the development of a novel class of vaccines designed to induce a broad and robust protective immune response to both disease-relevant polysaccharides and disease-relevant proteins in a single vaccine. Affinivax designs each of its vaccine candidates to optimize the protective immune response to one or both of these antigens utilizing the distinctive plug-and-play nature of its proprietary MAPS™ technology platform, presenting the potential opportunity to make a significant step forward in addressing major healthcare challenges posed by novel and resistant infectious diseases. Affinivax was founded in 2014 with an exclusive license to the MAPS technology from Boston Children's Hospital. For more information, visit [www.affinivax.com](http://www.affinivax.com).

## About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

## Cautionary Notes (Astellas)

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. 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.

1 GBD 2016 Lower Respiratory Infections Collaborators. Estimates of the global, regional, and national morbidity, mortality, and aetiologies of lower respiratory infections in 195 countries, 1990-2016: A systematic analysis for the Global Burden of Disease Study 2016. *Lancet Infect Dis.* 2018 Sep 19. pii: S1473-3099(18)30310-4. doi: 10.1016/S1473-3099(18)30310-4.

#####

Contacts for inquiries or additional information:

### For Affinivax:

#### Media contact

Kathryn Morris, The Yates Network  
914-204-6412  
[kathryn@theyatesnetwork.com](mailto:kathryn@theyatesnetwork.com)

### For Astellas:

#### Media contact

Corporate Advocacy & Relations  
TEL: +81-3-3244-3201