Affinivax and Astellas Present Safety and Immunogenicity Data from Phase 2 Study of ASP3772, a Novel 24 valent MAPS™ Vaccine for *Streptococcus pneumoniae*

Study results were selected for oral presentation at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID)

ASP3772 has also received FDA Breakthrough Therapy Designation

CAMBRIDGE, Mass, USA, and TOKYO, Japan, July 13, 2021 -- Affinivax, Inc. ("Affinivax") and Astellas Pharma Inc. ("Astellas") announced results from the Phase 2 clinical trial of ASP3772, a novel vaccine candidate targeting *Streptococcus pneumoniae*. Developed using Affinivax's proprietary MAPS™ (Multiple Antigen-Presenting System) platform technology, ASP3772 is designed to offer 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 Phase 2 data for ASP3772 were delivered in an oral presentation at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), taking place online from 9 – 12 July 2021.

The U.S. Food and Drug Administration (FDA) has also 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 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. Designation is based upon preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints.

The Phase 2 clinical trial[1] of ASP3772 was conducted in 503 adults 65 to 85 years of age, and 293 adults received ASP3772, 97 adults received Prevnar13® and 113 adults (who were previously vaccinated with Prevnar13®) received Pneumovax®23. The primary objective was to evaluate safety/tolerability and reactogenicity of ASP3772 compared to Prevnar13®. The secondary objective was to evaluate the immunogenicity of ASP3772, versus Prevnar13 or Pneumovax®23. A summary of the results is below:

- ASP3772 was observed to be well tolerated with mild and self-limited injection site and systemic reactions, similar to those seen in the Prevnar13® group. Frequently reported local reactions were tenderness and pain, occurring within the first 2-3 days with no clear difference across ASP3772 and Prevnar13® cohorts. Neither serious vaccine-related adverse events, nor clinically relevant

abnormalities (vital signs, ECGs, laboratory parameters), were observed. No serious adverse events or medically attended adverse events related to immunization and no potentially immune mediated adverse events were observed in subjects through the 180-day safety assessment period post-immunization.

- At the three dose levels studied, ASP3772 induced a robust immune response to all 24 pneumococcal serotypes in the MAPS™ vaccine, as measured by both immunoglobulin G (IgG) and opsonophagocytic activity (OPA).
- When compared to Prevnar13® alone, ASP3772 demonstrated a similar or better IgG and OPA immune response to the 13 shared serotypes included in both ASP3772 and Prevnar13®. Of note, ASP3772 demonstrated a statistically higher immune response to serotype 3 at all ASP3772 dose levels, as well as a statistically higher immune response to serotypes 5 and 19F at the highest ASP3772 dose tested. ASP3772 also demonstrated a statistically higher immune responses for all remaining 11 serotypes that are not included in Prevnar13®.
- When compared to Prevnar13® plus Pneumovax®23, ASP3772 demonstrated a similar or better IgG and OPA immune response to the 13 shared serotypes with Prevnar13®. Of note, ASP3772 demonstrated a statistically higher immune responses for serotypes 3, 4, 5, 6A, 7F, 9V, and 18C at the highest dose tested. ASP3772 also demonstrated a similar, and in most cases statistically higher, immune response for all remaining 11 serotypes.
- ASP3772 also demonstrated an increase in antibodies (more than 2-fold, as measured by geometric mean fold rise in IgG) response to the conserved proteins included in the MAPS™ vaccine design (i.e., each polysaccharide was combined to a fusion of the two conserved pneumococcal proteins). There were no increases observed in the Prevnar13® group.

“Extending the coverage to 24 *Streptococcus pneumoniae* strains, we believe that ASP3772 has the potential to offer broader protection than any pneumococcal vaccine currently on the market or in clinical testing today , and we look forward to continuing to advance this important vaccine candidate through clinical trials in both adults and infants,” said Steven B. Brugger, CEO of Affinivax. “Demonstrating strong immunogenicity to both the polysaccharides and proteins in our ASP3772 vaccine also represents a significant step forward in clinically validating our MAPS™ technology platform and highlights the promising potential for future MAPS™ vaccines in our pipeline.”

“The MAPS™ technology offers new ways to address unmet needs for infectious diseases, such as *Streptococcus pneumoniae*, that affect millions of people” said Salim Mujais, M.D., Senior Vice President and Therapeutic Area Head, Medical Specialties, Astellas. “We believe that ASP3772 can offer significant potential to provide broader protection from pneumococcal infections that impact both infants and adults in our global community.”

The ASP3772 clinical development program includes indications for protection against *Streptococcus pneumoniae* infections in both adults and infants. The pivotal Phase 3 registration clinical trials in adults are under preparation. A Phase 2 clinical trial with ASP3772 in infants is planned to start following the successful completion of the ongoing Phase 1 study in healthy toddlers 12 to 15 months of age.

In February 2017, Affinivax and Astellas entered into an exclusive worldwide license agreement to develop and commercialize a ASP3772 using Affinivax’s proprietary MAPS™.

About the ASP3772 Phase 2 Clinical Trial[1]

The primary objective of the Phase 2 clinical trial in healthy adults aged 65 to 85 was to evaluate the safety and tolerability of three different dose levels of ASP3772 (1 µg, 2 µg and 5 µg per serotype) compared with Prevnar13®. The secondary objectives were to evaluate the immunogenicity of the three different dose levels of ASP3772, compared with Prevnar13® and Pneumovax®23. The study was a dose-escalation, active-controlled, observer-blinded study. The pneumococcal vaccine-naïve subjects were randomly assigned in a 3:1 ratio to receive either ASP3772 (single intramuscular injection at one of three different dose levels) or Prevnar13® (single intramuscular injection). An additional fifth group of study subjects, who had all received prior immunization with Prevnar13® prior to entering the study, were immunized with Pneumovax®23 as part of their participation in this study. Safety and tolerability were assessed for each group through 30 days post-immunization, with safety assessments for serious adverse events and medically attended adverse events continued through 180 days post-immunization. Serum samples to measure immunoglobulin G (IgG) and opsonophagocytic activity (OPA) were collected on Day 1 (before the first study immunization) and on Day 30 post-immunization.

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 spreads 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[2]. 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™ platform technology, 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 a seed investment from the Bill & Melinda Gates Foundation and an exclusive license to the MAPS technology from Boston Children's Hospital. For more information, visit 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] Phase 2 of the ASP3772 Phase 1/2 Clinical Study (NCT03803202)

[2] 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.

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® Pneumovax is a registered trademark of Merck.

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