ImmBio Initiates First-in-Human Studies of its Novel Pneumococcal Vaccine, PnuBioVax

Cambridge, UK, 10 December 2015 — ImmunoBiology Ltd ("ImmBio" or the Company), a biopharmaceutical company developing next generation anti-infective vaccines based on its proprietary ImmBioVax™ technology, today announces that it has initiated enrolment for a First-in-Human study of its novel vaccine ("PnuBioVax™") against the bacterial pathogen *Streptococcus pneumoniae*.

The study will look at the safety and tolerability of PnuBioVax for three different dosages compared to placebo. Each dose will be given as a prime and two boosts in male and female adults, in a double blind procedure. Conducted by Simbec Research Ltd at its site in Glamorgan, Wales, the study expects to enrol 36 volunteers, with results anticipated in Q2 2016. The primary endpoints of the study are safety and tolerability, as well as selected immunological markers of response. As a measure of secondary outcomes, a range of immunological assays will investigate the likely impact of the vaccine on asymptomatic carriage of the pathogen, and generation of key antibodies, including PnuBioVax's ability to neutralise pneumolysin, a toxin produced by *S. pneumoniae*.

S. pneumoniae commonly resides asymptomatically in the nasal passages of healthy people. However, in susceptible individuals, such as the elderly, young children and the immunocompromised, it can propagate to the blood and vital organs, leading to life threatening diseases[1] including meningitis, sepsis, pneumonia, endocarditis and pericarditis. Despite the availability of antibiotics, the death rate associated with pneumococcal disease, once invasive infection has occurred, is around 14%, making early preventative treatment vital.

There are over 90 serotypes of *S. pneumoniae* in circulation, and individual antibodies against the bacteria provide serotype-specific protection, making vaccine development challenging. Currently

marketed vaccines are relatively expensive to produce and only target a limited number of serotypes each and, by their design, cannot cover emerging strains or serotype replacement[2].

ImmBioVax uses a novel process, incorporating heat shock proteins[3] (HSPs). These proteins are produced by cells in response to stress, for example, heat, and are known to activate both the adaptive and innate arms of the immune response. The PnuBioVax vaccine contains HSPs and multiple antigens produced by a modified form of *S.pneumoniae*, leading to a mechanism of action which is expected to be strain-independent. Consequently PnuBioVax has the potential of being protective across a broad range of current and emergent serotypes, in contrast to currently-available products. In addition, the manufacturing process has a high yield and low production costs, with the potential of being more readily affordable.

"Preclinical studies of PnuBioVax[4] have found its immune response to be serotype-independent, and we expect this to be reflected in the upcoming clinical trial**."** said Dr Chris Bailey, Development Director at ImmBio. He continued: "We will be investigating multiple immunological outcomes based on T-cell and functional antibody responses."

Graham Clarke, CEO of ImmBio, commented: "ImmBio aspires to create a universal vaccine for the huge unmet need of pneumococcal disease. Whilst this has proved elusive to date, we are encouraged that the unique multi-protein design of PnuBioVax offers a viable way to achieve this. Progression of PnuBioVax into First-in-Human studies provides validation of our progress in preclinical studies and manufacturing, and takes us a step closer to a potentially more effective and affordable vaccine for this life threatening disease."

ImmBio's commercial strategy is to develop its vaccine candidates through to proof-of-concept in man, and to find partners to progress late stage development, manufacturing and marketing.

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Notes to editors:

ImmBio

ImmunoBiology Ltd ("ImmBio") is developing next-generation anti-infective vaccines. The Company has an established product and process patent estate around the technology, under the proprietary name ImmBioVax. This safely mimics the normal immune response to a pathogen *ex vivo*, resulting in a vaccine which appropriately primes the host's immune system, so that it is able to block any subsequent infection by the pathogen.

ImmBio's product development portfolio has been selected in areas of high unmet need, where the risk and consequence of infection are severe.

ImmBio is based at the Babraham Research Campus in Cambridge, UK.

For more information, please visit the website at www.immbio.com.

Streptococcus pneumoniae

Streptococcus pneumoniae safely and asymptomatically resides in the nasopharynx of many healthy people. Between 5-10% of all adults and 20-40% of children are carriers, with an even higher figure in infants. However, particularly in susceptible individuals, the pathogen can spread to other locations and cause disease[5]. In addition to pneumonia, *S. pneumoniae* can lead to acute sinusitis, otitis media, meningitis, sepsis, endocarditis and pericarditis. It is a major cause of mortality in the young and elderly globally. For infants, globally pneumococcal disease causes greater mortality than TB, HIV and malaria combined[6].

Once infected, therapeutic intervention using antibiotics combined with intensive care can be insufficient and expensive, while antibiotic drug resistance is growing. Consequently prophylactic intervention is preferable, with a strong health economic benefit.

Products currently available use the polysaccharide of a specific serotype, which is the current basis of defining the strain. These provide very good protection against that serotype. "Breadth" is achieved by adding together a number of vaccines ("multi-valent"), the most common being a 13-valent composition. However, this approach cannot provide a broad, cost effective vaccine.

Epidemiological studies show that whilst current vaccines have successfully addressed the serotypes they contain, other serotypes have increased in frequency[2,7]. In addition new strains have emerged. The types of strains found in different part of the world vary, so the level of protection offered by a serotype-specific vaccine varies geographically. Thus a cost-effective, strain-independent or "universal" vaccine would address a major global healthcare need.

For more information, see: http://www.who.int/biologicals/vaccines/pneumococcal/en/

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