First-In-Human Study of Immbio's Novel Pneumococcal Vaccine Pnubiovax Shows Vaccine to be Safe and Immunogenic

Data presented as invited oral presentation at 10th International Symposium on Pneumococci & Pneumococcal Diseases

- Antibody responses to ubiquitous antigens across strains shown, indicative of broad protection
- Statistically significant increases in antibody response were achieved in the 200 (mid) and 500 µg (high) dose groups, in comparison to the placebo group
- 100% of subjects in the high dose group achieved a significant immune response
- Study demonstrated a dose response relationship
- Proven safety will allow further development of the vaccine, specific to at-risk groups for pneumococcal disease

Cambridge, UK, 30 June 2016 — ImmunoBiology Ltd ("ImmBio" or the Company), a biopharmaceutical company developing next generation anti-infective vaccines based on its proprietary ImmBioVax™ technology, reports positive results from the First-in-Human study of its novel vaccine, PnuBioVax™, against the bacterial pathogen *Streptococcus pneumoniae* (NCT02572635). PnuBioVax was found to be safe and well tolerated, and capable of producing antibody responses against key *S. pneumoniae* antigens broadly conserved across strains. The data was presented today at the International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD), Glasgow, UK.

"The results of this study have demonstrated the safety of PnuBioVax in adults, and we are now looking at developing the vaccine further, focusing on the at-risk populations for pneumococcal disease of the young and the elderly" said Dr Chris Bailey, Development Director at ImmBio.

Graham Clarke, CEO of ImmBio, commented: “Demonstrating that PnuBioVax is safe and immunogenic through this phase I clinical study is a fundamental step in our mission to create a universal vaccine against pneumococcal disease. This provides the real prospect of a strain-independent pneumococcal disease prophylactic vaccine. We are now looking for partners to progress PnuBioVax through late stage clinical development, manufacturing and marketing”.

Study Design

The randomised, double blind study assessed the safety and immunogenicity of PnuBioVax for three different dosages (50 µg, 200 µg, and 500 µg) compared to placebo. Doses of PnuBioVax were administered intramuscularly on three occasions, 28 days apart. A total of 36 healthy males and females, aged 18 to 40 years, were recruited for the study.

In addition to monitoring volunteers for adverse events, antibody responses to PnuBioVax were measured by ELISA, using blood samples taken from the volunteers at four separate occasions throughout the study. The presence of specific antibodies, against antigens selected for their ubiquity across strains and role in causing disease, was also measured. The functional capacity of these antibodies was assessed using an opsonophagocytic assay, commonly used as an indicator of an antibodies’ ability to kill the pathogen and therefore protect against disease. The ability of antibodies raised against PnuBioVax to neutralise the toxic component of *S.pneumoniae*, Pneumolysin (Ply), was also assessed.

Safety data

Assessment of safety data concluded that no clinically-significant changes of vital signs, ECG and blood chemistries were observed as a result of treatment with PnuBioVax, and, importantly, no serious adverse events were seen. Overall, PnuBioVax was concluded to be safe and well tolerated. This is in accordance with expectations of PnuBioVax’s safety profile as a self adjuvanting vaccine.

Immunogenicity data

A statistically significant increase in total antibody response was seen in the 200 and 500 µg dose groups compared to placebo, showing PnuBioVax to be immunogenic. In addition, 100% of subjects in the high dose group achieved a significant immune response. Response to specific disease relevant antigens, such as Ply and Pneumococcal surface protein A (PspA) were also observed, indicating PnuBioVax’s capability of broad protection across strains. The range of doses used was able to demonstrate a relationship between dose and antibody response. The study showed no clear

advantage of a 500 µg dose over 200 µg dose of PnuBioVax.

A correlation was seen between antibodies generated against Ply and inhibition of the haemolytic effects of the pathogen on red blood cells. This is indicative of PnuBioVax's ability to neutralise the Ply toxin, a factor implicated in the virulence of *S. pneumoniae.*

Dr Chris Bailey presented the phase I data today during the session 'Invited Oral Poster Presentations 07: New Pneumococcal Vaccines' at ISPPD. The abstract can be found online, here: http://www.isppd2016.kenes.com/scientific-program-(2)/scientific-program-2#.V2v77FUrLGg

ImmBio is also presenting three posters focused on PnuBioVax at ISPPD.

Ends

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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[1]. 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[2].

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[3, 4]. 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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