Alopexx completes first-in-man trial of its novel, broad-spectrum anti-microbial vaccine

Potential to prevent wide range of infections including those caused by antibiotic-resistant organisms.

- Phase 2 Studies Planned for First Quarter 2018 -

CONCORD, Mass. October 25, 2017—Alopexx Vaccine LLC today announced that it has completed a Phase 1 clinical trial with AV0328, a vaccine targeting the broadly expressed microbial antigen, poly-*N*-acetyl glucosamine (PNAG). Antibodies to PNAG have the potential to prevent many serious and life-threatening infections such as pneumonia, meningitis, bloodstream infections, gonorrhea, and also those caused by antibiotic resistant bacteria such as MRSA. The World Health Organization has warned that the increasing development of numerous antibiotic-resistant "superbugs" pose an enormous threat to human health. Based on these results, Alopexx plans to initiate a Phase 2 clinical study with AV0328 in the first quarter of 2018.

"We are very encouraged by these early clinical data demonstrating the safety, tolerability and initial indications of clinical activity of AV0328 in humans," said Hal Landy, M.D., Chief Medical Officer at Alopexx. "We look forward to further evaluating AV0328 against a breadth of infections caused by PNAG-expressing pathogens, including serious soft-tissue infections caused by methicillin-resistant *S. aureus* (MRSA), pneumonia, meningitis, tuberculosis and sexually transmitted diseases, including those caused by antibiotic-resistant organisms."

"Our modified, synthetic vaccine that targets natural PNAG expressed on the surface of most pathogenic bacteria, as well as important eukaryotic pathogens like malaria and numerous fungi, could represent a new paradigm for disease prevention by inducing protection against a large number of infectious agents, including those manifesting high levels of antibiotic resistance" Gerald B. Pier, Professor of Medicine, Harvard Medical School, Microbiologist, Brigham and Women's Hospital.

About the Phase 1 Clinical Study

The Phase 1 clinical study was designed to evaluate the safety, tolerability, pharmacodynamics (PD) and preliminary efficacy of AV0328 in 16 healthy volunteers across four dosing cohorts ranging from 15 to 150 μg. PD was assessed by measuring the increase and time course of serum titers against PNAG and complement binding (C1q deposition) activity. Clinical efficacy was assessed by measuring killing of PNAG-expressing pathogens by subject sera *in vitro*.

AV0328 was safe and well-tolerated in this study with only minor and transient injection site reactions observed in each dose group. At the two highest doses (75 μg and 150 μg), clear increases were noted in antibody titers against PNAG, as well as a positive indication of protective immunity, as measured by complement activation and binding to the PNAG antigen. In addition, robust bactericidal killing of *N. gonorrhea,* including antibiotic-resistant strains, and *N. meningitidis* (serogroups A, B, C, W, Y), as well as opsonic killing of *S. pneumoniae,* multi-drug resistant *Klebsiella pneumonia,* colistin and multi-drug resistant strains of *E. coli* and *S. aureus,* including MRSA clinical isolates, was observed.

About AV0328

AV0328 is a synthetic pentameric oligosaccharide of β-1-6-linked D-glucosamine sugars conjugated to tetanus toxoid that elicits a protective antibody response against a large number of microbial pathogens associated with infections. PNAG, which is expressed on the surface of various bacteria, fungi and protozoan organisms, has been shown to be a critical factor in the virulence of many pathogens. In its natural state, PNAG has a profound ability to avoid eliciting an effective immune response. Bacterial strains that lose the ability to produce PNAG generally have a significantly reduced ability to cause infections. The fact that so many pathogens express PNAG suggests that it is a critical evolutionary feature for both microbial survival and for evading the mammalian immune system. A vaccine that effectively overcomes immune evasion to elicit antibodies that kill PNAG-producing pathogens could provide protection against not just individual strains or even an entire species of a pathogen, but against a wide array of serious microbial infectious agents.

About Alopexx Vaccines LLC

Alopexx Vaccines LLC, part of the Alopexx Enterprises portfolio of companies, specializes in the development of vaccines against a range of pathogens and infections. For more information please visit www.Alopexx.com.

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