

Alopexx Announces Collaboration with Bharat Biotech for the Development and Commercialization of Broad-Spectrum Anti-Microbial Vaccine AV0328

Strategic Collaboration Aims to Accelerate Global Access to Potentially Life-Saving Vaccine

Cambridge, MA, Sept. 10, 2024 (GLOBE NEWSWIRE) -- Alopexx, Inc., a clinical-stage biotechnology company focused on developing novel, broad-spectrum immune-mediated therapeutics for the prevention and treatment of bacterial, fungal, and parasitic infections, today announced a collaboration with Bharat Biotech for the co-development and commercialization of Alopexx's proprietary broad-spectrum anti-microbial vaccine, **AV0328**, in India and other low income and lower middle-income countries.

Bharat Biotech is a pioneering biotechnology company known for its world-class research and development and manufacturing capabilities. As part of the collaboration, the companies will co-develop and commercialize **AV0328**, a synthetic vaccine targeting *poly N-acetyl glucosamine* (PNAG), in India and other licensed territories. Alopexx would be entitled to a one-time upfront payment and milestone payments, as well as royalties on future sales of **AV0328** in the licensed territories.

"We are excited to enter into this collaboration with Bharat Biotech," said Dr. Daniel Vlock, CEO of Alopexx. "To partner with a company with such vast experience and expertise in vaccine development is a significant validation of the value and potential of Alopexx's technology. This collaboration brings us one step closer to addressing the critical need for affordable, broad-spectrum antimicrobial solutions, especially in low-and middle-income countries."

Dr. Vlock added, "We also deeply appreciate the collaborative support provided by Bharat Biotech. This support is not only crucial for the advancement of **AV0328**, but will also significantly bolster our overall clinical programs. The broad and breakthrough potential of our platforms in treating a wide array of bacterial, fungal, and parasitic infections represents a transformative approach to combating infectious diseases on a global scale."

Dr. Krishna Ella, Executive Chairman of Bharat Biotech, commented, "We are proud to collaborate with Alopexx to bring **AV0328** to the regions where it is most needed. Our goal is to develop solutions to reduce anti-microbial resistance through vaccination. This collaboration aligns with our mission to provide safe, affordable, and high-quality vaccines to combat infectious diseases globally."

About AV0328

AV0328 is a synthetic vaccine designed to target *poly N-acetyl glucosamine* (PNAG), a substance found on the surface of a wide range of bacterial, fungal, and parasitic pathogens. In pre-clinical studies, targeting PNAG has shown effectiveness in preventing and treating infections caused by over 15 different pathogens. A phase I, first-in-human trial has been completed, demonstrating that **AV0328** is well-tolerated with no serious adverse events observed. The vaccine induced antibodies capable of killing a wide range of PNAG-expressing pathogens, reaffirming its potential as a broad-spectrum antimicrobial solution.

About Bharat Biotech International Limited (BBIL)

Bharat Biotech (BBIL) is a biotech company in Genome Valley, Hyderabad, India. BBIL is a global leader with 145 patents, ~20 vaccines and bio-therapeutics, and registrations in 125 countries. These vaccines were developed through clinical trials in more than 20 countries worldwide and have been published in more than 100 peer-reviewed journals. The company has manufactured and supplied more than 9 billion doses of vaccines globally, saving millions of lives and livelihoods annually.

The company has world-class vaccine and bio-therapeutics research, product development, manufacturing, and distribution facilities. BBIL has developed vaccines for infectious diseases, including Hepatitis B, Pentavalent (DPT+HepB+Hib), Rabies, Typhoid, polio, H1N1 influenza, Japanese Encephalitis (JENVAC[®]), India's first Rotavirus vaccine, the world's first Typhoid conjugate vaccine, TYPBAR TCV[®], novel vaccines for COVID-19 such as COVAXIN[®] and INCOVACC[®]. BBIL introduced WHO pre-qualified vaccines, namely BIOPOLIO[®], ROTAVAC[®], ROTAVAC 5D[®], and TYPBAR TCV[®], in several countries worldwide.

BBIL has a strong pipeline of innovative vaccines against malaria, tuberculosis, Para Typhi A, non-typhoidal salmonella, chikungunya, and Zika. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as one of the world's largest rabies vaccine manufacturers with CHIRORAB[®] and INDIRAB[®]. To learn more about BBIL, visit www.bharatbiotech.com.

About Alopexx, Inc.

Alopexx is a clinical-stage biotechnology company targeting novel immune therapeutics for the prevention and treatment of bacterial, fungal and parasitic microbial infections. The target of our therapeutics, poly N-acetyl glucosamine (PNAG), has been found in a wide range of pathogens. Our vaccine candidate, **AV0328**, has been shown to induce protective antibodies against a wide range of PNAG-expressing pathogens in a Phase I trial. F598, our fully human monoclonal antibody, has been shown to be safe and well tolerated in phase I and pilot trials. Following a single infusion, it can provide protection for 2-3 months. Our goal is to develop a broad-spectrum, non-antibiotic therapeutic platform for the treatment and prevention of microbial infections. These immune therapeutics will reduce reliance on antibiotics and the development of antimicrobial resistance. For more information, please visit www.Alopexx.com.

Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans,

objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although Alopexx's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Alopexx that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC made by Alopexx, including those listed under "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in Alopexx's registration statement on Form S-1. Other than as required by applicable law, Alopexx does not undertake any obligation to update or revise any forward-looking information or statements.

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Source: Alopexx, Inc.