



## **Artax Biopharma Granted MHRA Clinical Trial Authorization for AX-158**

*Authorization Represents Start of Clinical Program for Company's  
Global Platform of T Cell-Mediated Diseases*

*Phase 1 Clinical Trial Expected to Start in Second Half of this Year*

**Cambridge, Mass., July 13, 2021** – Artax Biopharma, Inc., a biotechnology company focused on transforming the treatment of T Cell-mediated diseases, today announced that the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) has granted clinical trial authorization to evaluate AX-158 in a Phase 1 clinical trial for the treatment of T Cell-Mediated Diseases.

The MHRA authorization marks the start of Artax's clinical trial program for its global platform of T Cell-mediated diseases. The AX-158 Phase 1 clinical trial is expected to start in the second half of this year.

Artax's lead compound AX-158 is a first-in-class, oral small molecule immunomodulating agent for the treatment of T Cell-mediated diseases. AX-158 employs a novel mechanism of action that selectively modulates, or adjusts, T cell responses that play a critical role in immune system function. In preclinical studies, AX-158 decreased key cytokines including  $\text{INF}\gamma$ ,  $\text{TNF}\alpha$  and IL-2. Based on this activity, Artax is planning future clinical development in autoimmune diseases, T cell malignancies and other related T cell pathologies.

"This authorization to study the tremendous science behind AX-158 is fantastic news for the immunology field," said Dr. Lawrence Steinman, Stanford University Zimmerman Professor of Neurology and Neurosciences, Pediatrics, and Genetics and Artax Scientific Advisory Board member. "Artax Biopharma's Nck inhibitor AX-158 has shown impressive experimental biologic and mechanistic impact on T Cell modulation - managing autoimmune disease without inducing the profound immunosuppression associated with current conventional or biological therapies."

"There is a great need for oral therapeutics that offer efficacy with fewer side effects for the many patients suffering from debilitating and life-threatening T Cell-mediated diseases including autoimmune diseases and T cell malignancies" Artax Biopharma Chief Executive Officer Joseph Lobacki stated. "The MHRA approval and opportunity to initiate clinical trials for AX-158 is a significant milestone, and we look forward to bringing this first-in-class treatment option to the clinic."

## **About Artax Science and Immunomodulation**

A healthy immune system eliminates harmful foreign pathogens, while being tolerant of self-tissues and organs. The T Cell Receptor (TCR) is central to healthy T Cell function and a well-functioning immune system. When TCR signaling becomes dysregulated, T Cells behave abnormally. This behavior results in T Cell-driven conditions including autoimmune diseases, T Cell malignancies (lymphomas), and induced T Cell pathologies in which medical treatments result in immune reactions (such as stem cell transplants resulting in acute graft-versus-host-disease or immune-oncology treatments resulting in immune related-adverse events). Artax believes immunomodulation - during which our medicines assist the immune system to maintain healthy control and eliminate a direct cause of T Cell-mediated diseases while not impacting patients' ability to properly fight foreign pathogens - holds great potential.

## **About Artax-158**

AX-158 is a first-in-class, oral small molecule immunomodulating agent in development for the treatment of T Cell-mediated diseases. AX-158 employs a novel mechanism of action that selectively modulates, or adjusts, T Cell responses that play a critical role in immune system function. Nck is a protein that naturally amplifies T Cell signaling directly at the TCR, contributing to pathogenic responses. AX-158 is a Nck SH3.1 domain inhibitor which selectively counteracts the role of Nck in T Cells. This process of immunomodulation eliminates a direct factor in T Cell-mediated diseases. Importantly, data suggest AX-158 is not immunosuppressive and does not impact the immune system's ability to mount a strong response to foreign pathogens and infections.

## **About Artax Biopharma**

Artax Biopharma is a biotechnology company transforming T Cell-mediated disease treatment by developing innovative small molecules that modulate the immune system. Artax science holds broad potential to treat T Cell-mediated diseases such as autoimmune diseases, induced T cell pathologies (such as acute graft versus host disease and immune-oncology treatment-related adverse events) and T Cell malignancies (lymphomas), while simultaneously allowing the body to fight foreign pathogens. For more information, please visit [www.artaxbiopharma.com](http://www.artaxbiopharma.com).

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