Zai Lab and argenx Announce Approval of VYVGART Hytrulo for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in China

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First and only NMPA-approved treatment for patients with CIDP in China

Third approval for efgartigimod franchise in China demonstrating Zai Lab's deep expertise developing innovative treatments across a broad range of diseases

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 11, 2024-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) and argenx (Euronext & Nasdaq: ARGX) today announced that China's National Medical Products Administration (NMPA) approved the supplemental Biologics License Application (sBLA) for VYVGART Hytrulo 1,000mg (5.6ml)/vial [Efgartigimod Alfa Injection (Subcutaneous Injection)] for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo is approved for CIDP as a once weekly 30-to-90 second subcutaneous injection. It is the first and only therapy approved in China for the treatment of CIDP, a debilitating, often progressive, immune-mediated neuromuscular disorder of the peripheral nervous system.

"We are pleased to receive NMPA approval for VYVGART Hytrulo, marking a groundbreaking milestone for CIDP patients in China," said Rafael G. Amado, M.D., President, Head of Global Research and Development at Zai Lab. "This approval brings a much-needed treatment option to patients who have been suffering from CIDP for far too long. We appreciate the NMPA for their thorough assessment and recognition of the therapy's differentiated profile and the large unmet patient medical need in China. We will continue to work with argenx to explore the potential in other Immunoglobulin G (IgG)-mediated autoimmune indications."

"VYVGART Hytrulo is a precision therapy for patients living with CIDP, many of whom have been waiting for a new treatment innovation," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We are grateful to our partners at Zai Lab for collaborating with argenx to reach CIDP patients in China, and to the NMPA for approving VYVGART Hytrulo for CIDP. Zai has a strong record of impeccable execution and a shared value of doing all that we can, together, for patients in need. We look forward to continuing our partnership with Zai as argenx continues to reach more patients in one of the world's fastest growing markets."

"CIDP is a serious and debilitating disease with approximately 50,000 diagnosed patients in China[1], with only a small fraction of patients able to achieve remission on corticosteroids and plasma-derived therapies, the current standard of care." said Prof. Ting Chang, M.D., Deputy Chief Physician and Associate Professor, Department of Neurology, Tangdu Hospital. "In addition, existing treatment options are problematic and challenging for some patients. VYVGART Hytrulo provides a new, safe and effective treatment option that can meaningfully improve and stabilize disease symptoms and potentially lessen the burden of treatment for these patients. This is an important advancement for the patient community, and we are grateful to Zai Lab for their work supporting patients who have been devastated by this disease for so long."

The NMPA approval is supported by the positive results from the ADHERE (NCT04281472) study, a multicenter, randomized, double-blind, placebo-controlled trial evaluating VYVGART Hytrulo for the treatment of CIDP. The ADHERE study included an open-label period to identify responders who then entered a randomized-withdrawal, double-blinded period. Zai Lab enrolled patients into the ADHERE trial in Greater China and treatment response in these participants was consistent with global study outcomes. Subgroup analysis of Chinese participants demonstrated a 69% reduction in the risk of relapse with VYVGART Hytrulo compared to placebo. In addition, 78% of Chinese participants treated in the open-label period of the study demonstrated evidence of clinical improvement, further confirming the role IgG autoantibodies play in the underlying biology of CIDP. The favorable safety and tolerability profile of VYVGART Hytrulo dosed weekly in the Chinese patient cohort was consistent with what was shown in global trial participants.

In May 2024, Zai Lab announced that the Centre for Drug Evaluation (CDE) accepted the sBLA with priority review designation for VYVGART Hytrulo for CIDP in China. The CDE granted the Breakthrough Therapy Designation for the treatment of patients with CIDP in September 2023.

About VYVGART Hytrulo

VYVGART Hytrulo is a subcutaneous product that consists of efgartigimod alfa, a human IgG1 antibody fragment, and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE ® drug delivery technology to facilitate subcutaneous delivery of biologics. The product is a single subcutaneous injection (1,000 mg fixed dose) delivered over 30-to-90 seconds and given weekly. VYVGART Hytrulo can be administered by a healthcare professional or at home by the patient or caregiver after adequate training in the subcutaneous injection technique. It is approved in the United States (marketed as VYVGART® Hytrulo for generalized myasthenia gravis (gMG) and CIDP), EU (marketed as VYVGART® SC for gMG), Japan (marketed as VYVDURA® for gMG) and China (marketed as VYVGART Hytrulo® for gMG and CIDP).

Zai Lab has an exclusive license agreement with argenx to develop and commercialize efgartigimod in mainland China, Hong Kong, Macau, and Taiwan (collectively, Greater China).

About CIDP in China

There are an estimated 50,000 patients diagnosed with CIDP in mainland China.[1] Current treatment options are primarily corticosteroids and intravenous immunoglobulin (IVIg), with plasma exchange (PLEX) generally reserved for refractory patients. There is limited access to PLEX or IVIg in many parts of the world, including China. Because most patients require treatment for an extended period, there remains a significant unmet need for alternative treatment options that are effective, well-tolerated, and convenient for patients with CIDP in China.

[1] *Chronic inflammatory demyelinating polyneuropathy and diabetes, 2020.*

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx developed and is commercializing the first approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan, Israel, the EU, the UK, Canada and China. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, X/Twitter, Instagram, Facebook, and YouTube.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for development and commercialization of efgartigimod in Greater China, the safety and efficacy of efgartigimod, and the potential treatment of patients with CIDP and other autoimmune disorders in Greater China. These forward-looking statements may contain words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would,” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact or guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) risks related to doing business in China, and (6) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Our SEC filings can be found on our website at www.zailaboratory.com and the SEC’s website at www.sec.gov.

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