argenx and Zai Lab Announce Strategic Collaboration for Efgartigimod in Greater China

January 6, 2021

- Collaboration to expand and accelerate global development of efgartigimod; expected to allow argenx to more rapidly advance new potential indications into clinical development each year
- Zai Lab granted exclusive rights to develop and commercialize efgartigimod in Greater China
- argenx to receive $75 million in upfront Zai Lab equity and $100 million in near-term milestone and other payments

Regulated Information/Inside Information

BREDA, the Netherlands and SHANGHAI and SAN FRANCISCO, Jan. 06, 2021 (GLOBE NEWSWIRE) -- argenx SE (Euronext & NASDAQ: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced an exclusive license agreement for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau.

“Through this collaboration with Zai Lab, we are expanding our global footprint in one of the world’s fastest growing markets and reaching more people living with severe autoimmune diseases. By leveraging Zai Lab’s strong local expertise within Greater China and proven development capabilities, we aim to provide broad access to efgartigimod in these important markets as well as accelerate the number of autoimmune indications in clinical development,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We believe that Zai Lab is the ideal partner for us ahead of our first potential approval of efgartigimod in generalized myasthenia gravis (gMG) in the U.S. and we are aligned in our mutual passion to bring potential innovative immunology therapies to patients in need.”

“argenx is building a leading immunology company and we are excited to collaborate with them during this important time. Efgartigimod is being evaluated in a broad range of autoimmune diseases and we look forward to bringing this potentially first-in-class product to patients in Greater China,” said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. “This collaboration also significantly expands and strengthens our pipeline in severe autoimmune diseases, where there is an urgent and serious need for new therapeutic options.”

“There are an estimated 200,000 people living with MG in China,” said Dr. Harald Reinhart, Chief Medical Officer for Autoimmune and Infectious Diseases, Zai Lab. “The unmet medical need is significant for these patients, with very limited treatment options. We believe efgartigimod has a promising profile that, if approved, can potentially change the treatment paradigm not only of gMG but of other autoimmune diseases.”

Under the terms of the agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will recruit Chinese patients to argenx’s global registrational trials for the development of efgartigimod. Additionally, this agreement is expected to allow argenx to accelerate efgartigimod development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications.

argenx will receive $175 million in collaboration payments, comprised of a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132.00 per share, $75 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and an additional $25 million milestone payment upon approval of efgartigimod in the U.S. argenx is also eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

About Efgartigimod

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation. Blocking FcRn reduces IgG antibody levels, representing a logical potential therapeutic approach for several autoimmune diseases known to be driven by disease-causing IgG antibodies, including: myasthenia gravis (MG), a chronic disease that causes muscle weakness; pemphigus vulgaris (PV), a chronic disease characterized by severe blistering of the skin; immune thrombocytopenia (ITP), a chronic bruising and bleeding disease; and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disease leading to impaired motor function.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. 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 is evaluating efgartigimod in multiple serious autoimmune diseases, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. For more information, visit www.argenx.com and follow us on LinkedIn at https://www.linkedin.com/company/argenx/.

About Zai Lab

Zai Lab (NASDAQ:ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and drug candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us on Linkedin at https://www.linkedin.com/company/zai-lab/mycompany/ and Twitter at www.twitter.com/ZaiLab_Global.

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argenx Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, forward-looking statements. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, intends, may, will, or should, and include statements argenx makes concerning the therapeutic potential of its product candidates; the intended results of its strategy; the expected benefits of the collaboration with Zai Lab; its and its collaboration partners' clinical development and regulatory plans, including the timing, design and outcome of ongoing and planned clinical trials and the timing and outcome of regulatory filings and approvals; and the timing and progress of commercialization activities. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including the effects of the COVID-19 pandemic, the inherent uncertainties associated with preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing efgartigimod in Greater China. 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 nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's 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) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly 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 Zai Lab's views as of any date subsequent to the date of this press release.



Source: Zai Lab Limited