Zai Lab Announces First Patient Treated in Greater China Portion of Potentially Registrational, Global Phase 2 Study of Odronextamab

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Zai Lab expects to enroll Chinese patients across several disease-specific B-cell non-Hodgkin lymphoma (B-NHL) cohorts in the potentially pivotal, global Phase 2 study of odronextamab monotherapy

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Oct. 25, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the first patient has been treated in the Greater China portion of the potentially registrational, global study of odronextamab monotherapy being conducted by its partner Regeneron and Zai Lab in patients with B-cell NHL.

“Odronextamab has demonstrated considerable clinical activity in a Phase 1 clinical trial and represents a promising therapeutic opportunity for heavily pre-treated patients across a range of B-cell NHL subtypes,” said Alan Sandler, M.D., President and Head of Global Development, Oncology. “Zai Lab is excited to have dosed the first patient in the China portion of this potentially registrational Phase 2 study. Our participation in this study underscores Zai’s commitment to excellent execution and to bringing innovative therapeutic approaches to patients.”

The global study is a Phase 2, open-label, multi-cohort clinical trial of odronextamab monotherapy in patients with B-NHL who have relapsed after, or are refractory to, systemic therapy. The study consists of five cohorts in specific subtypes of B-NHL: follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma, marginal zone lymphoma, and other B-NHL subtypes. Patients will be given 12 weekly doses followed by dosing once every two weeks until either disease progression or other protocol-defined reasons for treatment discontinuation. The primary objective is to assess the anti-tumor activity of single agent odronextamab as measured by the objective response rate according to the Lugano classification of response in malignant lymphoma and as assessed by independent central review. Secondary objectives include safety and tolerability, complete response rate, progression-free survival, overall survival, duration of response, and disease control rate.

About B-Cell Non-Hodgkin Lymphoma (B-NHL) in China

Non-Hodgkin lymphoma (NHL) represents a diverse group of cancers that originate from B-, T-, or natural-killer-cells, with annual incidence and death rates, respectively, in China of 92,834 and 54,351 according to Globocan 2020. NHL originating in B-cells (B-NHL) make up approximately 85% of all NHL cases, with the two most common subtypes being DLBCL and FL. DLBCL is an aggressive form of B-NHL, with up to 50% of patients with advanced-stage disease progressing after first-line treatment (e.g., relapsing or becoming refractory to treatment). For patients with relapsed or refractory DLBCL, treatment options are limited and the prognosis is poor. FL is an indolent (slow-growing) form of B-NHL, with most cases diagnosed in advanced stages. Although median survival ranges from 8 to 15 years in advanced FL, current therapeutic options are not curative, and most patients relapse within five years regardless of the regimen. In some cases, FL can transform into DLBCL, at which point it is often treated in the same way as DLBCL.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. 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 product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product 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 at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements regarding the possible benefits, safety and efficacy
of odronextamab monotherapy, the identification and treatment of B-cell NHL and risks and uncertainties associated with drug development and commercialization. These statements may be identified by 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 nor are they 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 finance our operations and business initiatives and obtain funding for such activities, (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) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and

Exchange Commission. 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.

For more information, please contact:

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