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中國抗體製藥有限公司
SinoMab BioScience Limited
(Incorporated in Hong Kong with limited liability)
(Stock Code: 3681)

SinoMab (03681.HK) Globally First-in-Class SM03 (Suciraslimab) Achieves Breakthrough Preclinical Results in SLE, Demonstrating Positive Immune Modulation with Potential Multi-Organ Protection and Superior Long-Term Safety

(10 July 2025 - Hong Kong) **SinoMab BioScience Limited ("SinoMab" or the "Company", stock code: 03681.HK),** is pleased to announce that its globally first-in-class innovative drug SM03 (Suciraslimab) targeting Systemic Lupus Erythematosus (SLE) has achieved breakthrough pre-clinical results from In-vivo study. As a monoclonal antibody targeting CD22(a sialic acid-binding transmembrane protein primarily expressed on B cells and associated with various autoimmune and neurodegenerative diseases), SM03 leverages its unique advantages of "Modulation of autoimmune network through B cell interaction and multi-organ protective effects" to address the unmet needs of long-term medication safety and organ protection benefits in SLE treatment, providing patients worldwide with a safer and greater efficacy new therapeutic option.

Competitive Advantages of SM03 in the Treatment of SLE:

"**B Cell Modulation Without Depletion"**: Differentiating from traditional B cell depletion therapies (BCDTs) such as anti-CD20 therapies, SM03 specifically regulates autoreactive B cells without depleting normal B cells, thereby reducing infection risks and maintaining immune surveillance.
"**Dual Mechanism and Dual Regulation"**: The primary mechanism of SM03 involves upstream inhibition of autoreactive B cell activation and autoantibody production, addressing humoral immune dysregulation (humoral immune axis). The synergistic mechanism can also modulate B and other immune cell interactions, thereby ensuring an alleviation of systemic autoreactive inflammation through a regulation of the immune network.
"**Organ Protection"**: SM03 possesses unique advantage among competitors by reducing proteinuria and alleviating glomerular tissue damage mediated by immune complex deposition, which is critical for lupus nephritis (LN). Additionally, through its dual-regulation effects, SM03 mitigates immune-mediated pulmonary complications of lupus such as recurrent alveolar hemorrhage or pulmonary arterial hypertension. These organ-protective effects have clinical meaningfulness and are vital for treatment prognosis in the SLE area.

By utilizing a humanized animal (murine) model that closely recapitulate the key pathological features of human systemic lupus erythematosus (SLE)—including the production of pathogenic

autoantibodies, multi-organ immune complex deposition, and progressive tissue damage—SM03 treatment demonstrated distinctive and advantageous immunomodulatory properties. The candidate drug selectively inhibits activated B cell subsets (e.g., $CD27^+/CD38^+$) while sparing the overall B cell population, marking a significant differentiation to the prevailing immunosuppression therapies induced by commercially available drugs. Notably, SM03 significantly reduces serum levels of anti-double-stranded DNA (anti-dsDNA) antibodies. Such findings have clinical significance, with a high prevalence in approximately 70% of SLE patients, these autoantibodies not only serve as biomarkers for disease activity but also contribute directly to organ damage by forming immune complexes in tissues such as the kidneys, skin, and joints. These complexes activate the complement cascade and drive progressive organ injury, particularly playing a vital role in the pathological deterioration of lupus nephritis (LN).

Current B cell-targeted therapies in clinical application can reduce autoantibody levels but often fail to significantly improve end-organ damage—an issue is significantly found in lupus nephritis (LN), which affects approximately 50% of SLE patients. Moreover, systemic complications such as pulmonary interstitial disease also lack effective therapy. In contrast, SM03 has demonstrated breakthrough organ-protective effects in preclinical studies: a restoration of proteinuria comparative to healthy animal levels while also significantly reduced the intensity of glomerular immune complex deposition. Additionally, SM03 suppressed pulmonary inflammatory infiltration and fibrosis progression, with histopathological improvements surpassing those observed with comparator drugs.

This differentiated advantage stems from SM03's innovative mechanism of action: by regulating autoreactive B cell function in a non-depleting manner, it modulates autoantibody production while enhancing B cell to other immune cell interaction networks to suppress downstream immune cell activation cascades. This enables coordinated protection across multiple organs. Given its clearly in vivo efficacy and favorable safety profile, SM03 is expected to be a superior therapeutic option for LN and multi-organ damage in SLE.

Note: The research findings presented in this report are excerpts from ongoing studies. Detailed methodology, complete data, and analyses will be submitted for publication in a peer-reviewed academic journal.

Dr. Shui On LEUNG, Executive Director, Chairman and Chief Executive Officer of SinoMab, comments: "While the global rheumatoid arthritis (RA) treatment market continues to expand, the competitive landscape of therapeutically dominant drug is remains relatively fierce. In contrast, systemic lupus erythematosus (SLE), a life-threatening disease, still lacks a treatment that can both effectively overcome long-term immune tolerance and provide comprehensive organ protection. This represents a significant unmet medical need and offers a substantial market potential."

As the pioneering antibody targeting CD22, SM03 has made significant preclinical progress in the field of systemic lupus erythematosus (SLE). Leveraging its unique dual mechanism of action, SM03 not only precisely modulates B cell activation and differentiation but also reprograms multicellular interaction networks with B cells as the central immune hub. SM03 has demonstrated its superior

efficacy and safety characteristics compared to conventional B cell depletion therapies in animal models.

These findings provide early evidence that SM03 has the potential of inducing immune tolerance, reducing autoantibody production, and providing multi-organ protection. The drug is well-poised to become a first-in-class innovative therapy addressing the unmet clinical needs of lupus nephritis (LN) and refractory SLE. Going forward, the company will accelerate the clinical development of SM03 for the SLE indication and further expand its impact in the field of autoimmune diseases, offering this innovative therapy to more patients worldwide.

About Systemic Lupus Erythematosus (SLE) Market

SLE treatment refers to a range of medical interventions aimed at managing and alleviating the symptoms of the disease. SLE is a chronic autoimmune disorder characterized by the immune system attacking the body's own tissues and organs, resulting in widespread inflammation and tissue damage. In recent years, the incidence of SLE has been rising globally, and the SLE treatment market is experiencing unprecedented rapid expansion. According to a report by Frost & Sullivan, there are currently approximately 1.0349 million SLE patients in China, a figure projected to increase to 1.0947 million by 2030. Research Nester estimates that the global SLE treatment market exceeded USD 2.4 billion in 2024 and is forecasted to grow at a compound annual growth rate (CAGR) of more than 7.8%, reaching over USD 6.37 billion by 2037.

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About SinoMab BioScience Limited

SinoMab BioScience Limited (Stock Code: 03681.HK) is dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases. SinoMab is headquartered in Hong Kong with its R&D base in Hong Kong and production base in mainland China. The Company's flagship product Suciraslimab (SM03) is a potential global first-in-class mAb against CD22 for the treatment of rheumatoid arthritis (RA) and other immunological diseases. SM03 (Suciraslimab) has completed the Phase 3 clinical trial for RA in China and is pending NMPA's marketing approval for RA in China. In addition, the Company possesses other potential first-in-class drug candidates, some of which are already in clinical stage, with their indications covering rheumatoid arthritis (RA), Sjogren's syndrome (SS), systemic lupus erythematosus (SLE), atopic dermatitis (AD), idiopathic pulmonary fibrosis (IPF), asthma, and other diseases with major unmet clinical needs.

This press release is issued by Zhenzhuo on behalf of SinoMab BioScience Limited.
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