StarMab BioMed's First-in-Class, Dual-Target Anti-Tumor Drug SM2275 for Novel Immunotherapy Receives FDA IND Approval

StarMab announces that US FDA has approved its Investigational New Drug (IND) application for SM2275, a novel dual-target nanobody-based anti-tumor therapy.

BEIJING, CHINA, April 7, 2025 /EINPresswire.com/ -- Beijing StarMab BioMed Technology , Ltd. ("StarMab"; http://www.starmab.com.cn/front) today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for SM2275, a novel dual-target nanobody-based anti-tumor therapy.

This milestone marks the global clinical debut of the first immunotherapy to simultaneously target EGFR and PD-L1 while conditionally activating CD28 co-stimulatory signaling in the tumor microenvironment.

As a next-generation cancer immunotherapy, SM2275 has demonstrated broad anti-tumor potential in preclinical studies and is expected to offer a transformative treatment option for patients with lung, gastric, breast, and head and neck cancers, among other solid tumors.

> The IND approval of SM2275 is a pivotal milestone in our mission to bring next-generation cancer treatments to patients globally, a paradigm shift for those individuals with limited treatment options."
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> *Yanbin L*

A First-in-Class Mechanism to Overcome Resistance and Boost Immune Response

SM2275 introduces a "dual-target + conditional co-stimulation" mechanism of action that distinguishes it from existing therapies. It blocks the EGFR pathway and the PD-L1 immune checkpoint, while selectively activating CD28 signaling to enhance the tumor-killing capacity of T cells within the tumor microenvironment.

This innovative approach not only halts tumor progression but also addresses resistance to current PD-1/PD-L1 inhibitors, a major clinical challenge.

Preclinical studies have confirmed SM2275's potent and sustained antitumor activity across multiple solid tumor models. With no comparable drug currently in clinical development worldwide, the FDA's IND approval of SM2275 highlights StarMab's pioneering position in the field.

StarMab has appointed The Sage Group (www.sagehealthcare.com) to provide support for its search for commercial and clinical partners.

Advancing Toward Global Development and Access
"The IND approval of SM2275 is a pivotal milestone in our mission to bring next-generation cancer treatments to patients globally," said Dr. Yanbin Liang, the company's Founder and CEO. "As the first drug of its kind, SM2275 represents a potential paradigm shift for patients with limited treatment options. We are now focused on rapidly initiating global clinical trials and advancing toward commercialization."

About StarMab BioMed
StarMab BioMed is a biotechnology company committed to developing cutting-edge immunotherapies for cancer. As a pioneer in nanobody-based multi-specific antibody technology, StarMab BioMed has established a proprietary R&D platform offering significant advantages in precision targeting, stability, and therapeutic efficacy.

The company's clinical pipeline includes several innovative candidates such as SM2275 and SM3321. SM3321 has already received regulatory approval for clinical trials in both China and the United States and is currently undergoing Phase Ib/II studies in China.

StarMab BioMed operates under the core mission of "science-driven innovation, patient-first solutions", and continues to accelerate the global development of breakthrough therapies to benefit patients worldwide.

Media Contact:
Zhidan Li
Beijing StarMab BioMed Technology, Ltd.
Phone: +86-13401097029
Email: Zhidan.Li@StarMab.com.cn

Advisor Contact:
Dr. Bill Mason
Director, The Sage Group
Phone: +44 7785 950134
Email: wtm@sagehealthcare.com

email us here

W T Mason
Sage Healthcare
+44 7785 950134
email us here