Shawn Leung â?? CEO, SinoMab China

While China remains a cornerstone of our strategy, its pricing regulations limit revenue potential. Expanding into international markets, particularly the US, is critical to fully realize the value of our innovations

17.12.2024

Tags:

China, Asia, SinoMab

Shawn Leung, CEO of Chinese biotech SinoMab, discusses theâ?•Biotech 3.0â?³ philosophy that characterizes the company as it strives for both scientific innovation and differentiation. He highlights SinoMabâ??s atopic dermatitis and asthma candidate that aims to fill current treatment gaps and its rheumatoid arthritis therapy, which has already cleared two major regulatory stages in China. Leung also outlines the biotechâ??s ambitions for global expansion, leveraging the strengths of the Chinese biotech ecosystem while maintaining a competitive edge globally.

What is â??Biotech 3.0,â?• and how is SinoMab positioned to lead this transformative era?

In my opinion, â??Biotech 3.0â?• represents the next wave of innovation in the pharmaceutical industry, as described in a Boston Consulting Group (BCG) analysis. The journey began with Biotech 1.0, which focused on developing biosimilars and targeting well-validated mechanisms such as PD-1 and TNF-alpha. It progressed to Biotech 2.0, where companies like Akeso Biopharma innovated by combining these validated targets, such as in PD-1/VEGF bispecific antibodies. Biotech 3.0, however, goes further by embracing novel targets and mechanisms of action that have never been explored, which is the foundation of SinoMabâ??s strategy.

At SinoMab, we specialize in first-in-class innovations. For instance, our CD22-targeting therapies and IL25RB targeting SM17 for atopic dermatitis address pathways no other company has ventured into. These products epitomize the essence of Biotech 3.0â??developing novel and unique

treatments with the potential to be not only first-in-class but also best-in-class. Unlike many competitors who are transitioning from Biotech 2.0, SinoMab has been leading this approach from the outset, which provides us with a distinct first-mover advantage in this new era.

This ambitious strategy does come with challenges. Developing truly novel therapies involves higher risks and extended timelines, but it allows us to avoid the intense competition prevalent in China, where rapid and cost-efficient development often takes precedence. Instead, we focus on differentiationâ??creating treatments with unique therapeutic effects that go beyond what current modalities offer. By targeting international markets, particularly the United States, where innovation is more appreciated and rewarded, we are confident that our approach positions SinoMab as a global pioneer in Biotech 3.0.

How is SinoMab addressing unmet needs in atopic dermatitis and asthma, and what are its future clinical and strategic plans?

SinoMab is advancing innovation in atopic dermatitis and asthma through SM17, a candidate designed to address critical gaps in existing treatments. While Dupixent (Dupilumab) leads the market due to its safety and efficacy, its slow anti-itching effect presents a significant limitation. In contrast, alternatives like JAK inhibitors, such as Upadacitinib, offer faster relief but carry substantial safety concerns, including black box warnings. SM17 bridges this divide by delivering rapid itch suppression alongside notable skin healing, as evidenced in Phase 1B trials involving 32 patients. This balance of speed, safety, and efficacy positions SM17 as a potential first-in-class and best-in-class treatment.

Our clinical trials have been conducted across the US and China, with Phase 1 studies in the US confirming safety in 77 participants. Bridging studies in China validated these findings, allowing us to efficiently initiate Phase 1B trials to test the preliminary safety, efficacy and pharmacodynamic characteristic of SM17. Though the data remains blinded, preliminary observations indicate a clear differentiation between non-responders and fast-responders, with rapid symptom relief and skin improvement noted early in the treatment cycle. These results underscore the compoundâ??s ability to address key patient priorities, particularly the urgent need for effective itch relief.

Looking forward, we are actively exploring partnerships with major pharmaceutical companies to support Phase 2 development and eventual regulatory approval in global markets, including the US and Europe. Collaboration is essential to scaling our efforts while ensuring that we retain development rights for China. Beyond SM17, we are progressing a biologic targeting the JAK3 pathway for alopecia areata, which has already attracted early interest. This compound builds on the success of treatments like Pfizerâ??s Ritlecitinib but offers a biologic alternative that aligns better with patient preferences.

SinoMabâ??s overarching strategy focuses on differentiation through ground-breaking innovation. By targeting novel mechanisms and addressing unmet clinical needs, we aim to deliver treatments that set new benchmarks in their respective fields. With strong early data and strategic partnerships on the horizon, we are well-positioned to redefine standards in atopic dermatitis, asthma, and beyond.

What progress has SinoMab made with SM03, and what are the plans for its commercialization strategy?

SM03 (Suciraslimab) represents a significant milestone for SinoMab and a testament to our commitment to innovation. Recently, the product cleared two major regulatory stages under the National Medical Products Administration (NMPA): approval for our GMP (Good Manufacturing Practice) facility and clinical trial sites. We now await the final market approval decision.

Initially designed to treat rheumatoid arthritis (RA), SM03 has demonstrated impressive versatility during clinical trials. For example, some patients with RA and coexisting debilitating diseases experienced complete symptom resolution within just two doses. This discovery prompted further exploration, uncovering the drugâ??s potential to treat conditions such as Mild Cognitive Impairment (MCI) associated with Alzheimerâ??s disease. Its novel B-cell mechanism effectively reduces inflammation and clears amyloid-beta plaques, showcasing its promise for broader applications across multiple therapeutic areas.

Our commercialization strategy is evolving to balance operational efficiency and market potential. While building an in-house marketing team is under consideration, the aggressive and resource-intensive nature of Chinaâ??s market makes partnerships with established pharmaceutical companies a more viable option. These collaborations would leverage their robust marketing and distribution networks, allowing SinoMab to focus on its core strength: pioneering innovative therapies. Whether we retain China market rights or license them will ultimately depend on the terms of partnership agreements and their alignment with shareholder interests.

On the manufacturing front, we are assessing the feasibility of transitioning to a light-asset model. Although our existing facilities were essential under earlier regulatory frameworks, the current trend toward outsourcing production to Contract Development and Manufacturing Organizations (CDMOs) offers cost advantages and operational flexibility. Should a partnership materialize, manufacturing would likely shift to external providers to optimize resources further.

Looking ahead, SinoMab aims to amplify its global footprint. While China remains a cornerstone of our strategy, its pricing regulations limit revenue potential. Expanding into international markets, particularly the US, is critical to fully realize the value of our innovations. By securing strong Phase 1 data and proof of concept in the US, we intend to attract global partners for further development and commercialization, enhancing our companyâ??s valuation and ensuring long-term growth. Every decisionâ??whether about retaining or licensing market rightsâ??will prioritize the companyâ??s strategic vision and its commitment to delivering exceptional value to stakeholders.

How is SinoMab navigating financial challenges, and what differentiates its pipeline products?

The current capital market environment is undoubtedly challenging, yet SinoMab has maintained a stable financial footing, with sufficient resources to sustain operations and execute our strategic initiatives. We are adopting a flexible strategy, focusing on equity investment and positive developments such as advancements with SM17, which could drive an increase in our share price. Licensing SM17 is another key opportunity under consideration, offering the potential to strengthen our financial position without resorting to unfavourable equity issuance.

The challenges we face are not unique to SinoMab but reflect broader market dynamics in the Chinese biotech sector. While many companies generate revenue domestically, operational costs often exceed these earnings, making profitability elusive. We firmly believe that true financial success requires a global outlook, particularly targeting markets like the U.S., where innovation and differentiation are more highly valued. This perspective underpins our commitment to Biotech 3.0, focusing on first-in-class therapies with robust global patent protection and clear competitive

advantages.

Our innovation-driven approach is epitomized by SM17, which addresses unmet needs in the treatment of diseases involving the Interleukin-25 (IL-25) pathway. Unlike competing therapies that either neutralize IL-25 or block its receptor binding, SM17 interrupts signalling directly at the receptor-engagement point, immediately halting the inflammatory cascade responsible for irritation and lesions. This unique mechanism allows for a significantly faster therapeutic response compared to traditional approaches. Moreover, the precision required to target the specific epitope responsible for signal interruption sets SM17 apart, making it both highly effective and challenging to replicate.

By focusing on innovation and differentiation, SinoMab is creating a pipeline designed to excel in both local and international markets. This strategy ensures that our products not only address unmet medical needs but also maintain a competitive edge in increasingly saturated therapeutic spaces. With a robust approach to financing and a steadfast commitment to ground-breaking science, we are positioning SinoMab for sustainable growth and long-term success.

What are the advantages and challenges of operating within the Chinese biotech ecosystem?

SinoMabâ??s strategic positioning allows us to harness the strengths of the Chinese biotech ecosystem while maintaining a competitive edge globally. One of the key advantages is access to mainland Chinaâ??s extensive infrastructure for manufacturing and preclinical research, which offers unparalleled cost efficiencies. Contract Development and Manufacturing Organizations (CDMOs) in China now operate at nearly half of their peak pricing, enabling us to optimize resources without sacrificing quality or speed. For example, SM17 was manufactured in China in collaboration with a globally recognized partner, while preclinical studies were conducted at U.S.-accredited facilities, ensuring compliance with international standards and paving the way for a successful Investigational New Drug (IND) application in the United States.

Operating within this ecosystem also allows us to streamline processes by leveraging local resources for face-to-face collaboration. This proximity eliminates logistical complexities such as time zone differences and cultural barriers that can arise when relying entirely on U.S.-based teams. The ability to oversee operations directly ensures greater efficiency in decision-making and smoother execution of clinical and manufacturing activities.

By integrating the cost-effectiveness and speed of Chinaâ??s biotech capabilities with international compliance and standards, SinoMab is positioned to achieve both operational agility and scientific excellence. This approach ensures we can innovate efficiently while maintaining the competitive edge required to excel in global markets.

What are SinoMabâ??s key objectives for 2025, and how will they influence the companyâ??s global strategy?

As we look ahead to 2025, SinoMab is focused on achieving three pivotal milestones that will define its path forward. The first priority is obtaining final regulatory approval for SM03, a critical step that will not only validate the productâ??s potential but also serve as the foundation for broader commercialization efforts. This approval is expected to unlock significant opportunities for partnerships and market expansion.

The second objective is to secure a licensing agreement for SM17, an innovative therapy with strong global potential. A strategic licensing deal will enable us to accelerate its development and commercialization in key international markets, ensuring that this ground-breaking product reaches the patients who need it most.

The third priority is establishing a physical presence in sophisticated and highly regulated markets such as the United States and Europe by introducing variable innovative products including SM17 and other novel targets. This involves forging collaborations or operational frameworks that will allow SinoMab to effectively integrate into these regions. By doing so, we aim to strengthen our global footprint, align with the highest regulatory standards, and enhance our ability to compete in these critical markets.

These three interconnected goalsâ??regulatory approval for SM03, a licensing deal for SM17, and the establishment of an international presenceâ??are integral to SinoMabâ??s vision of becoming a globally competitive biotech leader. Together, they provide a clear roadmap for delivering innovative, life-changing therapies while positioning the company for long-term growth and success.

What differentiates SinoMab from other Chinese biotech companies as a potential partner?

SinoMab stands out as a partner through its steadfast focus on scientific innovation and differentiation. Unlike many mainland biotech companies that often rely on validated or trending targets, we concentrate on first-in-class therapies designed to address unmet medical needs. This focus ensures our products are not only unique but also capable of providing solutions where existing treatments fall short.

Our commitment to innovation is a defining characteristic. While mainland companies are often recognized for their speed, SinoMab leverages its creativity and scientific depth to develop transformative solutions. This innovation-driven approach has enabled us to gain greater recognition on the global stage, as our therapies are not confined to incremental improvements but aim to redefine standards in their respective fields.

Partnerships with SinoMab are rooted in this ethos of originality and excellence. Our dedication to advancing science transcends geographical and cultural boundaries, ensuring that our collaborations are built on a foundation of trust, shared vision, and a commitment to delivering ground-breaking outcomes. This makes SinoMab an ideal partner for those seeking to drive meaningful progress in the biotech industry.

See more interviews