Yoshitaka Koketsu – Chairman and CEO, Sumitomo Pharma Group in China

The transition to annual updates [of China's National Reimbursement Drug List] has greatly enhanced patient access to innovative drugs, reflecting positive changes in the regulatory landscape

17.05.2024

Tags: China, Sumitomo, CNS, AMR, Access, Strategy

Yoshitaka Koketsu explains Sumitomo Pharma Group's positioning in the China market as a relatively recent market entrant with a six-product portfolio but with plentiful opportunities for further growth, particularly in combating infectious diseases and antimicrobial resistance (AMR). Koketsu outlines how the company is well-aligned with China's regulatory changes, and how its tailored approach responds to specific regional health needs and market demands.

Could you offer an overview of Sumitomo Pharma Group in China, including its mission and primary therapeutic areas of focus? Additionally, could you share what motivated you to join the company?

Sumitomo Pharma stemmed from several factors, chief among them being the company's unwavering commitment to innovation and its forward-looking approach encapsulated in the slogan "Innovation today, healthier tomorrows." Sumitomo Pharma stands out as the sole entity within the Sumitomo Group solely dedicated to pharmaceutical pursuits. As a subsidiary of Sumitomo Chemicals, which holds a majority share of 52 percent, we benefit from the robust backing of a parent company renowned for its global presence and diversified portfolio. Our operations span across Japan, the US, and various Asian territories, with China emerging as a pivotal market due to its substantial growth potential. With two decades of establishment in China,

Sumitomo Pharma has witnessed steady expansion, albeit with a modest product portfolio currently comprising six offerings. Despite this, our strategic focus on innovation and our strategic positioning within the Sumitomo Pharma Group provides a compelling platform for driving meaningful change in the pharmaceutical landscape.

Could you provide insight into the therapeutic areas in which Sumitomo Pharma is globally involved?

Historically, Sumitomo Pharma has been active in various therapeutic areas, with a notable focus on central nervous system (CNS) disorders. Our flagship product, Lurasidone (marketed as Latuda), was a significant contributor to our global portfolio, particularly in the treatment of schizophrenia and depression. However, last year, we experienced a shift in our product landscape following the expiration of patents, impacting the sales dynamics significantly. While CNS remains a key area for us, our global portfolio isn’t marketed uniformly across all regions. Instead, our approach is to adapt to market circumstances by tailoring our portfolio to meet the specific needs and preferences of each region. For instance, in the US, we have a distinct portfolio comprising three major products, while in Japan and China, our offerings differ based on market demands and our longstanding presence in these regions. Notably, in China, where we’ve operated for two decades, our focus has predominantly been on antibiotics, reflecting the unique market dynamics and demands in the region. As for my tenure with Sumitomo Pharma, I’ve been with the company for six years.

What primarily drove your decision to transition to Sumitomo Pharma six years ago? Did you perceive the company as undergoing transformation, or were you motivated by a desire to remain in China, or perhaps another factor altogether?

My decision to join Sumitomo Pharma was driven by a combination of factors. Initially, I was drawn to the company’s vision and its focus on expanding its presence in the Asian market. This aligned well with my expertise and experience in the region. When I started with Sumitomo Pharma, I was tasked with spearheading expansion efforts in Singapore, which involved establishing new business operations in markets like Taiwan area, Thailand, and Malaysia. This opportunity allowed me to play a pivotal role in shaping Sumitomo Pharma’s footprint in Asia. While Sumitomo Pharma may have been perceived as a latecomer to international expansion, I believe our success hinged more on tapping into untapped talent and seizing strategic opportunities rather than solely relying on

portfolio considerations. Overall, my motivation stemmed from the chance to contribute to Sumitomo Pharma’s growth trajectory and expand its global reach.

When you initially assessed Sumitomo Pharma‘s operations in China upon your arrival 20 years into its establishment there, what areas did you identify for improvement, and what strategies did you implement, perhaps encapsulated in a “China plan,” to drive growth and efficiency?

Upon my arrival, I noticed there was room for improvement in our operations, particularly in terms of our business spirit, which appeared somewhat conservative. Recognizing the high potential of the market, I focused on instilling a clear growth strategy within the organization to guide our efforts more effectively. This involved establishing a definitive direction for our business and ensuring everyone understood our objectives. Together with the management team, we worked on shifting mindsets and clarifying our business strategy. Given our product portfolio’s limitations, we emphasized maximizing the value of each product, especially considering that antibiotics contribute significantly to our revenues in China. We’re currently working on launching a new pneumonia product, focusing on localization to improve cost efficiency and better cater to the market’s needs. This approach aligns with our goal of maintaining a sustainable business and leveraging opportunities for growth in the Chinese market.

Regarding the new infections product launch strategy, how does your sales team factor into the plan? Do you anticipate hiring additional resources or leveraging existing ones for the launch?

As for our launching strategy, we currently have around 400 sales representatives, with approximately 200 dedicated to the infectious disease area. We plan to utilize our existing resources for the launch, primarily targeting key physicians in grade three hospitals. Initially, we’ll leverage the influence of these key opinion leaders to gradually expand our product reach. As for revenue expectations, our goal is to achieve similar sales levels to our current flagship product, MEPIN, which is currently our highest-grossing product. Our revenue projections are optimistic, but we anticipate substantial growth in the years following the product launch. In terms of business development, our primary focus remains on the infectious disease area, leveraging the synergy within our current portfolio. Additionally, our strong reputation in the Chinese market opens doors for potential collaborations with other companies. This presents a significant opportunity for us,

both internally and externally.

While infectious diseases encompass a wide range of conditions, our focus lies particularly in combating antimicrobial resistance (AMR). We aim to promote the appropriate use of antibiotics, rather than simply pushing for their widespread usage. This approach not only addresses the urgent issue of AMR but also aligns with our core values of responsible antibiotic stewardship. So, while collaboration opportunities in infectious diseases may be limited, our commitment to tackling AMR presents a unique and vital area for collaboration with other companies and healthcare professionals.

With the European Medicines Agency and other regulators expressing concerns about antimicrobial resistance (AMR) post-COVID, do you sense a similar emphasis from Chinese regulators? Given China's role as the epicenter of the pandemic, is there a stronger national agenda advocating for the proper use of antibiotics?

There is a heightened focus on antimicrobial resistance (AMR) from the Chinese authorities, particularly in the wake of the COVID-19 pandemic. The Chinese government has underscored the importance of combating AMR as part of its broader Policy 2030 framework. This policy serves as a foundational guide for various sectors, including the pharmaceutical industry. Consequently, there is a sense of urgency surrounding AMR within the Chinese regulatory landscape, aligning closely with Sumitomo Pharma's goals of promoting responsible antibiotic use.

Looking ahead, do you anticipate growth for Sumitomo Pharma in China, with a continued focus on infectious diseases? Additionally, I've heard about a re-branding effort within the company. How do you plan to enhance Sumitomo Pharma's recognition in the Chinese market, given its fragmentation? What values or qualities does the Sumitomo Pharma brand embody, particularly for clinicians?

We expect to see growth for Sumitomo Pharma in China, with a persistent emphasis on addressing infectious diseases. Regarding our re-branding, our strategy revolves around highlighting the value we bring to patients. We prioritize innovation that directly benefits patients, whether it's through new products or enhancing the efficacy of existing ones. This approach ensures that even older medications, remain relevant if they continue to provide value to patients. Our goal is to strengthen Sumitomo Pharma's reputation in the Chinese market by demonstrating our

commitment to patient-centric innovation.

Are there any other key objectives you hope to achieve for Sumitomo China?

One of our key objectives is to align with Sumitomo Pharma's vision of becoming a Global Specialized Player by 2033. This vision centres around innovating to enhance patient well-being and contribute positively to society. While our current portfolio is somewhat limited, we have two exciting products under development, one focusing on antibiotics and the other on treating overactive bladder (OAB). The OAB market in China, although currently not as significant, holds immense potential due to factors like an aging population and changing lifestyles. By introducing innovative products like our OAB treatment, we aim to make a meaningful impact on patients' lives and contribute to the growth of Sumitomo Pharma in China.

Regarding the new product acquisition, since the company acquired the global license, does this mean it will be launched in multiple markets? Is China included in these plans?

The product acquisition involves markets beyond the US, including Taiwan, Singapore, Hong Kong, and Indonesia. However, China operates under a separate agreement due to territorial restrictions. We anticipate filing for approval in China early next year, with an expected launch timeline of 2 to 3 years. While approval timelines can vary, our experience suggests a timeframe of at least 2 years. Our sales strategy for this product will differ from our existing portfolio, requiring a specialized sales team dedicated to its promotion, distinct from our current approach.

Do you have any other comments?

I'd like to highlight the significant regulatory improvements in China, particularly regarding the National Reimbursement Drug List (NRDL). The transition to annual updates has greatly enhanced patient access to innovative drugs, reflecting positive changes in the regulatory landscape. Despite these advancements, challenges remain, such as delays in multi-regional clinical trials (MRCT), which can affect global product development. Addressing these issues will further enhance China's attractiveness for pharmaceutical research and investment.

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