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These three elements—expertise, quality, and efficiency—make Hong Kong a unique and valuable location for our clinical trials

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Roche has a strong presence in Hong Kong with a local footprint dating back to 1971. Diana Liu, general manager of the Swiss pharma's Hong Kong & Macau affiliate, outlines its growing local clinical research commitment, one that has seen its clinical trial activities increase 2.5 times and reach an investment of CHF 6 million. She also shares the collaboration with the University of Hong Kong that has led to one of the largest real-world data pools in Asia and advances in Roche's rare disease portfolio with its Spinal Muscular Atrophy (SMA) therapy recently reaching approval for reimbursement.

You were recently in Switzerland with a delegation from the Hong Kong government, including Professor Lo Chung Mau, the Secretary of Health, and other colleagues. What was the objective of that visit, and how did Roche facilitate or contribute to it?

It was a great honour for us to host the visit of Professor Lo and his team. The government’s commitment and determination to implementing courageous changes to advance Hong Kong are commendable. These changes include the One Plus policy to accelerate regulatory approvals, introducing measures to enhance clinical trials in Hong Kong, and improving collaboration with the Greater Bay Area (GBA). This involves accelerating the enrollment and reimbursement process, such as waiving some of the lengthy procedures that may save at least three months, and

accelerating patient access in Hong Kong. We also discussed how to maximize real-world evidence and clinical trials within the GBA to support regulatory filings and potential patient access in China. It was a very fruitful discussion, and we brainstormed about ways Roche can partner with the government to make these initiatives happen.

It is important to note that this visit was possible because it coincided with the World Health Assembly, which provided a convenient location and an event the Secretary of Health was attending. Additionally, I believe Roche's reputation as the number one R&D company in the world played a significant role. Most of the visit took place at our main office, where we engaged in detailed discussions. It was an exciting opportunity for us, demonstrating our strong partnership with the government, and we aimed to make the conversation as insightful and fruitful as possible.

What has been the trajectory of Roche's journey in Hong Kong thus far?

Roche has had a footprint in Hong Kong since 1971, so we have been here for about 53 years. While that not long compared to Roche's 127-year global history, we are very proud of our longstanding presence. This history demonstrates our commitment to partnering with various stakeholders in the healthcare ecosystem. We have invested significantly in clinical trials and R&D, collaborating not only with government officials but also with academia and clinicians to bring innovation to patients.

In fact, our clinical trial activities have increased 2.5 times compared to three years ago, equating to an investment of 6 million Swiss francs. This is substantial. Additionally, we offer compassionate use programs to support patients in need, which provide considerable benefits to patients before official product launches.

Roche also supported the University of Hong Kong in the Precision Oncology Programme for Non-Small Cell Lung Cancer. Through this collaboration, comprehensive genomic profiling services were established in seven public hospitals, which have offered more than 1,100 free tests to cancer patients. With patient consent, we have collected data from their initial and follow-up visits, creating one of the largest real-world data pools of its kind in Asia. Researchers from the University of Hong Kong and Hospital Authority have used this valuable data to conduct a variety of studies and presented in several international conferences. Based on all the lessons learned, experts from this programme joined forces with experts from Macau and mainland China to publish the Consensus Statements on Precision Oncology in the Greater Bay Area.

Moreover, We have partnered with Hong Kong Science & Technology Parks Corporation to co-incubate biotech start-up companies from both Hong Kong and mainland China. This initiative started last year, and we have already seen success, with our first company – BayOmics – setting up an office in Hong Kong a few weeks ago. This project focuses on mentoring these start-ups, helping them to think differently and facilitating their establishment, whether they are moving from mainland China to Hong Kong or vice versa.

Can you walk us through the reasons why Roche has suddenly increased its clinical trial investments in Hong Kong?

I would not say that it is was a sudden increase; it is more like continuous growth. We see the value and importance of conducting clinical trials in Hong Kong for several reasons. Firstly, we have world-renowned doctors here, which adds significant value. Our footprint includes not only oncology but also rare diseases and ophthalmology, where we have initiated new clinical trials.

The second factor is quality. For Phase III pivotal studies, quality is paramount. The FDA can come to Hong Kong to inspect our clinical trials to ensure compliance with good clinical practice (GCP) guidelines. The third factor is efficiency. These three elements—expertise, quality, and efficiency—make Hong Kong a unique and valuable location for our clinical trials.

In addition to pivotal Phase III clinical trials, we are confident and looking to expand our footprint to include more early phase trials. We have established strong connections with our early development teams and are eager to bring more Phase I and Phase II clinical trials to Hong Kong.

How does Hong Kong compare with other potential Asian clinical trial hubs like Korea and mainland China?

Clinical trials in Asia are very competitive, with Japan, Korea, and mainland China conducting large volumes. However, we do not compete on volume due to Hong Kong’s smaller population of 7.5 million. Instead, we compete on expertise, quality, and speed. Our scientific expertise helps us design better clinical trials, the quality of our trials meets rigorous standards, and our efficiency ensures swift progress. These three elements make Hong Kong an excellent choice for clinical trials.

Hong Kong’s compact and well-connected environment is ideal for conducting comprehensive and high-quality clinical trials, especially for rare diseases.

If we speak about therapeutic areas, one can think that such a compact ecosystem can also be an advantage for establishing and managing your rare disease portfolio here in Hong Kong?

Indeed, our rare disease portfolio is also present in Hong Kong. For example, we have an oral treatment indicated for Spinal Muscular Atrophy (SMA). Before its official launch, we supported 27 patients through our compassionate use program, providing the treatment for free. We are very proud that our product can support so many patients with this rare condition.

SMA patients often receive early diagnosis due to the life-threatening nature of the disease. While identifying young patients has been relatively manageable, locating adult patients has posed more challenges. However, we are delighted to share that our product has been instrumental in supporting both young and adult patients through our compassionate use program.

In addition to providing support, we have also established robust partnerships with patient groups, treating physicians, and the government, all of whom recognize the value of this treatment. This collaboration has been instrumental in ensuring access to care for SMA patients across different age groups. Furthermore, we are grateful to announce that our product received approval for reimbursement starting last year. This is a significant achievement that not only benefits a larger number of patients, but it also provides relief to their caregivers.

In a market with universal healthcare (UHC) where the government foots the bill, there is often a tense discussion about moving from compassionate use to reimbursement. Is the situation different in Hong Kong?

One aspect I appreciate about Hong Kong is the government’s willingness to recognize innovation. Both the government and the local healthcare community value new treatments. Hong Kong has a well-established hospital authority (HA) sector, which evaluates different products systematically. There is also a thriving private sector where patients and doctors are eager to pursue innovative treatments, often willing to pay out of pocket for them.

It is important to mention that additionally, we have the Macau market, where the government funds meaningful treatments that can save lives. And now with the larger plans for the Greater Bay Area, innovations approved in Hong Kong but not yet in mainland China can be used already in 19 hospitals. This mechanism allows for treatments to be applied in Hong Kong and then potentially in mainland China, making Hong Kong and Macau very attractive markets for pharmaceutical companies that can bring to patients breakthrough innovative therapies.

How do you manage relationships with hospitals in the GBA to ensure this is a value proposition for the company, patients and the healthcare system?

It requires significant collaboration. Internally, we need to align across teams within Roche and other companies. Our role in the GBA is to serve not only Hong Kong but also the broader Chinese market. We focus on enhancing our collaboration to launch products smoothly in Hong Kong, share our experiences with the GBA, and improve launch readiness for China. Effective communication and collaboration between our teams are crucial to achieving this.

The 1+ mechanism for drug approvals seems appealing but still needs to be evaluated. There is also the potential for a full-fledged regulatory system in Hong Kong in the future. This could be beneficial, but not all companies might be willing to file in Hong Kong. What is Roche's position on this? How does Hong Kong rank as a priority market for innovation in your region?

Hong Kong is indeed a priority market for us. When Professor Lo visited our headquarters, our senior manager facilitated and hosted his visit, highlighting Hong Kong's importance in our global footprint. We are always part of the first wave of registrations and filings, which demonstrates our commitment to this market. This prioritization is not just our initiative; it requires global support with relevant dossiers to ensure we can be in the first wave.

Regarding the 1+ mechanism, we see it as a very positive change. It makes our approach more flexible while maintaining the critical elements of speed and quality. Flexibility and speed are unique strengths for Hong Kong. Any changes we implement should not compromise these strengths.

Speed is crucial because it allows us to lead and become a world-leading innovation hub, not just in Asia but globally. Faster product approval in Hong Kong extends the window of opportunity in the

GBA. With mainland China's approval times becoming faster, Hong Kong's willingness to change and expedite approvals can significantly enhance our impact on the GBA.

Roche has long been a pioneer in oncology but is currently expanding into other therapeutic areas like ophthalmology, rare diseases, and neurology. How is this enlargement of the portfolio being handled in Hong Kong?

I feel super excited about expanding our portfolio beyond oncology. It is an incredible opportunity to support more patients across various disease areas. Roche has always been a pioneer in oncology, and we continue to have a robust pipeline, including immunotherapy and innovative treatments for different cancer types. For instance, we have promising data for Hepatocellular carcinoma (HCC), which I am particularly proud to be part of in Asia.

In addition to oncology, we are expanding our efforts into rare diseases. We have a therapy for SMA and are launching gene therapy for DMD in many countries, including conducting clinical trials here in Hong Kong. Hong Kong is one of only two clinical trial centres for DMD in Asia, which is a significant achievement. We are fortunate to work with world-renowned experts like Dr Sophelia Chan.

Our ophthalmology portfolio is also growing. Age-related vision impairment is a common issue, and we have developed a new generation bispecific antibody that helps delay or maintain vision, thereby improving quality of life. Professor Timothy Lai, a top-tier expert here in Hong Kong, plays a crucial role in facilitating Phase III clinical trials and sharing data at world leading conferences.

As Roche continues to establish a formidable presence in the field of oncology and expands its reach into other disease areas, it becomes increasingly important to engage with various channels and stakeholders beyond traditional hospital settings. This diversification necessitates the training of our team members to effectively navigate these new areas, ensuring our continued success in the evolving healthcare landscape.

How are these efforts aligned here, considering Hong Kong's relatively small population of only 7.5 million people? How does Roche ensure agility and multi-faceted engagement if you need to enlarge your channels beyond hospitals?

Our main customer base still lies within hospitals because all our products require prescriptions. However, our key interactions extend across various physician specialties. What is crucial for us is agility. Hong Kong provides an excellent environment for us to exercise agility, not just in terms of speed but also in resource allocation. We need to swiftly shift our resources—whether it is financial investment or manpower—to the right places. This means seizing opportunities quickly, experimenting with new ideas, maximizing the potential, and timely reallocating resources as needed. It is a balance that requires strategic thinking and a high level of trust within the team.

Talent is crucial. We need not just individual talents but also a cohesive team built on trust. Having a team that trusts each other and the company enables us to re-allocate resources effectively and thrive in this dynamic market.

You have been the GM for Roche Hong Kong & Macau for about two years now; how would you evaluate Roche Hong Kong & Macau's performance and what are you looking forward to achieving?

I am proud of our business performance, with our growth rate consistently in the double digits and our ranking among the top pharma companies in Hong Kong. We have accelerated patient access to reimbursement and made strides in clinical trials and R&D, including strong engagement with top-tier experts and support for biotech start-ups. I am also honoured to be part of the Hong Kong Association of the Pharmaceutical Industry Board of Directors which allows us to set a common agenda and collaborate with our peers to benefit patients in Hong Kong and the Greater Bay Area.

In the next two to three years, I hope to see Hong Kong become a global hub for science and health innovation, with high-speed regulatory approvals and robust recognition of innovation. This would attract more R&D investment and multinational companies to set up offices here.

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