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Derek Chang introduces some of the key therapeutic advancements Novartis has been able to introduce in Hong Kong, including cell therapy and siRNA therapies, and its ongoing focus on targeted radioligand therapies, which benefit from the territory's robust legislative framework. Chang also touches on the importance of Hong Kong's "1+" regulatory pathway, which accelerates the approval process for critical drugs, and how Novartis is expanding its clinical trial operations in Hong Kong and across the Greater Bay Area.

In the year since we last spoke, what have been the highlights for Novartis Hong Kong? And what are you excited about ahead, specifically regarding upcoming launches?

Over the past year, we have introduced several innovative therapies and clinical trials to Hong Kong, significantly contributing to the local healthcare ecosystem. This has led Novartis to double-digit sales growth, which is quite remarkable given the global economic climate.

Hong Kong values technology and innovation, and Novartis has been able to bring in advanced therapies like cell therapy for cancer treatment and siRNA therapies for managing chronic disease areas. These innovations have had a positive impact on patient outcomes and have been well-received in the local market.

Looking ahead, we are excited about our radioligand therapy, which has already been commercialized here and is proving to be effective against cancer. We look forward to advancing

our studies and continuing to innovate in this critical area of oncology to offer new hope for patients who haven’t responded well to existing treatments.

What are the distinctive features of radioligand therapies and why is Hong Kong a good fit for these innovations?

We are particularly focused on our radioligand therapy, which represents the next generation of therapies for cancer. Unlike traditional radiation therapies that affect surrounding tissues, radioligand therapy precisely targets cancer cells using a radioactive ligand. This targeted approach minimizes collateral damage and enhances safety and efficacy. We are excited about its potential and our ongoing efforts to establish Hong Kong as a hub for radioligand therapy in the region, leveraging our advanced policies and governance in nuclear medicine.

It is important to highlight that having legislation about radioactive substances is paramount to hosting these types of therapeutics. Hong Kong already boasts robust legislation dating back to the 1950s governing radioactive substances, ensuring strict safety protocols for their use, transportation, and disposal. This foundation is crucial as we update policies to support cutting-edge therapies like radioligand therapy, which are significantly safer and more targeted than their predecessors. Our collaboration with local authorities aims to establish world-leading policies that facilitate safe and effective treatment delivery.

We are enthusiastic about the potential of radioligand therapy in Hong Kong and beyond, supported by our strong partnerships and advanced infrastructure. We are committed to advancing healthcare innovations that benefit patients globally, reflecting our ongoing dedication to excellence in medical science and patient care.

Hong Kong has recently embraced the “1+” regulatory pathway, accepting only one certificate of pharmaceutical product (CPP) instead of two prior to market approval. How has this move been received so far?

The regulatory landscape in Hong Kong has shown notable advancements, particularly with initiatives like the ”1+” mechanism. This pathway is designed to accelerate approvals for drugs that address urgent medical needs, requiring local clinical data and local expert endorsements. Novartis has been at the forefront of leveraging these pathways, with one of our compounds for a haematology rare disease already progressing through the “1+” track, marking our pioneering

involvement in this streamlined approval process. It is a pleasure to learn that this new drug met the standards of safety, efficacy and quality and got the approval in Hong Kong in July, only 7 months after the FDA approval.

This initiative represents a significant step forward in efficiently and effectively meeting critical medical needs of patients who urgently require innovative therapies.

With over 40 ongoing clinical trials at Novartis Hong Kong, it is quite an extensive portfolio. How does Novartis also engage in clinical development and local data generation in the territory?

Managing such a robust pipeline across phases from one to four demonstrates Novartis's strong commitment to advancing healthcare. In Hong Kong, our approach aligns closely with Chief Executive John Lee's policy address to establish Hong Kong as a hub for medical and health innovation. From Novartis's perspective, supporting local clinical trials remains a pivotal goal. Hong Kong offers exceptional advantages, including leading professors, top-tier hospitals, and a regulatory environment conducive to swift approvals. In fact, we often achieve milestones like the 'first patient first visit' ahead of other regions in Asia, underscoring our ability to initiate and conduct high-quality trials efficiently.

Regarding leveraging existing data and pathways, we must maximize efficiencies without duplicating efforts unnecessarily. We recognize the value of streamlined regulatory pathways like the "1+" initiative for new drugs addressing urgent medical needs. This allows us to build upon existing data where applicable, ensuring that innovative therapies reach patients swiftly and safely. Our global support for expanding clinical trials in Hong Kong reflects confidence in the region's capabilities and reinforces our commitment to advancing medical science while meeting patient needs effectively.

Secretary of Health Lo visited Novartis during his trip to Switzerland for the WHO conference. Can you share more about this visit and its significance?

Professor Lo's visit to Switzerland was indeed significant. He attended a WHO conference and also took the opportunity to visit Novartis Headquarters and other facilities. During his visit, we facilitated discussions with our global clinical operations head, trial design feasibility head, radioligand therapy clinical trials lead, and regulatory affairs team. This exchange allowed our

global colleagues to better understand Hong Kong's healthcare initiatives, while also enabling the government team to grasp how our global operations support local healthcare advancements.

Did the number of clinical studies that are being conducted by Novartis in Hong Kong increase in 2023?

We are indeed increasing our studies here in Hong Kong. Professor Lo's recent visit to our headquarters in Basel provided further clarity on this expansion, particularly his vision for the GBA International Clinical Trial Institute. In addition, significant progress has been made with the establishment of offices and coordination mechanisms with the Hospital Authority (HA). These developments broaden the patient pool and aim to enhance recruitment processes and streamline trial execution.

Hong Kong has long been recognized for its high-quality clinical trial environment, boasting leading medical professionals and efficient regulatory pathways. These factors make Hong Kong a competitive location to attract more clinical trials.

How do you see Novartis and other companies contributing further to Hong Kong's biomedical community in the future?

Hong Kong has exceptional qualities, and the government has ambitious plans. Companies like Novartis would like to take the initiative by collaborating closely with universities and government stakeholders. By fostering more networking and collaborations, we can collectively drive progress. Initiatives such as the "1+" pathway, and enhancement in Drug Advisory Committee contribute to accelerating drug approvals and access for patients. Novartis remains committed to actively engaging in these discussions to enhance healthcare delivery in Hong Kong.

By fostering closer ties with esteemed institutions like the University of Hong Kong and the Chinese University of Hong Kong, where leading professors and researchers are instrumental, we can create a mutually beneficial environment. This synergy aims to accelerate the delivery of new treatments to patients, addressing critical needs more efficiently.

The creation of the GBA International Clinical Trials Institute aimed at ICH members is a pivotal step in Hong Kong's biomedical landscape. This initiative not only underscores the government's commitment to advancing healthcare innovation but also opens doors for global collaboration and

knowledge exchange.

Looking forward to 2024, what are your expectations in terms of performance?

We are feeling optimistic about 2024 following the strong performance in 2023. Our objective is to achieve double-digit growth and solidify our position in the Hong Kong market. After helping one million patients in Hong Kong and Macau in 2023, we aspire to serve two million patients by 2030 with our healthcare partners and government to make Hong Kong a hub for medical and health innovation, especially in Radioligand Therapy. Our primary focus remains on introducing over 50 new innovative products, indications, and line extension sin the next five years to benefit patients in Hong Kong. This growth strategy is backed by our teams in China and globally, ensuring that Hong Kong plays a pivotal role in our regional and global contributions.

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