Hong Chow – General Manager, Roche Pharma China

One could say we were able to ride the wave of the recent healthcare reforms

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Hong Chow, general manager of Roche Pharma China, shares Roche China's incredible milestones over the past few years, including four pivotal oncology drugs listed on the National Reimbursement Drug List (NRDL) in 2017; the company's USD 129 million investment in a new innovation center in Shanghai, the third strategic innovation hub in their global network; and the role that China can play within the Group's global expansion and commitment to 'delivering innovative medicines to more patients faster'.

Hong, you have been GM of Roche Pharmaceuticals China for nearly four years now, during a very dynamic period of changes and reforms to China's healthcare ecosystem. What has been the affiliate's journey during that time?

We saw very positive development in the last few years – one could say we were able to ride the wave of the recent healthcare reforms, in particular, the movement of the industry from mature, established products to innovative products, as well as the shift of focus from primary care away to oncology and even rare diseases. These changes have benefited us more than many of our peers in the market.

When I joined Roche in March 2015, it was a time when pharmaceutical sales growth was slowing down. Roche's pharma business in China was suffering from the decline of sales growth from double digits to single digits as well as the challenges of getting new medicines approved and

reimbursed. The majority of Roche's oncology revenue was from the self-pay market. When I shared at my first town hall meeting that my "China Dream" is to make our innovative medicines accessible and affordable to every eligible Chinese patient, it might have sounded totally unrealistic.

I am Chinese-born but have spent a large part of my school and university education, and professional career in Europe. When I first took a China management position with Bayer in 2011, I was astonished by how healthcare was lagging behind other industries. I noticed that China was already the largest market for many consumer brands. They would introduce their newest models to China first. The largest store for Louis Vuitton in the world is in China, for instance! However, up until a few years ago, life-saving drugs like Herceptin® had to wait four to six years to receive market approval in China, and a further 15 years to become affordable to Chinese patients!

Who would have thought, including myself, that only four years later my "China Dream" has become a reality for patients who are in need of our cancer drugs! The biggest milestone for Roche in the last four years was in 2017 when our innovative oncology drugs received national reimbursement through listing on the National Reimbursement Drug List (NRDL). It was the first time for the Chinese government to use negotiation as a mechanism to include high-value drugs on the NRDL. 45 drugs were selected, out of which four were from Roche. When we were faced with the decision to reduce prices to gain reimbursement, we collectively decided to take this risk in order to allow for improved patient care in China. It was a unique opportunity to support the government's efforts in expanding access for innovative medicines, which eventually will help the entire industry in the long run.

What really surprised everyone was that the implementation and roll-out of the new additions to the NRDL happened much faster than everyone expected. The price negotiations ended in July 2017 and by September 2017, the implementation had already started. By the end of the year, it had been implemented in almost all provinces. Therefore, while we had prepared for a negative impact in the short run, we actually ended up seeing immediate high new patient uptake, which became the key driver for our sales growth of 28 percent for Roche Pharma China in 2018.

We are very proud of this performance. I think we set an encouraging example for the industry, which was recognized from our stakeholders including the government. What was broadly reported in media was Premier Li Keqiang's visit to our Roche Shanghai HQ in April 2018, reflecting the government's appreciation for our efforts in bringing innovative medicines to Chinese patients.

Following the successful NRDL negotiation in 2017, the government started another round in 2018 and added 17 more cancer drugs to the NRDL, including our Zelboraf® for the treatment of metastatic melanoma with BRAF V600 mutation, which is another success to celebrate because this reimbursement came only a year after regulatory approval.

For many of the Big Pharma companies, their portfolio in China is still majority off-patent or legacy medicines. Roche defines itself globally as one of the leaders in biotech innovation so how well is this DNA represented in your portfolio in China?

Roche is relatively well-positioned because we have perhaps the lowest share of our portfolio in off-patent originators (OPOs) amongst our peers in China. However, it is still a considerable amount. The shift from OPOs to innovative medicines in my view needs to happen and is overall positive for the healthcare industry, although it might be painful in the short run. In order to improve patient access to innovative medicines, there is a need to optimize public medical insurance fund. This means among other cost measures moving funds from OPOs and adjuvant drugs.

Looking at cancer as an example, in China previously, 80 percent of cancer treatment was chemotherapy and only 20 percent was innovative medicines. It is the reverse in developed markets like the US or Germany. The lack of access to innovative medicines is one of the reasons for the low cancer survival rate in China; in 2015, overall five-year cancer survival rate in China was only 37 percent, compared to 70 percent in the US. We are particularly happy to see that in the national “Healthy China 2030” strategy, one of the targets is to increase the five-year cancer survival rate by 15 percent to reach over 50 percent. This shows the determination of the Chinese government to improve the health and welfare of its people.

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On the product portfolio side, we are definitely closing the gap between global and Chinese portfolios. However, there are still a few products from our global portfolio that are not yet launched in China. With the regulatory reform, we are excited about the opportunities to bring our innovative medicines faster to Chinese patients. I am also optimistic that in the future there will be dynamic reimbursement review for new medicines.

In August 2018, our lung cancer drug Alecensa® was granted approval as first-line treatment for patients with ALK-positive NSCLC with an unprecedented timeline of 5 months after obtaining the

priority review. The Chinese approval came just eight and nine months after the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) approvals, respectively. Only two months after commercial launch, Alecensa® received first reimbursement in the city of Shenzhen. Later in the year, we received approval for Perjeta® for the combination use with Herceptin to treat HER2-positive breast cancer and Hemlibra® to treat haemophilia A with factor VIII inhibitors. We hope these drugs can be included in the next NRDL review to benefit all Chinese patients, no matter in which part of China they live.

With China today aspiring to become a biotech innovation hub and focus on delivering new therapies and solutions to unmet medical needs, as a global leader in these fields, how is Roche contributing its expertise and innovations, not just in terms of new products but also knowledge and best practices?

As you know, our Roche Pharma China HQ is located in Zhangjiang Hi-Tech Park in Shanghai Pudong and we are one of the flagship companies of this area because we were the first foreign-invested company to establish in this area. When we first arrived in 1994, there was only farmland around us! During the inauguration ceremony of our site back then, the municipal government expressed their vision to make Zhangjiang Hi-Tech Park another Bay Area / Silicon Valley for biopharmaceuticals. Today, that has clearly been realized, with many multinational pharma companies setting up R&D operations here as well as aspiring local biotech start-ups and research laboratories. We are proud to have been here since the very beginning.

In 2004, we built on that foundation by establishing our first research centre in China. In October 2015, we also announced a CNY 863 million (USD 129 million) investment in building a new innovation centre, which will be the company’s third-largest strategic centre globally and will focus on drug discovery in infection- and immunology-related disease areas.

In 2007, we also established the Pharma Development Center in Shanghai, which works on late-stage clinical development. Over the past decades, we have trained a group of outstanding interdisciplinary researchers, leading to highly promising results through collaborations with Chinese companies and academic institutions. Prominent examples of Roche’s local collaboration are our partnership with Ascletis and Hua Medicine, two local biotech companies recently listed on the HK stock exchange. Both companies started initially with the development of compounds discovered in Roche labs, one in the area of HCV and the other in diabetes care.

We are proud that besides bringing innovative medicines to China, we have been one of the key contributors to the pharmaceutical innovation ecosystem. I am also very much actively involved personally. As Vice-Chairman of the industry association RDPAC (R&D-based Pharmaceutical Association Committee), I work closely with my industry peers to drive the innovation agenda. Since 2015, I am the sponsor of RDPAC's R&D Working Group, which consists of R&D Heads of member companies. One of our key achievements was the white paper on "Driving towards a Sustainable Pharmaceutical Ecosystem in China" published in 2016. We developed it in collaboration with domestic Industry Associations and with the support of McKinsey. It was a holistic analysis of the entire Chinese biopharma innovation ecosystem including top-down design, capabilities and mindset shift. The paper has received broad recognition and many of the proposals were later adopted by the relevant regulators.

Since then, our working group continued to deep dive into different aspects of the ecosystem. Last year we published a white paper on the challenges relating to clinical research and the importance of building clinical capabilities in China. Even though the Chinese FDA (now the National Medical Products Administration (NMPA)) has accelerated the approval of clinical trials as well as drug registration and approval, there are still challenges like insufficient number of clinical trial centres in China to meet the increasing demand and a lack of incentives for physicians to run clinical trials.

To drive innovation, there are many elements that need to be in place. Whether you are an MNC or a local company, the agenda is about innovation. I think there is lot of expertise and experience we could share.

How do you expect the Chinese pharma industry to further evolve in the next few years?

First of all, I am optimistic that the China healthcare market will continue to grow. Currently, healthcare spending in China is only six percent of GDP compared to an OECD average of 10 percent and 18 percent in the US. Secondly, the market is moving in a more sustainable direction, with more emphasis on quality and innovation.

What is absolutely critical is that the industry as a whole maintains its commitment to quality and compliance. This cannot be sacrificed. It is important to make drugs more affordable but the goal is really to supply affordable and high-quality, reliable drugs at a price point that values and encourages innovation.

GQCE (Generic Quality Consistency Evaluation) is a national priority to enhance the quality of local generics, and Volume based Procurements favouring low-cost generics passing GQCE will increasingly exert price pressure on off-patent originators. For the benefit of patients and sustainable development of the industry, there shall be a sufficient transition period for the implementation to ensure that local generics consistently provide high-quality products over time, without compromising quality for lowest cost. I also hope to see a system allowing the co-existence of high-quality generics and OPO to meet diversified patient needs. This could be managed by reimbursement standards, offering the patient the choice to pay out of pocket or through private insurance supporting the price premiums.

Despite the uncertainties related to GQCE implementation, it is already clear that price pressure will increase for OPOs, and companies need to accelerate their portfolio shift while at the same time adjusting their commercial model for OPOs. Looking into the future, for multinational companies, bringing new products faster to market with a speedy market penetration will become the winning factor. To achieve that, having the right talents and an agile organization becomes critical.

From a more global perspective, I also hope to see more Chinese talents within the global pharmaceutical industry, just as historically, many global pharma executives have been trained or worked in the US. I hope to see more Chinese voices or people with China experience participate in global decision-making.

You also said that China is moving towards becoming the ‘third’ strategic centre for Roche, in addition to Basel and San Francisco. Firstly, is the philosophy of innovation and R&D aligned across these three cities? Can China really contribute to Roche’s global R&D and innovation output? Secondly, with the exodus of top management and R&D executives from MNCs to local companies, should MNCs invest heavily in R&D operations in China?

The future role of pharma multinationals’ R&D centres in China is, in fact, the subject of the recent study conducted by our RDPAC R&D working group! A big question is whether we should be treating local R&D operations more as CROs or a really strategic part of the global R&D network? For Roche, the answer from the top is very clear: China is extremely strategic and we are very committed to doing innovation here. Our global CEO Severin Schwan insists that the same standards are applied in China as they are in San Francisco and in Basel. In fact, our new lab

facility in the Roche Innovation Center in Shanghai would be the most advanced in our global network.

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Roche has built full-fledged research capabilities in China and aims to address unmet needs in infection- and immunology-related disease areas. One of the focus areas is Hepatitis B Virus (HBV), which reflects the specific medical needs in China. About one-third of the world's 240 million people with chronic HBV live in this country. China has also a very high incidence of liver cancer, and the uniqueness of Chinese liver cancer patients is that the major cause is HBV, unlike in the West where HCV, alcohol liver or metabolic disorders are the predominant risk factors. We are doing genuinely important R&D here in Shanghai, not simply project management or clinical trials coordination. Up to now, the centre has generated 210 IPs with half already granted. Several anti-HBV molecules have also entered in Phase 1 clinical development.

Previously, we spoke about being 'in China for China'. Roche is now looking at 'in China for the world'. This again is in alignment with the country's ambition to become a global hub for pharmaceutical innovation.

On that note, with so many of your peers having moved to local industry, what keeps you with Roche China?

I think independently of which path we choose to take, many of us share the same 'Healthy China dream'. For me personally, I can see that the impact I can make on the industry as General Manager of Roche China is huge. The 2017 national reimbursement example is a testament to that. Roche provides me with a fantastic platform to accelerate the introduction of high-quality, affordable and innovative medicines to China.

Globally, Roche is going through a transformation as well and our top mission is to make our innovative medicines accessible to more patients faster. There are high unmet medical needs in China and China has a vast population so it is clear that Roche has a great mission to fulfil in China.

Another reason is that I see myself as a bridge between China and the West. It is not about local versus multinational companies, because innovation does not have boundaries. It is not about where innovation is created, but where innovation benefits people! Roche benefits the global

population and especially here in China.

My experience as the head of Roche China has perhaps been rather uniquely positive. Everything is moving in the right direction. I have also personally benefited from China's new policies. In 2017, I had the great honour to receive the country's first "green card" after the government introduced a new policy to attract foreign talents to the free trade zones. It gives me the same privileges as a Chinese citizen. The Chinese government is not only incredibly open to scientific and research talents but also business management expertise and skills. This is also critical to foster an innovation ecosystem.

Looking at the next few years, what will the future hold for Roche China?

Obviously, like in many other peer companies, the Chinese affiliate will further increase its contribution to improving access to innovative medicines. This is an inspiring vision.

In September 2018, Roche reorganized its pharma division and China now reports directly to Pharma International. It is clear that the global vision is for China to play a much more significant and strategic role within the global Roche Group.

Finding innovative solutions for unmet medical needs is always at the heart of what we do. We continue to invest up to 20 percent of sales globally in R&D and China is an integral part. China is now included by default in all of our global clinical programs. Going forward, we also hope that China can increasingly lead global clinical programs, particularly in areas where China has strong clinical expertise and/or exceptional medical needs. Leveraging China's large patient population will help us to accelerate global drug development, especially in rare diseases. For instance, we are currently developing a drug for spinal muscular atrophy (SMA). This is defined as a rare disease but there are 50,000 patients in China with this condition.

We hope that in the future, not only is simultaneous launch the new norm but also, where it makes sense, that China could be the first country to launch a new global drug, for example in a disease of specific high unmet medical need in China. We also look forward to the day where innovative medicines discovered in our Research Innovation Center in Shanghai can benefit patients globally.

Besides innovative medicines, our vision is to unlock the full potential of personalized healthcare for patients by combining Roche's strengths in diagnostics and pharmaceuticals, plus genetic profiling and clinical and real-world data, to support physicians to select the right treatment for the right patient. China is already very advanced in digital technology, which provides possibilities to

generate insights from meaningful data and increasingly tailored medical treatment to the specific profile of a patient. For personalized healthcare to become a reality in China, it needs joint efforts from the industry, healthcare institutions and the government, and Roche is fully committed. Personally, I am extremely excited about the opportunities to make an impact on people’s health in the years ahead.

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