Gary Zieziula – President & Region Head North America, Kyowa Kirin

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Gary Zieziula, president & region head North America for Kyowa Kirin, a specialty care-focused Japan-based global pharma company, highlights the tremendous growth the affiliate has seen over the past three years on track to become a USD 500 million+ organization within the next year; the exciting products and assets that will continue to drive growth for Kyowa Kirin in North America; and the intentional, diverse and patient-centric culture he is looking to foster within the organization.

Gary, you were appointed a non-executive director on the board of Kyowa Kirin in summer 2019 and then president and region head of North America less than a year later. Could you briefly highlight your background and share your motivation for leading Kyowa Kirin?

I have about 40 years of experience in the pharma industry, having started with Merck & Co. (MSD outside of the US and Canada) following my college graduation before stints at BMS, Roche – where I spent 11 years – and AMAG Pharmaceuticals, and most recently, I was president and managing director of EMD Serono, the North American subsidiary of Germany-headquartered Merck KGaA.

I accepted an invitation to join Kyowa Kirin as a North America Board Member in June 2019 because of the people I met within the leadership team – both from our Japanese HQ and in the North

America business. I thought it was a great opportunity. The company had seen three new products launched within the past three years – POTELIGEO®; CRYSVITA®, which is currently being marketed in the US by our partner, Ultragenyx; and NOURIANZ®, – all performing quite well.

About five months ago, leadership in Japan, as well as the chairman of the board for North America, asked me to assume responsibility as president of North America. I accepted again because I saw a great opportunity to join a company experiencing tremendous growth. To illustrate, three years ago, our revenues were USD 25 million. This year, we expect to contribute over half a billion dollars in revenue to the global organization! And within the next five years, we are looking to represent 50 percent of global revenues outside of Japan. We currently stand at around 29-30 percent. In addition to our three existing products, we also have an exciting pipeline with several new investigational products we hope to bring to the market in the 2025-2030 timeframe.

I have a lot of energy and optimism about the future for Kyowa Kirin. Across research, development, and commercialization, our team is focused on advancing innovations that can address unmet needs, and we expect to see huge growth despite the ongoing global pandemic. The pandemic makes the current operating environment complicated. You know, I have not even been to our Princeton, New Jersey office in my capacity as president!

My job right now is first and foremost to keep everyone safe, but also to ensure that our business continues doing the right thing for patients and pursuing the opportunities we see for growth. I want to build on our success and make Kyowa Kirin more well-known in the US as a Japan-based, global pharma with a focus on specialty care.

Kyowa Kirin Group has implemented a new One Kyowa Kirin global management structure. How has that manifested in the North American operations?

In 2019, we formally combined our research capabilities in La Jolla, CA with our Development, Regulatory and Commercial capabilities centred in Princeton, NJ and Bedminster, NJ under one regional management structure. As a Japanese company, we use the term ‘wa’ – which means ‘teamwork’ in Japanese – in a way that emphasizes bringing people together with a common purpose and mission. Previously, our teams and operations were very site-specific, but we have been working hard to unify and harmonize these different groups under the One Kyowa Kirin initiative. We are still in the midst of implementing the processes and systems to facilitate more collaboration across the region, but we are happy with the progress we have made.

With your focus on specialty care and rare diseases, what has been key to the success Kyowa Kirin has seen over the past couple of years?

We are committed to focusing on CNS, haematology, immunology and rare diseases. We think we excel in specialty care and rare disease, and we work hard to meet unmet medical needs in these areas.

Patient-finding initiatives are key. We have digital patient-finding programs in place, and we are building much more robust digital education and communication programs to reach patients and healthcare practitioners (HCPs). I think we are well on our way, and we look forward to having a much more comprehensive digital infrastructure by 2021 or 2022, supported by a new Digital Center of Excellence.

What is interesting about Kyowa Kirin is that the majority of your assets have been developed internally. How much has this been a factor to Kyowa Kirin's success in the US?

Certainly, the majority of Kyowa Kirin's portfolio and pipeline originated either from our R&D site in LA Jolla, California, or HQ in Japan. As a company, we have always had this incredible R&D engine and highly productive research facilities but historically, outside of Japan, we relied mainly on partnerships to help commercialize our medicines.

A few years ago, Kyowa Kirin decided the time was right to build our own commercial capabilities in order to maximize the value of our global assets. Adding commercial capabilities allows us to fully mine the internal passion and knowledge for a drug or disease, and the relationships that are built while managing the clinical studies, to propel commercial success. As I was not with the company at the time, my understanding is Kyowa Kirin targeted acquisitions with the commercial infrastructure to support the launches of its most promising pipeline assets. Confidence in the North American team to manage and market our assets has increased through the launches of Poteglieo and Nourianz, and we are working now on the plans to transition full commercial responsibility forCRYSVITA® from our partner, Ultragenyx, to us in April 2023.

This does not mean that we will never consider partnering or licensing out again. In fact, we just signed an agreement with MEI Pharma for a lymphoma asset, ME-401. We will co-develop and co-commercialize this compound in North America, and in the rest of the world, we will co-develop and

commercialize the asset, hopefully in a broad range of B-cell malignancies.

Overall, Kyowa Kirin is definitely punching above our weight class when it comes to our pipeline, and as our portfolio continues to grow, we are adding important commercial capabilities to be more successful in market. I believe these efforts can help us become a multi-billion dollar affiliate over the next three to five years.

With Kyowa Kirin's great pipeline, which asset are you most excited about?

I have to say our investigational asset KHK4083, which is just finishing Phase 2 trials. The first indication we are exploring is in atopic dermatitis. Our asset is an anti-OX40 monoclonal antibody, a different mechanism of action from the category leader, Dupixent®.

If the data supports an approval, our goal is to have the first anti-OX40 for the treatment of atopic dermatitis, which is a USD 10 billion category in the US. We acknowledge that there are other products already on the market but we believe there is space for new products, particularly if there are differentiating features in the product profile and because patients respond differently to different drugs.

With product launches being key to Kyowa Kirin's growth, what would you highlight as key learnings for specialty care product launches?

The most important learning in our experience has been that you can never begin preparing too early! For POTELIGEO® and NOURIANZ®, though both are performing well, in retrospect the company realized we could have begun preparing for launch a little earlier. Drawing upon that lesson, for CRYSVITA®, we have already formed a business unit and hired a business unit head to manage the transition of that product.

We also have a market access team within our commercial organization that has done a great job with our three brands so far, working with pharmacy benefit managers (PBMs) and national insurers to ensure that patients have access to our products. I think the most important thing here is ultimately to have good products and the data to support their value propositions. In specialty care, it is important to design and implement Phase 3 trials that allow for the demonstration of the value of the products to patients, whether it means using health outcomes data or secondary and tertiary endpoints or other means. Once you have that data, access becomes a lot easier because

it is evident how valuable the product is to patients.

On a final note, you highlighted that Kyowa Kirin, despite its successes over the past few years, is still not a household name in the US. How has this affected your talent acquisition and management strategy?

Certainly, we want to increase awareness of Kyowa Kirin as a specialty care company working to meet the unmet patient needs in the core areas of CNS, haematology, immunology and rare diseases. We are actively engaging with patients and advocacy groups, as well as participating in conferences and congresses, to grow our role in the community.

When it comes to talent, we *are* hearing from Big Pharma executives, who tell us that our growth story is fantastic and really appealing. The ability to be part of a company growing as rapidly as Kyowa Kirin is incredibly attractive to talented people. Many people working in Big Pharma companies recognize that it can be hard to make a tangible difference within such large organizations. At Kyowa Kirin, people can make an impact immediately.

We also want to continue to build on the positive culture that we have by ensuring Kyowa Kirin is a place where everyone is welcomed and able to contribute their best. I am an advocate for women, for people of color, and diversity, in general. I believe our company and our patients will benefit from having more diverse perspectives in the company, and in leadership so we are working to bring that talent in as we grow.

Particularly during this difficult COVID-19 period, I have been very proud of my team and how much they have been able to accomplish. They have been very resilient and are working very hard to get things done to help the patients that we serve.

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