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Takeda USA's Ramona Sequeira outlines her expanded role as president of global portfolio commercialization, the crucial importance of investing in culture, and the company's multifaceted response to the COVID-19 crisis.

Ramona, you have been with Takeda for the past five years as head of Takeda's US business and in April 2020 you were appointed president of global portfolio commercialization. What is the significance of this appointment?

In my expanded role, I lead our commercial partnership with R&D through every stage of development through launch. My goal is twofold: bring a consolidated commercial voice into our R&D plans and leverage scientific expertise to help shape our commercial plans.

Takeda has taken a unique approach by connecting the role of global commercialization with our largest market, the US versus other companies that tend to keep it a purely global function. There is a certain pragmatism this approach brings to the commercialization process. As a company, we know we must look at both speed to market and accessibility to as many patients as possible. Having a commercial business leader leading global portfolio commercialization allows us to make

those decisions with a strong understanding of what's best for patients across multiple markets.

For example, from a commercial perspective, we spend a lot of time understanding different market needs because healthcare systems around the world are all different. We then consolidate that feedback into clear inputs for R&D, such as the most relevant comparators to use in our trials, the required standards of care, and the issues that are most important to patients. In addition, when we think about brand positioning, it is valuable to have R&D insight into what the molecule does and where it works best.

Given that our Wave 1 pipeline is expected to deliver roughly ten to 12 launches over the next five years, co-locating our global portfolio team here in Boston with R&D will ensure we are prepared to successfully launch these potential products quickly and with the best possible access for patients globally.

As part of my new role, I also chair a committee with our head of emerging markets, our head of Japan and our head of Europe and Canada (EUCAN), and together we look at the development and launch plans of our pipeline assets to evaluate our overall progress. My job is to synthesize the various inputs and ensure that we are advancing as a global organization to deliver best in class launches of our amazing pipeline.

With such a broad scope in an important global role, how have you adjusted to your new responsibilities, especially against the backdrop of a global pandemic that has restricted your ability to visit other country affiliates in person?

As I've taken on roles of increasingly responsibility throughout my career, I've learned that to be effective it's important to work differently, *not* just do more. If you can prioritize where you want to add value and then surround yourself with a strong leadership team, you can focus your time where you can have the most impact. Working remotely during a global pandemic has its challenges, but on the positive side, I can participate in virtual meetings and reviews with countries all over the world without traveling constantly. While I look forward to meeting more people in person over time, I'm taking advantage of our remote engagement tools to connect with employees and customers as much as possible.

With Takeda's acquisition of Shire, how did the integration of the two organizations progress in a market like the US, which is so critical to the global business?

I have to say the integration seems so long ago now. Certainly, given the size of our business in the US, speed was a critical success factor for us. Setting up a high-functioning organization as fast as possible was a top priority. Months before the acquisition was completed, I spent time with both the Shire and Takeda leadership teams designing and finalizing our operating model. The day we completed the acquisition, we announced our leadership team in the US, which included a mix of leaders from both legacy companies. Designing the rest of the organization proceeded very quickly from there. We closed the acquisition in January 2018. By April 2018, we had the US organization designed, the majority of employees knew what their roles were, and we started to move forward on our business plan.

If you speak to our US employees today, I find we no longer talk about who came from what legacy company. And that's because we've spent a lot of time investing in our company culture and bringing people together. Simultaneously, we've also hired many people from other companies, so our focus has been to bring all three groups together to help us function as one company and one team, so that we can best support the needs of patients and other stakeholders.

On paper, M&As often seem like a good business case in terms of financials and other aspects but all too often fail in terms of culture and the subsequent impact on employee satisfaction and other stakeholder-based outcomes. How has Takeda been managing this?

People take culture for granted. Sometimes, leadership teams think it's more important to invest in other things first and leave culture until later. At Takeda, we invested a ton of time in culture from day one of the integration. We describe our culture as 'curious, connected and courageous.' We are curious about what our patients need from us and about how we can help each other solve challenges. We are connected in the sense that we partner externally with all our stakeholders, including payers, hospitals and patient groups. Our goal is to solve problems by partnering. Courageous means that we stand up for what's right for our patients, and we encourage people to speak up, come with ideas and challenge the way we've always done things if it's not working or if it can be done better.

We also anchored on things we knew were not going to change. Takeda has a value system called 'Patient-Trust-Reputation-Business,' which grounds every business decision and which we amplified during the integration. We build our business by supporting patients and enhancing the trust and reputation of the company. A lot of pharma companies talk about patient centricity, but we are

unique in the focus we put on building trust with society and enhancing the reputation of our company.

One example of how this plays out is how we resource our rare genetic and hematology business. With rare disease, a healthcare provider might have just one patient with that type of disease using our medication. So naturally, the provider hasn't had the chance to build experience around that disease or therapy. The patient might feel alone, and the doctor might feel alone. At Takeda, we want to figure out how to alleviate this problem using the lens of Patient-Trust-Reputation-Business. The first step is getting close to patient communities and patient advocacy groups to really understand their needs and challenges. Based on what we learn, the second step is to increase support through medical and patient services. For instance, a provider might not need as much promotional support, but would welcome more medical information to help identify the right patients and learn more about the disease progression. Patients might need help navigating a difficult diagnostic process or complex reimbursement systems.

We have really invested in these areas, which has not only helped us support our customers and patients better, but it has also enhanced our reputation. Customers see that we're willing to tell them not only which patient is right for our therapy, but also which patient is *wrong* for our therapy. They see we're not just in it for us. We're committed to delivering success to our customers and patients.

As a result, we receive very high employee engagement scores. With statements like 'I feel like I really belong at Takeda', 'I am excited about the future of Takeda', "I understand how to apply Takeda's values of Patient-Trust-Reputation Business in my day to day actions" and 'I believe the combined company will better serve patients than either company would have alone', we receive favorable scores ranging from 80 to 90 percent.

Rare disease is a space where focus on patients is non-negotiable. How did you transfer these learnings from the rare disease space to other therapeutic areas within the Takeda portfolio?

Putting patients' needs first is non-negotiable in every therapy area. Certainly, the patient voice in rare disease is amplified because each individual patient is so unique. Every patient we see has been through a slightly different journey. For some, it might have taken ten years to receive a diagnosis, and for others, the disease might manifest differently.

Part of my global portfolio commercialization role is to make sure patient needs and the patient voice remain a core part of our commercial plans. And we've seen great learnings across our portfolio. Prior to the acquisition, Takeda developed sophisticated data and analytics capabilities to better meet the needs of our customers and patients. And Shire brought expertise in rare diseases, with long established and very strong patient services programs and relationships with patient advocates. We've taken these learnings and applied them to all parts of the integrated business, which has further strengthened our support of patients and customers.

Within the US, access and affordability seem to constantly be at the center of the national conversation around healthcare. How does this impact Takeda's commercialization strategy and models in the US?

Takeda's mission is 'better health, brighter future.' Better health for people leads to a better future for individuals, society and the economy. A lot of the customer and patient support work we do, in developed and developing markets alike, is to support more access to healthcare. We're also doing more to address healthcare disparities and inequities in care.

In the US, we are committed to ensuring that as many patients as possible can access our medicines. I sit on the board of PhRMA, the US innovative biopharma association, and we are working with this administration and will continue to work with future administrations on making innovative medicines accessible to all patients who need them.

From our conversations with patient groups in the US, one aspect that patients really value is both high quality care and access to high quality medicines. Whatever policies or measures we adopt in the US, we need to make sure that we do not reduce or delay access to innovative medicines for patients.

Another thing we've heard from patients is that they don't understand their insurance coverage. In fact, many of our own employees tell us they have a lot of questions about our insurance and we have an amazing plan! But some people have plans with very high deductibles for instance, that make medicines unaffordable. We need to find ways to make insurance more predictable and understandable for patients and make our medicines more accessible and affordable. There is more work to be done. We aren't yet in a place where we can say that we have good access to high quality care for all patients across the US

Another important aspect, from Takeda's perspective, is our R&D strategy. Andy Plump joined Takeda as chief medical and scientific officer in 2015 and he is now our president of R&D. He has really reinvigorated our R&D organization and its strategy to focus on highly innovative medicines in areas of high unmet need either because there is no approved treatment or because the existing standards of care can be elevated significantly. We're not a company developing 'me too' or 'me better' solutions.

As an example, the first Wave 1 asset we expect to launch next year in the US is TAK-721 for a disorder called eosinophilic esophagitis, which is a rare, chronic immune-mediated disease of the esophagus that occurs when eosinophils accumulate in the esophagus, resulting in inflammation. Patients with this condition have difficulties swallowing or eating. Their day-to-day lives are very challenging, and there are no approved treatments for this condition. This is the kind of area where we want to deliver medicines that truly make a difference to people's lives.

In every conversation we've had with US entities, there is the sense that it's quite difficult to move the needle because of market fragmentation and the multitude of players involved. What is the role of pharma companies in this context?

We absolutely have a role to play. Unfortunately, there are no simple solutions. As an industry, we need to work hard and work together to make positive changes that will reduce patient costs and stimulate innovation. Healthcare systems are extremely complex, so whenever new policies or initiatives are proposed, we must think carefully about any potential unintended consequences. And it needs to be a multi-stakeholder approach: ultimately, all the stakeholders in healthcare need to be willing to work across boundaries and make compromises to reach a better solution.

As a company, Takeda is very committed to finding ways to support patients today. For instance, we have a free medicines program so patients with an income level at or below 500 percent of the federal poverty level can access our medicines for free. With the COVID-19 pandemic, we expanded our patient support programs so that any patient who has been laid off or furloughed can access immediate aid programs instead of having to wait to hit the threshold income levels.

Takeda has also been very active in its COVID-19 response efforts. What is the significance of the work you are doing and how do you think this global pandemic will affect the future development trajectory of the industry?

First, this has been an incredible collaborative effort. Several medicines have already been given emergency use authorization by the US FDA and are in use today. And we are certainly going to add more treatments as time progresses. Vaccine development efforts are also ongoing at an incredibly rapid pace.

At Takeda, we have several initiatives underway. The first is our CoVlg-19 Plasma Alliance, a partnership of the world's leading plasma companies, spanning plasma collection, development, production, and distribution, that is developing hyperimmune globulin (H-Ig) therapy called CoVlg-19. Hyperimmune plasma is plasma that has been collected from recovered patients and is further processed into a medicine called hyperimmune globulin that has a more consistent antibody potency and more potent antibody concentration and is more suitable for longer-term use. We have just started our trial and the first patient was treated a few days ago.

We are also part of the 'The Fight Is In Us' campaign in the US, which works with public, private and NGO entities to encourage people who have recovered from COVID-19 to donate their plasma for the plasma therapies we are developing. That is an important collective effort because the plasma we need for plasma therapies cannot be manufactured in labs. It must be donated.

We are also involved in the COVID R&D Alliance, which is focused on finding treatments through shared expertise, data and evaluation of drug candidates. For instance, we're collaborating on adaptive trial models that allow for more efficient and informative outcomes to be achieved with no impact on scientific rigor. These trials require only a single, limited group of patients on the control treatment, which shortens the time required to test potential treatments and allows additional therapies to be added or removed throughout the trial.

In general, through the global COVID response, we've seen the walls between companies and across sectors come down as the industry thinks about tackling this public health crisis together. We've also seen barriers between industry and regulators come down, and certainly, we can be very proud of the US FDA for its phenomenal work in being proactive and responsive to the needs of patients. They've made it clear that they will not compromise on safety but have also made huge efforts to engage in dialogue quickly so that the industry can move rapidly in its R&D efforts.

From a reputational perspective, I think as an industry we will see a positive impact if we handle this well. We must make sure we put the science first, focus on safety and efficacy, and make therapies available and accessible to patients once they are approved. The pharma industry hasn't always had a positive reputation, and I see this as our chance to rise to the occasion. So far, we seem to be doing quite well on this aspect.

On a final note, do you have any reflections on being an industry leader and managing business operations during these challenging times?

In business school, we used to say, ‘culture eats strategy for breakfast,’ meaning culture could really hurt your strategy. Today, we view culture *as a strategy* because while other business strategies can easily be replicated, culture cannot. It is so unique to the organization and its identity, and it can enable the business’ success in a way that few other aspects can. That’s why it’s so important to invest in culture. My leadership teams and I have focused on building a culture based on trust and openness – and we understand that it starts with us. We need to be the kind of leaders who are comfortable surrounding ourselves with people who think differently from us, and we need to be willing to accept constructive criticism and different perspectives. Sometimes leaders surround themselves with people who tell them what they want to hear, instead of what they need to hear. That’s not good for diversity, culture or innovation. A big focus at Takeda has been giving employees a voice, taking time to explain the “why,” and encouraging personal accountability. Having diverse views and perspectives helps us solve problems more productively and effectively.

COVID has been a difficult time for leaders because we’re not able to connect face-to-face with each other or our teams. It will be very important to find better ways to connect with each other through technology and to invest in these areas. I don’t think Takeda will ever be a fully virtual company because we need that personal face-to-face connection, which is how we built the incredibly strong Takeda community that we have today. At the same time, we have learned to accomplish so much remotely. We anticipate a more hybrid workplace model that combines both in-office and remote work because there are benefits to both. But we’re also excited to return to more face-to-face engagement and social interactions with our customers, our patients and our Takeda community.

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