Maria Gabriela Pittis â?? Head of South Cone, Andean Region, Mexico & Central America and Caribbean, Takeda

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Maria Gabriela Pittis, Head of SAM (South Cone, Andean Region, Mexico & Central America and Caribbean) at Takeda, outlines the companyâ??s significant presence in the cluster, its double digit growth and plans to launch 14 new products there by 2025, most importantly its European Medicines Agency-approved dengue vaccine.

She also explains the shift that Takeda has undergone in LatAm since the acquisition of Shire, bringing onboard a large rare diseases portfolio as well as a plasma-derived unit.

Could you begin by outlining your career trajectory?

I have more than 25 yearsâ?? experience in the rare disease arena. I took my first steps in academia as a researcher at the Argentinian National Scientific and Technical Research Council (CONICET) and worked for the National Academy of Medicine and at the Hospital Garrahan, the largest paediatric hospital in Argentina, where I obtained a PhD in Molecular Biology from University of Buenos Aires.

After that, I moved to Italy for a postdoc position at the International Center of Genetic Engineering and Biotechnology (ICGEB). Having planned on staying for two years, I ended up spending 11 years there! I worked on multiple projects with the ICGEB and was heavily involved in research around the production of glucocerebrosidase in tobacco plants. Glucocerebrosidase is the enzyme that is missing in Gaucher disease, a rare disease, which triggered my entry into that world.

I moved from the ICGEB to the paediatric hospital in Trieste where I was able to build up its rare disease diagnosis centre, now one of the most important diagnosis centres in Italy. That gave me the opportunity to understand more about both rare diseases and rare disease patients, given that I was able to meet families, patients, and medical associations. This stoked a passion in me for the rare disease space and the impact that can be made on patientsâ?? lives.

For this reason, I decided to shift from clinical practice into industry. Having worked on a consultative basis with companies like Actelion and Genzyme, I finally got the opportunity to take on a full-time position within Shire Argentinaâ??s medical affairs team. When I joined, Argentina was the only country in which Shire had a presence in LatAm, and so I was closely involved in the companyâ??s expansion into Brazil, Colombia, and Mexico, working around the region to better understand the unmet needs that existed, how rare diseases were affecting these countries, and the impact that innovative products could have on peopleâ??s lives

Today at Takeda we have the same mission; delivering life-transforming treatments in rare diseases, oncology, gastroenterology, neurosciences and vaccines, to impact peopleâ??s lives and bringing innovation to tackle unmet medical needs

Do you have any regrets about leaving behind a career in clinical practice to join the pharma industry?

No! My prior experience has been a huge value-add. When I moved into the industry, I was very knowledgeable about what was going on over on the other side; things such as challenges for the families, unmet medical needs, the odysseys that patients were having to go through in the diagnosis process. That background helped shape my work in the industry and the vision initially for rare diseases in Latin America.

What is the scope of the cluster you oversee today and Takedaâ??s footprint there?

My remit is the entirety of LatAm, apart from Brazil, which Takeda treats as a standalone country. This is a huge business where Takeda has a significant presence, particularly in our biggest markets of Mexico, Colombia, Argentina, and Chile. We also have a manufacturing plant in Mexico that serves these countries and a quality control (QC) laboratory in Argentina, the result of a USD 15 million investment over the last three years. This state-of-the-art facility is located close to many other companiesâ?? labs, making it a good hub of knowledge exchange.

Did the countries under your remit previously have a stronger presence for Takeda or for Shire? How has the evolution of the combined companies played out in LatAm?

Takeda has been transforming its portfolio in the past few years and moving into highly specialised products and rare diseases. Pre-Shire acquisition, Takeda was present in gastroenterology and

oncology, plus primary care but post-acquisition a huge portfolio of rare diseases as well as a plasma-derived unit were added.

The situation in LatAm varied between country. For example, Shire had a large presence in Colombia due to the strong commitment to rare diseases, with Takeda only holding a more limited operation. As an illustration, Takeda Colombia grew by five times when the two companies were combined there. Chile only had a Shire affiliate previously, while Takeda had a stronger presence in Mexico with a manufacturing plant as well as an over the counter (OTC) and primary care portfolio available on the local market. While Takeda has since divested its OTC portfolio, Takeda Mexico still brings innovative primary care treatments to market. In the case of Argentina, both companies were equally strong, following each portfolio footprint. Bringing together this constellation of legacies requires a laser focus and a high level of prioritisation.

How has the cluster been performing in recent years?

In recent years we have achieved very healthy double-digit growth, predominantly driven by our main portfolio, which serves as a vindication for our portfolio strategy in the region. Takeda has managed to launch several products in the region and has 14 more planned between now and 2025, mainly in Mexico, Colombia, and Argentina.

The main asset on the way is our dengue vaccine, which recently received approval from the European Medicines Agency (EMA). It is a tetravalent vaccine that covers all four serotypes and can be used both in people that have and have not previously been exposed to dengue. This is a momentous achievement for Takeda and will have a big impact on LatAm, which â?? along with Asia â?? is home to many of the endemic regions for dengue. The World Health Organisation (WHO) ranks dengue among the top ten threats to public health, so we hope that this new vaccine will prove to be an important tool in this vital fight.

What are your expectations for the regulatory approval of Takedaâ??s dengue vaccine in LatAm?

The EMA approval was a very important step forward, not only because it comes from one of the worldâ??s most important regulatory agencies, but because the approval process was run with a special protocol, â??EU-Medicines for allâ?? or â??EU-M4allâ?? (previously known as Article 58).

Under EU-M4all, members of other countriesâ?? regulatory agencies are invited to be part of the evaluation process and access data at the same time as the EMA. Representatives of the Argentinian National Administration of Drugs, Food and Medical Devices (ANMAT), the Brazilian Health Regulatory Agency (ANVISA), the Colombian National Food and Drug Surveillance Institute (INVIMA), and the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) have therefore had access to information on Takedaâ??s dengue vaccine at the same time as EMA.

Takeda has also submitted dossiers within these four countries, which â?? following the EMA approval and given the amount of time that these four national regulators have had with the dossiers â?? should expedite the approval process. The approval of the vaccine in Indonesia â?? where it is set to be launched in February 2023 â?? should also be a catalyst for a quicker market entry process in LatAm. We have already had a positive recommendation from the new molecule committee in Mexico and are confident of obtaining in-country approvals in the next calendar year.

What about reimbursement of this vaccine? Do you expect it to become part of countriesâ?? national immunisation programs, something only available on the private market, or a mix of both?

Dengue is foremost in the thoughts of the WHO, as well as in those of governments in countries where the disease is endemic. Therefore, we are already starting to work with the governments because we believe that the dengue vaccine should be incorporated within national immunisation programs. Usually, this happens for specific cohorts or ages. We predict that parts of the population will be covered by the state, while Takeda will have to work hard to introduce the vaccine into the private market, where individuals will choose to take the vaccine to prevent dengue.

LatAm performs quite well in terms of vaccine rollout and adherence, as borne out by the fact that in some countries over 80 percent of the total population is vaccinated with a full dose against COVID-19. While working to introduce onto national immunisation programs country-by-country will take time, I foresee a massive opportunity with this product in this region.

National immunisation programs seldom see major changes; does this represent a once-in-a-lifetime opportunity for you and your team to change healthcare for people in LatAm?

Absolutely! As Takeda, we have a unique opportunity to impact peopleâ??s â?? not just patientsâ?? â?? lives and fight this challenging and devastating disease. On a personal level, having always been working in rare and highly specialised diseases, this also represents an opportunity to learn more about vaccines, a completely different area. This is a new challenge, a learning process, and opportunity to interact with different stakeholders.

Prioritisation, as I mentioned earlier, will be key. Right now, the dengue vaccine is my top priority and I need to make sure that we are ready, have the correct capabilities and plans in place, and are interacting with the correct stakeholders, including public sector payers. For example, we need to collaborate not only with Ministries of Health but also with Ministries of Environment, which also carry out anti-dengue campaigns. This broader spectrum across which we can have an impact is truly fascinating.

Different countries will also need different approaches. In Argentina, for example, dengue is only present in certain areas and therefore a full national immunisation program would not be necessary. However, in Brazil, Mexico and Colombia it is endemic across almost the entire country and a different strategy will be needed. Regardless, in all countries we will need to sit down with authorities, medical societies, NGOs, and various ministries to understand how to address dengue in a holistic way. It is not only about adding the vaccine to a national program but working collaboratively to make this a real success.

While the dengue vaccine may be Takedaâ??s top priority for 2023 in LatAm, rare diseases will continue to be an important part of your strategy. How would you characterise the situation for rare diseases in the region today?

â??Rare Diseasesâ?? covers a huge number of diseases, many of which currently have no treatment or solution. If you go disease by disease, it is true that the prevalence is very small, but when you put them all together, many people are affected.

Having worked extensively in rare diseases, I can say that a lot of efforts have been made from the medical side to raise awareness and educate physicians about these diseases, the unmet needs that they represent, and how patients can be better recognised and diagnosed. Early diagnosis is vital as patients have often spent years going from one physician to another without a correct diagnosis and receiving several interventions, some of them highly invasive, without any results. My vision is that we can impact this for the better.

As a pharmaceutical company, we can devote resources to raising awareness of the importance of correct and early diagnosis. That has a positive impact on the patient, who receives the correct treatment at an early stage; the system, which does not then have to spend a lot of money observing and treating the patient over a long period; and on patientsâ?? families and caregivers.

How would you characterise LatAm payersâ?? approach to innovative medicines?

Takeda has a very strong focus on value-based health care. This is our north star, and we work hard not only to bring forward innovation, but to do so for the right patient at the right time. Additionally, we work on value-based deals together with payers, institutions, and healthcare systems to find solutions and reduce uncertainty. The biggest struggle for payers is the uncertainty: how many patients will I receive? How much it will cost? Is it going to be effective or not? Are we paying for something that is really changing lives? Value-based healthcare aims to find solutions that close these uncertainty gaps and relieve pressure on the overall system.

For example, Takeda works to support rare disease diagnosis with various healthcare institutions and universities in the region, including at Universidad La Plata in Argentina. We also work with partners to provide home care so that the patient does not have to go to the hospital and use up hospital resources. These efforts all form part of our negotiations with governments and represent our commitment to bringing *solutions* to healthcare problems rather than just *treatments*.

Does LatAm form part of Takedaâ??s global clinical trial footprint? If so, why?

We do have clinical trials in LatAm but I would love to have more and advocate for such at a global level. LatAm is actually a very good place to do clinical trials with excellent levels of expertise, an improved regulatory framework â?? especially in Argentina and Colombia â?? and good quality institutions. For example, the trial for Takedaâ??s dengue vaccine was conducted across eight countries, four of which are in LatAm. While the fact that dengue is endemic in these countries is obviously a big factor in locating these trials there, it showed that we do have sufficient infrastructure.

R&D, especially clinical trials, are one of the biggest value-adds that our industry can give. An IQVIA study in nine LatAm countries shows that pharma companies, through R&D, have a huge impact on the economy. Clinical trials create a lot of value, not only on the kinds of jobs that we create, that are obviously very educated and valuable, but also on the number of jobs. For each direct job, there are 1.65 indirect jobs created.

Takeda has a long history and a long-term outlook; how does a concept like â??Takeda-ismâ?? work in a LatAm context, where there is sometimes a tendency for short-termism and reactionism?

Takedaâ??s long-term vision epitomises its stability and commitment to bringing innovative medicines to LatAm. Integrity, fairness, perseverance, and honesty are core parts of Takeda-ism and present in everything we do. We are not going anywhere and are committed to building up our strong reputation. Our decision-making process is based on patients, trust, reputation, and business (PTRB), in that order. At any point, if I or one of my colleagues is unsure on how to proceed, we look at the problem though those lenses and come to the right conclusion.

What would be your final message on behalf of LatAm for our international audience.

There are 640 million people in LatAm â?? a huge population â?? incredibly talented, spread over a highly diverse geography. Thanks to the ups and downs of our history we tend to be very resilient and able to manage in times of adversity, which is needed in our noble quest to deliver innovative solutions for complex unmet medical needs. The only way to do this will be through working collaboratively with all stakeholders in the health arena. We also need to ensure that our healthcare systems are sustainable so that we can continue to serve unmet needs across the region.

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