Interview: Heraldo Marchezini – CEO, BIOMM, Brazil

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Heraldo Marchezini, CEO of the Brazilian biotech company Biomm and one of the leading executives in the Brazilian biopharmaceutical sector, provides insights into the eye-catching international partnerships recently signed by this ambitious company and documents Biomm's vision to develop a balanced portfolio combining very innovative biologicals and leading biosimilars in order to maximize the access scenario of the Brazilian healthcare ecosystem.

You indisputably stand as one of the most respected Brazilian executives in the pharmaceutical sector after having honed a prestigious experience among leading multinational companies, including the position of SVP Latin America at Sanofi. Which key specificities of Biomm motivated you to embrace this new challenge in your career?

Biomm actually stands as the first biotech company ever set up in Brazil, a specificity that takes its roots in the legacy of the company Biobrás. The latter was set up in 1975 and rapidly became a pioneer in insulin production in Brazil. In 2001, Biomm was split from Biobrás, and all the intellectual property, know-how, researchers and executives who made Biobrás the fourth largest producer of insulin in the world were transferred to Biomm, while the shareholder control of Biobrás was sold.

We also stand as the first Brazilian biotech company focused on human health that has been publicly listed since its beginnings, which provides us with the resources needed to fulfill our ambitions and rapidly develop the company. To the contrary of more advanced biopharmaceutical hubs where biotech companies benefit from a natural and easy access to venture capital and to the

stock market, Biomm still stands as the exception within the Brazilian landscape.

Since 2001, Biomm's strategy has however evolved and we are now focus on making available a broad portfolio of biologicals through international partnerships with prestigious companies, while continuously leveraging our company's successful track record in developing and producing insulin. In this regard, Biomm is also engaged in a PDP with the Brazilian government for the production of human insulin, and our industrial commitment to the country also encompasses the construction of a world-class biotech facility in the state of Minas Gerais, which is now ready to operate.

In the grand scheme of things, Biomm's development vision is to first increase the access of Brazilian patients to in-licensed biological products and – in a second phase – to steadily expand our scope of action and renew with our company's origins in terms of product development.

With regards to portfolio expansion, Biomm has recently released exciting news with the signing of two new partnership agreements. Could you provide insights into the portfolio strategy followed by Biomm?

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We indeed recently forged two exciting partnerships that truly illustrate the two-fold development vision that we are implementing.

In the early summer of 2017, we entered in an agreement with the US company Mannkind for the marketing and distribution of Afrezza®, a very innovative fast-acting, inhaled insulin, which will make Brazil the first country outside the US to receive this life-changing product. The product was submitted to ANVISA at the end of October 2017 for product approval, and this filing actually includes new label information. With Afrezza®, Biomm truly showcases its enduring commitment to diabetes while delivering on our promises to bring the world's most innovative treatments to Brazilian patients, which emerges as the first pillar of our development strategy.

Nevertheless, we are a true biotech company and do not plan to limit ourselves to the diabetes field. This aspect leads me to our recently signed partnership with South Korea's Celltrion *Healthcare* for the distribution of Herzuma® in Brazil, a trastuzumab biosimilar prescribed for the treatment of breast tumors with HER2-Positive receptor status *[which affects over 25 percent of invasive breast cancer globally – Ed]*. As a company, we are particularly proud to have reached an agreement with Celltrion, which stands as the first biopharmaceutical company to have a biosimilar monoclonal antibody approved in Europe. Furthermore, this partnership perfectly embodies Biomm's commitment to explore a variety of critical therapeutic areas, while ensuring that

Brazilian patients hold more affordable and accessible options to treat the disease, which stands as the second pillar of our growth vision.

Despite ANVISA's increasing reputation on the global stage, biosimilars still remain a frontier area in Brazil with low visibility in terms of approval timelines. When do you envision launching this product in Brazil?

Celltrion Healthcare has already initiated this product's registration a few years ago and we did not have to start the approval process from scratch when inking the contract. However, we still remain very cautious regarding the disclosure of a potential launch date – although we do not expect to wait for an unreasonable time either. In this regard, I want to highlight the utmost quality of the registration dossier submitted by Celltrion, which actually did not come as a surprise given the exceptional track record built by our South Korean partner with the registration of infliximab and rituximab biosimilars in Europe.

Overall, the competitive landscape in the Brazilian biosimilar segment is very different from the one framing the chemical, generics products area, where we see a high level of market competition coming from local companies. We are however well aware that Biomm is not the only company in Brazil striving to bring a trastuzumab biosimilar to the Brazilian market, but our objective is to be among the first companies to reach this objective.

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Biomm still stands as a relatively young company in the Brazilian market. In this regard, how did you convince these prestigious international companies to choose Biomm as their partners for the Brazilian market?

The point that you mention actually relates to another key differentiator of Biomm, as we are able to combine the dynamism of a relatively young biotech company with the rich expertise accumulated by our company's executives. In addition to my experience among leading biopharmaceutical companies both in Brazil and regionally, we have also been able to attract many talented professionals to enrich our commercial and business arms. Our company's promising mix of talent and expertise therefore helped us to conduct successful high level meetings in both Seoul and Sao Paulo, and Celltrion Healthcare saw in Biomm and its people the reliable partners they were looking for.

The Brazilian government recently indicated that public spending would be tied to inflation rate for the next twenty years, while the overall number of Brazilians covered

by HMOs decreased from 50.4 million to 47.5 million between 2014 and 2017 *(according to QuintilesIMS)* as a consequence of the recent economic crisis. What rationales make you believe that it is the right time to bring a product portfolio centered on innovative products to the Brazilian market?

The first critical aspect to consider is that the Brazilian population has been rapidly aging over the past decade and over 30 million Brazilians will be over 65 year old by 2025. This aspect will naturally drive the demand of the Brazilian society for chronic diseases products – either through the private or the public market.

In the meantime, we see that the Brazilian demographic transition coincides with the entry of the global biotech industry into a new dimension, with regards to the innovation level (the overall number of new biotech products reaching the market) and to the fact that a great number of more mature biotech products are now moving toward the biosimilar stage.

Biomm's current portfolio perfectly echoes this global trend, as we hold on one hand Mannkind's extremely innovative insulin product and – on the other – Celltrion's biosimilar. As a company, we do not plan to exclusively concentrate our efforts on the most innovative products, as we consider that variety is the best way to leverage the growth potential of the Brazilian market and maximize the access scenario in the country. In this regard, our goal is to ensure that our portfolio reflect the subtleties of patients' needs in the biotech area.

As a pharmaceutical company, it is moreover impossible to overlook the tremendous pressure weighing on payers' shoulders, and we have the responsibility to offer affordable, alternative options that will help payers meet patient's demand for very innovative products. In the oncology area, we see very innovative treatments reaching the Brazilian market, but the latter will remain inaccessible to most patients if pharmaceutical companies do not make the effort to bring biosimilars in the meantime.

As CEO of Biomm what is your assessment regarding the country's biotech industry?

The biotech industry is very important for the innovation-oriented development of Brazil, our country should definitely allocate more resources to the dawn of this sector. Although we already see a few Brazilian companies operating in this area, there is still no clear policy in the country targeting the development of this industry in particular. In this regard, I feel that there is a need to better acknowledge and adapt to the key specificities of the biotech industry and not try to replicate the policy approach implemented for the chemical pharmaceutical business, which differs significantly from the biotech industry.

I believe that it is not too late for Brazil to enter the biologic arena and we can still expect a stronger local biotech industry to emerge in the coming years. I mentioned earlier that Biomm proudly stands as the only biotech company focused on human health that has been publicly listed since its beginnings; in this regard, we hope that the recent economic recovery and the low interest rates will incite private investors to steer more resources to the development of Brazilian biotech companies.

We feel that Biomm is about to enter a very exciting new phase of growth. Where would you like to see the company in five years?

In five years, we will expect to have assembled a significant portfolio of both innovative and biosimilar products, which would provide Brazilian patients with a broader access to life changing products and – in the meantime – translate into interesting revenue and profit streams for our shareholders.

In the grand scheme of things, we truly believe that within the next five years we can establish ourselves as an important biotech company in Brazil.

What is the vision that an executive with your experience strives to instill in Biomm's teams?

Driving the growth of a company like Biomm, which can objectively be considered as a Brazilian pioneer in many different ways, requires fostering and following a bold and flexible market approach on a daily basis.

When it comes to the Brazilian biotech industry, room for improvement still exists from a regulatory standpoint. Strong fundamentals have already been implemented, but some developments are still required in very specific areas. Given the uniqueness of our business model and our great value offering, we have to truly contribute to the Brazilian ecosystem enhancement.

What would be your final message to our international executive readership?

Biomm is particularly open to forge new win-win partnerships with international partners, while we consider ourselves as the best ally in Brazil for the production and marketing of biotech products. Moving forward, there is definitely a great market opportunity to seize in Brazil for Biomm and its partners. As per Biomm, we truly feel that we have a fundamental mission to accomplish: we want to bring the world's best biotech products and have an ever-increasing impact on the Brazilian healthcare reality while improving the country's access paradigm in the meantime.

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