Miguel Forte â?? CEO, Bone Therapeutics, Belgium

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Miguel Forte, CEO of Bone Therapeutics, walks through his journey leading the promising Belgian biotech company. He also shares with his view of the Belgian healthcare system and what makes the country a perfect environment for Bone Therapeutics as a biotech company focusing on innovative cell and gene therapy.

Please introduce yourself as CEO of Bone Therapeutics and give an overview of the company and the regulatory environment it has evolved in?

I am the CEO of Bone Therapeutics. I took this position at the beginning of this year. I am a multifaceted researcher, I have a MD PhD as my educational background but I have done clinical research, academic research, and I still hold an academic position, as well as regulatory work as a member of the European Medical Agency as part of the Committee for Medicinal Products for Human Use (CHMP).

I have been in the industry for a long time now, first with large organizations, like BMS where I was responsible for the medical organization, and then more recently with innovative organizations such as Biotech companies. More particularly, I am heavily involved in cell and gene therapies and, in addition to my role at Bone Therapeutics, I am also Chair of the Commercialization Committee of the

International Society of Cell Therapiy sitting at the board of directors. This committee is in line with Bone Therapeuticsâ?? vision as it focuses on innovation and the opportunities that it brings to the unmet medical needs, just like Bone Therapeutics is implementing innovative approaches and aiming to deliver benefits to patients with orthopaedic unmet medical needs.

One of the companyâ??s key assets is the protein solution, JTA-004, that has documented advantages over existing treatment for knee osteoarthritis, which is a very prevalent condition, and we also developed a cell therapy platform, ALLOB, which is allogenic and off-the-shelf. This is particularly relevant for the cell therapyâ??s value proposition because it takes advantage of the innovation of using the cellâ??s function through the ability of cells to form the bone: we produce it in a cost-effective way, it comes from a healthy donor and being cryopreserved is ready-to-use.

This technology is about to go into the next clinical studies. We already got the approval to conduct the Phase 3 study with JTA-004, so we are close to the marketing of the product which is a very exciting time for us! Our Phase 2b trial with ALLOB will confirm the previously generated data before we get to the next step. Over the next two years, these two studies will really be about taking the company to the next level and the resulting documented and controlled clinical data will take us there. This excitement really is my main motivation and what gets me up in the morning.

As a company, we are very proud to contribute to the Belgian ecosystem. I am a foreigner and moved to Belgium especially because of the biotech environment was very interesting and rapidly evolving. The Belgian healthcare system is well advanced, providing an essential service and has a great background for innovative activities, clinical trials, industrialization and commercialization as well. I really appreciate that the regulators have strong experience and that they implemented a fast-acting regulatory environment. The regulators in Belgium are integrated into the European regulatory system and they provide very useful guidance and precious pieces of advice when needed and especially to companies in development.

Within the member states, the regulators are fast decision-takers and enable a fast access to the clinical trial decision. As you know, Belgium is the country with the highest number of clinical trials per capita. One of the elements that led Belgium to this leading position is the regulatory environment and the other is the academic environment. The country has developed a lot of academic and scientific innovation and the clinical sites are motivated, ready and competent to realize the trial. The government and institutions like the SFPI, SRIW (Walloon Society of Regional Investments) and Sambrinvest that support and promote the industrialization enable local companies, especially biotech companies, and let them create the opportunity to go from an idea generated in the university to the establishment of a company, taking their product through clinical trials and delivering it through the industrialization to patients.

The biotech environment in Belgium is conscious of cell therapyâ??s potential and it is really involved and promoting these opportunities. I believe cell therapy is at the forefront of innovation, bringing enormous value to patients, not only in immune-oncology but also for situations that requires a regenerative approach dealing with significant morbidity that will have an important impact on the Belgian healthcare.

Having joined Bone therapeutics at the beginning of the year, what are your priorities as the new CEO that you set for yourself and for the company?

My first priority is to generate clinical evidence that supports our assets in terms of documenting clinical benefit that they bring to patients. In order to do so, we need to execute the clinical trials and our key focus is to make sure the organization has the talent, the structure and the resources to

timely deliver quality clinical trials.

Then it is also a priority for me to continue to sustain innovation. We have innovative products at the clinical stage, soon to be on the market but we have to have behind it additional potential new products capitalizing on the expertise that we have as well. As a company, we gathered a lot of experience and assets in the area of MSC (Mesenchymal Stem Cell) derived technology and in the future, more and more tailored cell functions will be applied to cover medical needs. That tailoring will be realized by cell differentiation including gene editing that will really promote additional benefit targeting the function of cells.

As the leader of Bone Therapeutics, my goal is to shape the organization to deliver on clinical trials and engage with partners to bring in this innovation and potentially commercialize our assets in Europe and beyond.

Your knee osteoarthritis asset has been approved for Phase 3 trials, so if all goes well commercialization is just around the corner. Are you looking to tackle this next stage on your own or is there potential opportunities for partnerships and utilizing the Big Pharmaâ??s resources?

We are an innovation-driven organization so we do not have the structure to do a broad commercialization. There may be an opportunity for us to be actively involved in a fraction of that commercialization, for example in Belgium or in a restricted geography. However, I believe that for the benefit of the asset, and in consequence for the benefit of patients, it would make sense to find partners that have the muscle to deliver commercially a product like this to a broader region. We are already engaged in discussions with potential partners in Asia, Europe and America and some with a global footprint. The idea would be, at a certain step of the development, to enter in collaboration and potentially complete the development but definitely use their resources and ability to commercialize our product and bring it to the market. Asia, for instance, is clearly an area where, due to the specificity of the market, we would be keen to find a partner that could take care of our asset and commercialize it locally without necessarily our direct involvement in the commercial activities. On the other hand, we would like to be involved in the strategy developed in the United States because it is a significant market and I think it will be a great opportunity for us to learn and grow as a company by taking part in this process. I consider it is our responsibility to establish a good partnership that will maximize the value of the asset for the stakeholders and above all optimize its access to the patients in need.

In the areas you mentioned, Asia, Europe, the United States, there is a high competition of promising biotech companies trying to position themselves as the next success story. How has been your experience so far with building these collaborations?

There are two crucial components in establishing the credibility of our value proposition: the value of our asset and the organizationâ??s experience. Potential collaborators will see the clinical value of our asset and if they believe that it is superior to the already existing products corresponding to the same medical need, which I believe is applicable for both of Bone Therapeuticsâ?? assets, then it is based on an objective rational reasoning that these companies will be interested in a collaboration. They will also do a partnership if they trust the experience that Bone Therapeutics has gathered as an organization.

That is also why at Bone Therapeutics we bring talents, such as our recently recruited Head of Business Development, Stefanos Theoharis, who used to work in the United Kingdom and comes in with an extensive experience in the exact area where we are bringing value in. That is with this trustable and collaborative organization, coming to the table with strong assets that has proven clinical value, that these discussions will become meaningful.

What is your vision for Bone Therapeutics in the upcoming years?

My vision for Bone Therapeuticsâ?? future is clearly to take a first asset into the market, most likely through a strong partnership. The company will continue to demonstrate the clinical value of our technologies, getting it ready to enter the market whilst continuing to drive the innovation according to our expertise and the medical needs we want to address. We will perpetuate our efforts to bring the value we have in our hands to benefit the patients. Our goal is to grow and play our role in the international biotech scene, but most particularly in Belgium.

Indeed, Belgium is a country that has a very conscious healthcare system and is concerned about their population providing them the help they need. We know that health issues, either chronic, acute or epidemic, will continue to challenge us and the society we have built. As a community and as players in the healthcare industry, it is our role to keep on generating and delivering innovation to the healthcare practitioners who are today at the forefront and facing the challenges. It is a fantastic and rewarding field to be in and, although it is very demanding and challenging, it will continue to contribute to a better care for patients and will ensure that Belgium plays a significant part in that progress.

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