Interview: Gerardo Cárdenas Vogel – CEO, Innovare R&D, Mexico

The increasing interest of the international community in investing in Mexican R&D activities nurtured our desire to transform Innovare's business model

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Gerardo Cárdenas Vogel, CEO of Innovare R&D, on transforming the company's business model to benefit from drug development opportunities, Mexico as a world-class clinical trial destination, and new, innovative treatments as part of their partnership with the French biotech company LFB.

When our colleagues met with you in February 2015, we were impressed to see how Innovare R&D distinguishes itself from most Mexican players: a research and innovation driven company, focused on intangible assets and on attracting clinical research investments in Mexico. To what extent has this unique positioning among the Mexican pharma landscape been paying off?

International investors seem to increasingly get the measure of the promising opportunities that Mexico holds with regards to the local development of innovative treatments. A year ago, I highlighted how American investors could be afraid to invest in a country where they don't really know the financial regulations, while the Mexican investment community isn't mature enough to massively invest in intangible assets, such as drug development platforms. Furthermore, our country probably still lacks healthcare-centered investors, while most of Mexican investment funds don't hold the scientific expertise required to truly gauge the economic potential of a drug development project.

Nevertheless, this increasing interest of the international community in investing in Mexican R&D activities nurtured our desire to transform Innovare's business model, on which we have been intensively working over the last twelve months. I cannot yet disclose the main details of this new business approach, which we will officially release at the beginning of 2017. Nevertheless, I can tell we are already working on adapting our company's structure, which used to be essentially focused on R&D. We are now hiring investment experts who hold international experience and expertise to best position our company in the eyes of investors from different countries. In this regard, we now also plan to adopt a broader geographical approach, which further highlights the necessity to adapt our business narrative to the different expectations and requirements that our potential partners would have. Given our geographical proximity with the United States, American investors will still hold a prominent place within our strategy, but we now also look at more closely engaging with European venture-capitalist funds as well as Chinese partners.

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How do you explain such an increasing interest from international investors to participate in clinical research activities in Mexico?

First of all, observers expect China's pharma market to overcome the value of the total European market in the mid-term horizon. Four out of the five largest banks in the world are (State-owned) Chinese banks, while healthcare stands as a rising priority in Beijing's political and economic agendas. As a result, we see unprecedented and rapidly increasing levels of healthcare investments coming from China, which could contribute to develop clinical activities in Mexico.

Furthermore, our close partners in the United States also tell us this year may stand as the perfect moment to finally trigger a greater R&D collaboration between Mexican and its neighbor. US presidential candidates are almost unanimously advocating for a better control of the pricing of innovative treatments, while it is true some companies happened to display scandalous and reckless price expectations over the past years. In the meantime, we see that bringing an innovative treatment from the early phase of product development to the market costs in average more than USD 1.25 billion in 2016. Considering the likelihood to see a stricter control of innovators pricing being soon implemented in the largest pharmaceutical market in the world, we understand why the pharmaceutical industry is increasingly looking at new, faster, and cheaper ways to develop innovative treatments. Depending of the clinical protocols, conducting clinical activities in Mexico can be up to six times cheaper than in Europe or in the US, while trials would however strictly follow the same protocols and involve the same number of patients and clinical centers.

Why are you confident to see cutting-edge biotech companies bringing clinical research activities in Mexico, whereas they know they will ultimately struggle to register their treatments in the public sector?

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Considering the current pricing context I just mentioned, I don't think market access would essentially count toward the decision to conduct clinical activities in a given geography. However, these companies are increasingly interested in competitive clinical research environments that would be credible enough in the eyes of the FDA or the EMA. Until recently, small and larger biotech companies were not even considering Mexico when it came to choose a destination for their clinical activities. Nevertheless, if we further improve our approval processes and fully leverage the attractiveness of our patient population, capitalizing on the quality of our research institutions and our country's cost competitiveness, this situation can rapidly and positively evolve.

Over the past years, Cofepris, Mexico's regulatory agency, has passed very important and ambitious reforms to attract more phase I and II clinical trials in Mexico, by notably concentrating its regulatory efforts on "molecules with limited clinical experience". Interestingly, this willingness to upgrade our research regulatory framework has also been nurtured by the Mexican Congress.

This openness of Mexico's public authorities to attract clinical research investments also proves it truly stands as a social priority. Compassionate drug use is particularly frequent in the US, while these new, unregistered molecules are sometimes developed by small biotech firms that don't conduct any clinical trials in Mexico. For example, personalized oncology treatments are already accessible in the United States through compassionate use, while – by lack of clinical activities – these breakthrough treatments are not available to Mexican patients.

You mentioned Cofepris' recent improvements to attract more phase I and II clinical trials in Mexico, but what are the remaining rooms for improvement that you still identify?

Despite all of the improvements realized by Cofepris over the past years, it is still extremely time consuming to import the samples required to conduct breakthrough research. This problem is still clearly impeding Mexico's ability to rapidly embark in world-class and multi-centric international research programs.

Furthermore, Mexico still lags behind other countries displaying similar development levels when it comes to basic healthcare research, whereas we managed to display impressive progress in other

sectors, such as energy and telecoms. Most of research projects currently conducted in Mexico are related to natural resources or products, while we haven't been able to catch up in terms of chemical or biotechnological research developments. In this regard, the administrative burden that still characterizes Mexico's public sector doesn't contribute to improve the situation, despite CONACYT's (National Council for Science and Technology) efforts to foster health research projects through public funding. Although financial resources may be available, our bureaucracy prevents researchers from allocating resources as efficiently as they wish.

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Considering the exciting developments the company is currently experiencing with the upcoming release of its new business model, what are the strategic priorities you will focus on over the next months?

Besides adapting our organization's structure and fine-tuning our business approach in order to be ready to implement our new business model, we continue to move forward on the other side of our operations, which notably relates to our distribution partnership with LFB in France. We are in the lucky position to have very exciting news regarding this side of our business as well, as innovative treatments are coming out of LFB's pipeline and will be soon launched in Mexico. This upcoming product launch will truly stand as an important milestone for LFB in Mexico, as our distribution partnership so far uniquely comprised LFB's plasma derived products.

The first of these upcoming innovative treatments to reach the Mexican market will be Clottafact®, human fibrinogen, which has already received an indication for severe hemorrhage in post-partum and obstetric complications or classical surgery. Given its remarkable clinical results, this treatment truly holds the potential to become a lifesaver in Mexico, where aggressions and road accidents pulled together unfortunately stand as the first cause of death in our country. We expect to launch this treatment during the second half of 2016.

This product will be the first innovative treatment of LFB that Innovare will introduce in Mexico on behalf of our French partner, but it will soon be followed by other treatments. As a matter of fact, in the upcoming months, we will submit approval requests to Cofepris for two new innovative treatments, which we want to launch in Mexico in 2017.

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