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Celgene is committed to improving the lives of patients through innovation. The country manager of the recently opened Mexico affiliate explains the importance of having a direct presence in the market, how pro-patients and pro-innovation policies need to be supported, how innovative ways need to be found to ensure patient access to innovative medicines and Celgene Mexico's commitment to change the course of health in cancer and immune-inflammatory diseases through bold pursuits in science and life enhancing medicines.

Celgene started operations in Mexico only very recently. What opportunities did you identify in the market?

Being in Mexico represents a huge opportunity for the company, but also a great responsibility. Celgene is committed to improving the lives of patients and having a real impact on life expectancy worldwide. The company is already present in more than 60 countries; before starting operations in Mexico this year, in Latin America we were present in 18 countries but only through partners. While the region offers many opportunities, it is also very diverse and presents lots of challenges. To be able to fulfill the commitment Celgene has with patients, the management decided it was time to have a direct presence in the region, namely in Mexico and Brazil. We think this is the only effective way to bring Celgene's medical innovation to patients, understand the

environment and leverage the opportunities in these two countries.

Taking in consideration Brazil is the largest market in the region, why did Celgene decide to first establish operations in Mexico?

We are starting operations in both countries, but Mexico offers some advantages that allowed us to accelerate the process. Over the last decade Mexico has implemented initiatives aimed at attracting investment in the pharmaceutical sector. It is no coincidence that today we have more than 230 pharmaceutical companies only in the Mexico City area. One of the most important incentives the regulatory authority offered has been eliminating the requirement to have a manufacturing plant to distribute products in the country. Especially when you are talking about disease-altering medicines, you cannot have manufacturing facilities everywhere because the technology required is very complex. You have to concentrate efforts in a limited number of sites and from there export to the rest of the world.

Also, Mexico offers a good environment for patent and data protection, better than in other countries in the region. When you work with medical innovation it's a virtuous circle: you have to make substantial investment in R&D to bring innovative therapies to the market and re-invest the profits to continue bringing next generation medicines that help patients live longer, better and healthier lives. Some aspects can still be improved – having a regulation in place does not necessarily mean it is always enforced –, but overall Mexico is attractive from this point of view.

Everyone in the industry says that today 'access is the name of the game'. What has been your experience so far with regard to market access?

The value that transformational science and life-enhancing medicines offer in the form of greater longevity and quality of life, reduced burden on healthcare systems and greater productivity which drives economies cannot be realized unless society has access to them. The regulatory authority COFEPRIS has taken a leading role to make sure medicines are granted access to the market, mainly through the implementation of third-authorized parties, which today allow for a fast-track registration process. This has been a first step, which is resulting to be very efficient. After the approval of COFEPRIS, you have to get a national formulary code; also this process has become faster. The main challenge we face today is getting the products approved by the different institutions because of the high fragmentation of the system. Even if there is a defined process and

you follow it, it does not mean the medicine will be granted access. Also, the time framework can be very long. Hence, the main objective of pharmaceutical companies focusing on innovation – as we do – is to look for innovative ways to generate access, which is something you can do only when you have a local presence. For this reason it was important for Celgene to have an affiliate in Mexico.

How are you working with other companies to ensure innovation is brought into the system?

Celgene is working very closely with the Mexican Association of Pharmaceutical Research Industries (AMIIF). All 42 members of the association have one common denominator: medical innovation. Hence, also the same challenges with regard to access. As an association we can really show government and authorities the key role medical innovation needs to play in society and that supporting it is impacting the economy, the health and also the GDP of the country. If you are able to reduce by one percent cancer-related deaths, you have an impact of USD 500 billion in societal value. These are all messages we need to show.

How open would you assess authorities in Mexico with regard to this kind of issues?

COFEPRIS really understands that they need to accelerate access to innovation. On the other hand the fragmentation of the system makes it complex. That being said, it’s the first time since a long time I’m seeing institutions looking for different ways to generate access and being open to find a common solution, because it’s a shared responsibility.

We know the company has a very rich pipeline. How is Celgene’s portfolio represented in Mexico?

In Mexico we currently have the marketing authorization for two therapies, one for multiple myeloma and one for myelodysplastic syndromes. In these two areas we have innovations able to really change the way the disease is treated and we have had a very positive impact on patients. In the last eight years the expectancy of life and the survival rates for multiple myeloma have increased by 50 percent. As for myelodysplastic syndromes in the 2004-08 period the survival rate has increased from 24 to 38 percent. Both medicines are already listed in the national formulary;

now we are working to get them listed at the different institutions.

Our objective is to bring new products to the market very soon, not only for hematological conditions but also for oncology and inflammation. Our aspiration in Mexico is to become the leading biopharmaceutical company in cancer and immune-inflammatory diseases. To do so, we have to diversify our portfolio with new products and new indications. We currently also have products in development in oncology, hematology, rheumatoid arthritis, psoriatic arthritis and other immunological diseases.

Also, we'll put innovation in the center of all our activities, as one of the main pillars of our company. The value of medical innovation will be the paradigm that will define every move we make in order to benefit the Mexican population.

Early and correct diagnosis of diseases is also a challenge. What steps are you taking to make sure patients are diagnosed, thus treated correctly?

It is important to note that in the US since 1975 83 percent of survival gains in cancer can be attributed to medical innovation. That said, as a company we need to ensure the right medicines are delivered to the right patients at the right time. Again, a challenge is the high fragmentation of the Mexican healthcare system, as diagnostics you may have at one institution, are not available at the other. For this reason, if the institution does not rely on the adequate means, we will be actively supporting the testing of those patients. Besides this we also need to work with patients' associations because a lot needs to be done in terms of education. Diagnosing and testing are challenging not only because of limited hospitals' resources, but also because patients in Mexico do not go to a physician or do not identify the symptoms. It's really important to find ways to support the efforts of patients' groups, who educate and help patients better understand symptoms and accelerate diagnosis. This is something we are working on with AMIIF as well as a company.

How are you working with the medical community?

We work with different medical associations to provide them with information about diseases and the population of patients. Several hospitals have made an active effort to map the burden of disease of multiple myeloma and myelodysplastic syndromes in the community, better understand where patients come through and work with the physicians who attend them. Again, we need to find innovative solutions to overcome the fragmentation of the system so healthcare is

administered holistically benefiting patients, healthcare and economy.

Jordi Martin, managing director of Celgene Spain, was very proud about the company's participation in 30 trials with 3,000 patients and the research center in Seville, Celgene's only center outside of the US. What can we expect from Mexico in terms of clinical research?

We think this is a field where we can make a difference. We have more than 300 clinical trials running worldwide and have some trials in Mexico for leukemia and myelodysplastic syndromes. For us clinical research is a way to bring medical innovation to patients, especially for those who otherwise would not have access to treatment. Also, authorities have understood that opening the doors to clinical research is a good way to provide access but also to provide early experience to physicians to learn about the products and better select the right patient. However, in order to be competitive at international level, as a country we need to expedite the approval and recruitment process for trials. We have the patients, the physicians and the need: if we do not move faster, we'll lose the opportunity.

Where can we expect to find Celgene Mexico in five years?

Our commitment with Mexico is to make a difference and be able to deliver medical innovation to patients. To do so we must partner up with all stakeholders and advocate for a robust healthcare ecosystem that benefits all. We are introducing ourselves to the market, the institutions and the authorities to let them know what we can offer to the patients, the healthcare system, the country economy as well as the institutions. To work in this direction we have been able to create an amazing team. Now we have to use this talent to position ourselves in the market and create value.

What attracted you to Celgene?

I'm a physician, so it was very important for me to work for a company focused on patients. I have been working in oncology and immunology for a long time and my experience tells me that you can really see the impact of your work on patients' lives. On the other hand, I have a very entrepreneurial spirit and having the opportunity to start the operations of the company in Mexico was a great honor. I identified with the company's values and they offered me to start Celgene

here in Mexico – there was no way to say no!

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