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Lillyâ??s Nabil Daoud highlights the evolution in the firmâ??s Spanish manufacturing and R&D footprint in recent years, discussed launch plans for its next-generation diabetes and obesity treatments, and outlines some of the key trends currently impacting healthcare in Spain.

Have there been any big structural changes at Lilly since your last PharmaBoardroom interview three years ago?

The main change has been the creation of the neuroscience business unit in the middle of 2021 which separated from the biomedicines business unit. This unit focuses on finding treatments for Alzheimerâ??s disease and other neurodegenerative disorders.

Lillyâ??s pharmaceutical business has historically been divided between the diabetes business unit, biomedicines unit, and oncology unit. The biomedicines unit has now been divided into two â?? neurology and immunology â?? thus creating four operating business units in regard to research and development (R&D).

What are the main therapeutic areas that Lilly manufactures products for in Spain?

Our site in Alcobendas (Madrid) is shifting focus from the high-volume solid formulations that it has traditionally catered for to specialized solid formulations such as precision medicine.

As a result, Lilly has been digitalizing its plants to manage the complexity of the medicine of the future. This will be precision medicine, produced in smaller batches with an enhanced level of complexity regarding flexibility in production and management of inventories for the same number of countries in the companyâ??s Alcobendas facility.

How varied is Lillyâ??s footprint in Spain today?

Lillyâ??s preclinical research began in Spain approximately 35 years ago and the company has a long tradition of conducting preclinical research in the country and has built a formidable team. Currently, more than 110 chemists and biologists are working at the Alcobendas site. This has grown by about 10 percent over the last few years.

The site focuses on the development of chemical products and it is one of the few sites in the world specializing in chemistry for therapeutic areas including cancer, immunology, endocrinology, and other small molecule treatments as the area of expertise. Additionally, Lily operates in collaboration with the rest of the network across the world in small molecule research.

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Why did the company choose Spain as a research environment?

Spain has quality scientists coming from its universities. Furthermore, it has an ecosystem that can collaborate closely with hospitals in the country. For example, when a molecule is developed for cancer, the iterative testing for developing a molecule can be sped up by testing the in vitro activity of that molecule on cancer cells.

In Spain, banks of cancer cells are available from hospitals to quickly test molecules under development against its activity on real life cells. This unique ecosystem built between academics, hospitals, and researchers is being recognized globally by research organizations as a productive center for molecule development.

What is the status of the companyâ??s type two diabetes drug?

The drug is exciting, and it is being studied for uses beyond type two diabetes for a multitude of metabolic conditions including obesity. This is a dual agonist product acting on two incretins. Its results in phase two led to the development of an ambitious phase three program called SURPASS, likely the most expensive and extensive phase three program in the industry. The phase is studying the product for a series of conditions as well as against many active products. Therefore, from the moment of launch, clinicians and patients will have significant data available comparing the drug

against the placebo and options in the market. Additionally, this molecule is being analyzed by many independent analysts as one of the molecules with the greatest potential in the industry.

The drug was submitted to regulatory agencies in the middle of 2021 and is under regulatory review for type two diabetes. In the near future, Lilly hopes to submit the clinical package for other conditions including obesity.

Do you have an update on the companyâ??s global plan to launch 20 new molecules in ten years and how successful has the company been in Spain over the last few years?

This corporate goal of launching 20 molecules in 10 years beginning in 2014 is on track to deliver this ambitious target. Lilly has had a successful journey in Spain over the last few years and has developed a robust immunology presence in that time with two molecules with multiple indications for rheumatoid arthritis, psioriasis, and psioratic artritis (PSA).

Furthermore, the company has increased its presence in diabetes with the launch of other molecules, and in cancer, by developing two to three products in multiple indications with a strong presence in breast and gastric cancers. Additionally, Lilly launched its first compound in the area of pain and expects to become present in neurodegenerative diseases if the companyâ??s investigative compounds become drugs.

These new launches have created a strong base in Spain for Lilly for the next decade by investing in different therapeutic areas and establishing a presence in all of those sections.

You have previously spoken about a change in the way the industry treats diabetes, moving from a glucose-centric approach to a metabolic one. Can you elaborate on that?

Today, most molecules coming to the market are being requested by regulators and clinicians to demonstrate that they can help HBA1C, the ultimate marker of glucose efficacy, but also prevent broader complications of diabetes. Cardiovascular disease remains the number one cause of death for diabetic patients.

Broadening the view to a metabolic view considers other parameters besides glucose levels in the blood to determine cardiovascular efficacy and aiding patients manage their weight and other metabolic conditions.

These new classes of medicines such as SGLT-2s and GLP-1s provide more clinical evidence and data that demonstrates efficacy beyond glucose control. This will become the bar for any new products entering the market and is changing the medical treatment guidelines of scientific societies for clinicians to consider these markers more broadly.

How does Lillyâ??s approach to obesity differ from that of other big players in the field?

Both Lilly and other pharma companies with a significant footprint in diabetes are working in the same direction and the approach is not very different. Obesity carries a number of comorbidities that are costly for healthcare systems, clinicians, and society.

Obesity needs to be considered as one of the most serious medical conditions that is able to be treated or prevented that will improve outcomes for many patients and needs to be placed at the centre of healthcare systemsâ?? preoccupations.

What is Connected Care in regard to insulin management?

Connected Care is the ability to connect the insulin device with other diabetes-related products being used by the patient to improve and facilitate the management of insulin.

Today, patients using insulin must have a continuous glucose monitoring patch that measures the level of glucose in the blood in a continuous format. Some patients may have an insulin pump that injects the insulin when it is needed. However, for others, they have a pen and need to decide for themselves when to inject insulin and how much to inject. Moreover, they often have a watch that measures their food intake, activity, and other factors associated with glucose levels in the blood.

Therefore, Connected Care is combining the insulin device to this ecosystem. It is a pen that measures the quantity of insulin injected and at what time, before centralizing this data with the rest of the data of management such as movement and activities and the level of glucose that the continuous glucose monitor provides.

This data can provide greater guidance for patients to adjust the quantity and timing of their next dose, increasing the patientâ??s control of their diabetes.

How important is the topic of diabetes here in Europe?

In Spain, there are approximately 5 million people living with diabetes, the majority of which is type two diabetes. Almost 11 million people are living with obesity in the country.

Therefore, obesity is also an issue. It is not an issue to the same extent as in the US or Mexico, however, as a proportion of the Spanish population suffering from these conditions with the potential implications for their health in the future, it needs to be better managed and controlled with any solutions available.

Which current trends in Spanish healthcare should our readers know about?

Spain has one of the highest life expectancies in Europe with an aging population. Therefore, the reality in Spain is that the demographics are demanding more from healthcare.

Simultaneously, Spain is one of the countries with one of the lowest investments in healthcare as a percentage of GDP compared to the average of the eurozone and OECD countries. There has been an increase during the pandemic from the government and the public sector with the hope that the investment injection from COVID-19 is managed strategically and not deducted following the pandemic.

It is encouraging that the next generation funds from Europe have healthcare as the second strategic frame after the automotive sector. This demonstrates that the current Spanish government understands the strategic importance of healthcare and its role in the recuperation and transformation of the country.

One of the greatest challenges has been the deterioration in access to innovation, including pharmaceutical innovation. In Spain in 2019, the â??Patients WAITâ?? (Patients Waiting to Access Innovative Therapies) indicator published by IQVIA measured that only 57 percent of medicines approved by the EMA between 2016 and 2019 were available in Spain for Spanish patients.

Furthermore, it takes approximately 450 days for the Spanish government to approve reimbursement of a new medicine for its citizens. The last two years are likely to demonstrate further deterioration given the challenges of the pandemic.

What are the main responsibilities of the industry and government in the sector?

The main responsibility of the industry is to generate more data and better evidence to confirm the value of the medicines combined with becoming creative such as with risk sharing agreements and outcome-based programs.

On the other hand, the industry is asking of the government for clear and predictable rules including transparency for the reimbursement and financing process. The departments which are responsible for evaluating the cost effectiveness of medicines and the reimbursement and financing decisions to reduce bottlenecks in the process need to be properly resourced. These resources need to cater to the delays in the evaluation of drugs which have not yet been evaluated as well as those that are coming. This is the main responsibility of government and regulators

Can you share any thoughts about neuroscience and Lillyâ??s work on Alzheimerâ??s?

Lilly has been working in the field of Alzheimerâ??s for 35 years. Amyloid theory and tau theory highlight that there are two proteins that are likely linked with Alzheimerâ??s disease.

Currently, there are multiple products in the clinical pipeline being tested on the amyloid and tau. The amyloid has a molecule called donanemab which functions similar to the Biogen compound. In phase two, it has demonstrated that it is the first molecule which slows down the progression of the disease and has moved to a phase three program and evaluation.

Is there anything you would like to say about COVID?

We hope to see the end of COVID to refocus the industry back on developing innovative medicines and solutions for other diseases. As COVID has advanced, people still suffer from other diseases and the focus needs to be shifted back to these chronic diseases and facilitate access for patients to healthcare institutions.

What are your goals and ambitions for the next few years?

Lilly wants its Alcobendas site to be a state-of-the-art manufacturing site in regard to catering for the medicine of tomorrow, including precision medicine and high specialty medicine which implies a manufacturing site with high flexibility and smaller batch sizes.

In the R&D sector, Lilly is consolidating its specialization as a chemistry-based centre of excellence within the global R&D network. Additionally, the company hopes to expand its collaborative research development through increasing collaborations, participating in R&D consortiums, and working with academic institutions across Europe.

Commercially, Lilly hopes to deliver its pipeline of products to patients and healthcare providers across the country. This includes collaborating with governments to gain access to the innovation as well as the medical community and healthcare providers to offer the data that is needed to make informed decisions on the patients that would benefit the most from these therapies.

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