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HIPRA is a world-leading animal health company that has launched a record 22 animal vaccines in the last 10 years. During the COVID-19 pandemic, the European company decided to jump into human health with its own vaccine candidate, currently in phase III trials. Carles Fàbrega, managing director of HIPRA's new Human Health division, recounts their R&D journey, how a local diagnostics collaboration led to a promising candidate, and the next steps. In addition, he highlights the importance of having alternatives to mRNA vaccines and touts the company's full in-house development and production and the fact that their recombinant protein does not use any novel substances as clear advantages.

Carles, you have worked with HIPRA for almost two decades. Can you explain your journey with the organisation, the role you played in helping it internationalise and how the company pivoted from being an animal health player to a human vaccine developer?

My first position with the company was as a financial controller, which made sense given my business administration degree. HIPRA was a completely different organisation when I started back in 2003, it had around 300 employees and was already a solid player in the animal health business, especially in Spain, with a reasonable presence worldwide through distributors. My journey coincided with the beginning of a new era for the company: the internationalisation strategy.

Taking on new business opportunities, I moved to the Philippines, from where HIPRA was planning to develop its business in Southeast Asia and China. After a few years, I came back as Subsidiaries Director, coordinating the internationalisation projects at a time when we were opening subsidiaries in new countries. The company established a long-term strategic plan to cover the main animal health markets with its own subsidiaries.

We knew that success was not about just becoming international but also being recognised in a certain way. Because of that, in 2008 we took a decision that would prove to be transcendental for the future of the company: we decided to focus exclusively on vaccines. It was not an easy decision because 80 percent of the animal health market came from antibiotics and pharmacological products. Saying goodbye to 80 percent of the market to focus on vaccines was a challenge, but the right decision. In retrospect, putting all our resources and efforts into becoming one of the best vaccine developers in the world has made HIPRA a great organisation. Since then, we have developed innovative vaccines; we do not support projects that do not bring something new to the market. HIPRA remains the company with the most registered vaccines with the EMA in the last 10 years with 22 vaccines.

So again, being focused on vaccine development has brought us to where we are today. Since we have worked with all kinds of vaccines, including viruses, bacteria and protozoan parasites, we felt very comfortable when jumping to human vaccines.

Today, HIPRA occupies the sixth position in the global rankings of animal health vaccines, competing with companies with way more resources, people and different business models. We are proud of the fact that the company’s growth has been organic since all our products have been researched, developed and manufactured internally.

To what extent will the company’s COVID-19 vaccine project change that strong full in-house development selling point?

Indeed, not outsourcing any part of the process is one of HIPRA’s main strengths, although we realise that controlling the whole value chain is something that perhaps will have to change as we grow and venture into human health. For our COVID-19 vaccine, for example, we have enjoyed control of the entire process which is one reason for the project’s success so far.

We have seen many promising projects in the laboratory setting that eventually faced many difficulties when transitioning into the industrial phase; that’s where HIPRA excels, it is precisely

what we do, move successfully from a laboratory scale into an industrial scale.

Can you walk us through the moment in which HIPRA decided to take a risk and develop a COVID-19 vaccine?

Way before the pandemic came, we had many internal discussions about jumping to human health but for one reason or another opted to remain focused in animal health.

The beginning of the project was quite organic. When the first wave of infections gained steam in Girona (Catalonia, Spain), in March 2020, hospitals were full, starting to crash and in need of resources. Coincidentally, we had been operating many diagnostic laboratories for many years, providing diagnostic services to our animal health customers all over the world. At that moment, we were about to move to a new laboratory in our HQ and were contacted by local hospitals to assisted them with PCRs since they lacked those resources; they came to see our facilities and were impressed. We started collaborating with them free of charge, willing to do anything we could to help the local community go through a sad situation; We conducted more than 35,000 PCRs and it was a very positive experience for us.

A few weeks later, we started developing our own ELISA kit to estimate antibodies in samples of COVID-19 patients, obtaining very encouraging preclinical results and after that we did a proof of concept with one the company’s vaccine platforms. At the end, we were trying to find ways in which HIPRA could make societal contributions, based on our experience and capabilities.

It was a tough time for the country; Spain was facing challenges in receiving masks and ventilators. Somehow, we were encouraged by the local agency, who knew HIPRA well after many years of auditing our facilities and processes for animal health products, to try to develop and produce a COVID-19 vaccine candidate. They support the company from the very beginning and at a certain point we realised that the R&D, scaling-up and production of human and animal vaccines were not so different. The only stage in which HIPRA had no experience was in clinical trials.

Our candidate started with the original SARS-CoV-2 Wuhan strain but, after seeing global developments, we decided to move into a variant platform (Alpha and Beta heterodimer).

The results we have seen in preclinical and clinical stages have been extremely promising; the project has confirmed that HIPRA is an excellent vaccine maker.

This experience has really changed the company's reality because, being an animal vaccine developer, we were well known among the veterinarian community, but we are now entering into a new ecosystem, the human health market. While we need to learn to adjust, we are doing it with optimism and satisfaction.

What is the current status of the new vaccine project? When are you expecting to launch the candidate to the market?

The vaccine developed by HIPRA is the first (and so far, the only one) bivalent (Alpha and Beta) recombinant protein vaccine developed to fight against variants, and it is now at the final steps of Phase III clinical studies in Europe and about to start the Rolling Review in front of the European Medicines Agency (EMA). [*As of March 14, 2022, four vaccine candidates are under EMA rolling review: Sinovac, Sanofi, Valneva and Russia's Gamaleya Research Institute*]

Our shot is designed to serve as a booster. Our new and exclusively dedicated facilities were inspected in January 2022 and are already GMP certificated. The company feels ready and is already manufacturing the antigen for the vaccine in order to deliver the product as early as mid-June when we expect to receive conditional marketing authorisation.

What is the company's plan in relation to the manufacturing process, is it going to be produced solely in Spain or through your global network of partners?

At the beginning everything will be done in our new facilities in Spain, exclusively dedicated to this COVID-19 vaccine project, but, of course, depending on the demand for the vaccine we might explore some alternative partners (fill and finish).

If and when the EMA gives authorisation for your COVID-19 vaccine, what are the next steps for the newly created Human Health division? Is it too early to say?

HIPRA is very good at developing vaccines. If it was important to remain focused when the company was dealing exclusively with animal health, it is also important to remain focused now that we have jumped into a new market.

We see that there are many zoonotic diseases that are shared between animals and humans, and HIPRA has great experience in working with many pathogens, putting us in a unique position to innovate in the area of human vaccines such as the flu, papilloma and many other pathogens that we have dealt with in the past. Similar to what we did with COVID-19, we can leverage our experience with viruses to develop a successful human vaccine platform; this is the first and most straightforward path to enter the market. However, the COVID vaccine project has given HIPRA great visibility, interesting connections and new opportunities. We are evaluating and need time because our resources are all going to the vaccine and the human health team is not that big yet.

Our plan is to analyse all opportunities and chose those that would benefit the most from HIPRA's capabilities, they have to be a good fit for us, not only interesting projects. This is precisely why HIPRA decided to divide the organisation into two divisions, to avoid distracting the team because our animal health activities are quite challenging.

HIPRA is the fastest-growing company in animal health, gaining global market share each year, launching 22 new animal vaccines in the last 10 years and over 50 vaccine projects in development. The company is investing 50-60 million euros every year in state-of-the-art facilities and reinvesting 10 percent of the yearly turnover in R&D and we will continue to do so in order to make sure the Animal Health division continues consolidating and bringing innovative solutions to the market.

Vaccines have been put in the spotlight throughout the pandemic and, particularly in Western countries, vaccine hesitancy has become a challenge. As a newcomer to human vaccines, how is HIPRA looking to gain trust from regulators, healthcare practitioners and the population?

That is something that we keep discussing internally. We realise that this is our first human vaccine project, and we cannot fail; all vaccines must perform well, but especially ours.

HIPRA is convinced that the recombinant protein technology will serve as a great complement to vaccines already in the market. So far, we have seen a high necessity not only in Europe but worldwide, and in the scientific community, for alternatives with population groups reluctant to receive booster doses of the vaccines available so far.

HIPRA has been producing coronavirus vaccines for different species for more than 30 years. That's why we felt confident when we started this COVID-19 project.

The results we have seen so far with the vaccine are very positive, both in terms of safety but also in terms of levels of antibodies against all variants of concern, specially Omicron.

Other benefits of our platform are its logistics (from 2ºC to 8ºC) as well as its adaptability to potential new variants that might appear in the future.

We are convinced that the fact that we use components widely used in vaccine production (adjuvant and others) and being a recombinant protein vaccine, will certainly help us gain trust from regulators, healthcare practitioners and the population.

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