Eric Halioua â?? President & CEO, PDC*line Pharma

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*PDC*line Pharmaâ??s Eric Halioula explains why he decided to establish a biotech in Belgium, outlines the progress that his immuno-oncology focused firm has made in clinical trials since our last conversation in 2020, and his hopes for establishing new alliances with manufacturers and Big Pharma players moving forward.*

After spending about 14 years in Belgium and being actively involved in the Belgian biotech ecosystem, you decided to set up PDC*line Pharma there. What factors contributed to that decision and what makes Belgium such an attractive biotech location?

To give you some background information, the technology developed by PDC*line Pharma is using is a cell line loaded with peptides that are derived from target tumour antigens, which is the core of our cancer vaccine platform. The technology was discovered by Dr Joel Plumas in an academic research laboratory associated with the French blood bank [*Etablissement FranÃ§ais du Sang (EFS)*] in Grenoble, France, where the company was first established in 2014.

When I joined as CEO in 2016, we decided PDC*line Pharma should be developed in Wallonia, the French-speaking part of Belgium. The reason for that decision was that I knew the area and its strong ecosystem already because I had been the CEO of a previous company for six years. It is

even stronger now with big pharma setting up headquarters here and bringing in a lot of talent. We have benefited from that, and most of our management team came from GSK vaccines.

Financing is one of the other strengths of Belgium to attract biotech. In Wallonia, for example, a lot of government funding is available, and there are also many VC funds present here. In addition, Belgium is very quick for setting up clinical trials.

How has PDC*line Pharmaâ??s pipeline progressed since we interviewed you in 2020? Can you walk us through the companyâ??s clinical development over the past two or three years?

We are currently in phase Ib/II of a clinical trial for non-small cell lung cancer. Since our last interview, we got through the COVID-19 pandemic, which was not an easy period for patient enrolment and have progressed quite a bit. We now have 17 active clinical centres in France, Belgium, Netherlands, Germany, and Poland. Because we are evaluating the vaccine at two different doses and we expect to enrol 64 evaluable patients. On one hand, we are evaluating it in an adjuvant setting as monotherapy, and on the other in first-line metastatic patients in association with anti-PD-1 treatment. We have four cohorts, are now finalising the last one, and expect to have a first interim report in August of this year and to have a second report in May 2024.

The initial results are encouraging in terms of immunological response and in terms of the first clinical signals we have seen with the vaccine. With these results, we have presented posters at two international conferences, at the 2022 European Society for Medical Oncology I-O (ESMO Immuno-Oncology) Annual Congress and the ESMO â?? European Society for Medical Oncology Annual Meeting 2022.

Apart from the progress of our pipeline, the company has grown, and we are now a team of 35 people. Most are based in LiÃ¨ge, but we still have a research lab in Grenoble. In addition, PDC*line Pharma is also setting up a manufacturing facility in LiÃ¨ge. It should be up and running by July of this year and we hope to become accredited for Good Manufacturing Practice (GMP) next year. This facility will be used to supply the vaccine candidate for our next clinical trial and is big enough for phase III and the first year of commercialisation. Afterwards, depending on the results and the timeline for commercialisation, we could increase the size of the facility and create others in the US and Asia.

Another advancement for us is that we have built a strong link with South Korea. We signed a licensing deal in 2019 with LG Chem and raised EUR 20 million in the B1 round of financing including three South Korean investors, including KIP, which is the biggest South Korean investment fund. In the second B2 round of financing in November 2021, which was to finance our current clinical trial, we had three new Korean investors. In fact, the deal with LG Chem brought the company a lot of credibility in Korea that got other investors interested. Currently, we have a mix of Belgian and South Korean investors as shareholders of the company.

How would your oncology vaccine candidate fit into existing regulatory frameworks? Could it be accepted as a PRIME designation in Europe or a breakthrough therapy in the US?

To be considered for that type of designation, you need to be very innovative and have good clinical data for a disease with a high unmet need. We definitely fit those criteria. Of course, we need to demonstrate the significant benefit over existing treatment., which is something we expect to do at

the end of the phase II randomized trial. Our vaccine is a therapeutic vaccine to treat patients with advanced-stage non-small cell lung cancer and like other immune-oncology drugs, we are eligible for that status.

You mentioned PDC*line Pharmaâ??s ties with South Korea. Is the intention to get to a certain development point and then out-license to a Korean firm, or is the company planning to become a full-fledged biopharma firm in its own right?

We already have a licencing deal as I mentioned and have licenced the rights for Asia which includes a straight licence in South Korea and options for the rest of Asia. Apart from that, we are interested to licence our product to big pharma for the rest of the world as soon as that makes sense. Maybe at the end of the current trial, or maybe after the second clinical trial because it is extremely difficult for a biotech to commercialise these products alone, to get approval, pricing, reimbursement, and to have the required marketing and sales muscle for such a large market (lung cancer).

It may be possible for PDC*line Pharma to develop new vaccines from the same platform for smaller indications and we could envisage going up to market approval for those, but today we are still limited in terms of size and funding and have to focus. We need to demonstrate our proof-of-concept and clinical benefits and after achieving it, I am hoping we will sign an even bigger licencing deal. With that money, we would be able to launch new clinical trials with products for new indications up to the market approval. For now, it is only a possibility.

So far, PDC*line Pharma has not conducted any clinical trials in Asia. Does the company plan to broaden the geographical scope of its clinical trials beyond Europe?

We decided that for the first clinical trial phase I/II with 64 patients to focus on Europe because it is easier to get patients and manage the trial appropriately. For the next clinical trial (phase two randomized study), which we hope to launch in 2025, we plan to include clinical centres from US and Asia.

Moving on to the companyâ??s development platform, how flexible is it and can it be used for new indications?

For the first vaccine candidate (including our PDC*line plus peptides representative of tumour antigens), we have selected six different shared tumour antigens that we know are frequently expressed by non-small cell lung cancer patients. For new indications, we can quickly select other antigens and make new vaccine candidates. This capacity makes our platform very versatile and it allows us to address potentially any kind of liquid or solid tumour.

We spent a significant amount of time before launching the non-small cell lung cancer trial making sure it was the right indication because when you start a clinical trial, you need to select the right populations, meaning populations that will still exist if the standard of care for the disease evolves. Moreover, the unmet need must be high enough to justify your clinical development and patient populations large enough to make patient enrolment in a reasonable time.

When we talk about advanced therapies, those in the cell and gene category have proven challenging to commercialise. Can your candidate, a vaccine, be considered a first-line therapy?

Yes, we are first line. The positioning in the current clinical trial is for metastatic patients with non-small cell lung cancer, meaning stage four or three B that cannot have surgery. They are diagnosed with metastatic cancer and have a PD-L1 level in the tumour above 50% and right away they are treated with the checkpoint inhibitor (Pemborluzimab) plus our cancer vaccine, so it is first line for metastatic patients. We are not in second or third line, and it is an add-on to the current standard of care in the targeted population: Pembrolizumab.

Our cancer vaccine is allogenic and off the shelf, we are using the same product for any patient and we have a very scalable manufacturing platform that allows us to ensure consistency of cancer vaccine batches produced and low cost of goods. All these elements will contribute to facilitate commercialization.

Vaccines have gained a lot of attention since the COVID-19 pandemic. Many oncology vaccines are being developed and there have been a number of M&As in the area. How positive is this trend for PDC*line Pharma?

Indeed, the perception has changed, and the experience and awareness related to the development of the COVID-19 vaccine was, of course, a big boost for cancer vaccines. Several other companies have vaccine projects in oncology that are moving forward. Recently, Moderna and Merck announced the positive results of a pivotal randomised phase two clinical trial in adjuvant melanoma with a personalized cancer vaccine in combination with a checkpoint inhibitor. I believe it is one of the first statistically positive randomised study with a personalized cancer vaccine. Merck has signed a big deal, which is particularly good news, and there is more and more positive data generated in the field.

The success of checkpoint inhibitors, which inhibit the mechanism of defence of tumours, opened the door to a new generation of cancer vaccines that stimulate the immunity of the patients. There is definitely synergy of mechanisms of action between both modalities. Today big pharmaâ??s interest in cancer vaccines has been restimulated.

Innovative new therapies often come with a very high price tag, especially in oncology. Could vaccines be a more affordable option and have a competitive advantage in terms of pricing?

Price is defined based on a specific target product profile (clinical benefits expected versus standard of care, target population, level of unmet needâ?¦). CAR-T cells, for example, one of the most expensive innovations in oncology get close to EUR 300,000 or 400,000 as a yearly treatment. They have demonstrated a transformative benefit in clinical trials in terms of overall survival for patients having specific leukaemia, and the high price can be justified thanks to the clinical benefits provided. Furthermore, the cost of goods sold of these products is very high. Expensive treatments like that can be an issue for healthcare systems because they cannot pay that much for all the patients who have cancer. But, with our vaccine, we have worked a lot on the manufacturing process to control the costs of goods sold (allogeneic cell line, production in single-use bioreactors, easy-to-use formulation system that can be stored in a -80Â°c fridge in a hospitalâ?¦). We are also expecting a very good clinical benefit but our price target is lower than the CAR-T-cells one.

Is there anything else you would like to share with PharmaBoardroomâ??s international audience?

I would just say that PDC*line Pharma is well-financed to complete our current clinical trial and I am already preparing a new round of financing for the next clinical trial. I am looking for a manufacturer for the supply of the checkpoint inhibitor we will use for the next clinical trial. Establishing new alliances with big pharma is also an objective.

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