Interview: Judith Greciet – CEO, Onxeo, France

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The CEO of Onxeo, recently formed through the merger of the French BioAlliance Pharma and the Danish Topotarget, discusses its strategic turning decision to focus on orphan oncology, its promising pipeline of innovative products, her "positively opportunistic" attitude towards partnerships and international expansion, and the company's overall strategy for differentiating and establishing itself within the competitive field of oncology.

Onxeo was created in 2014 through the merger of BioAlliance Pharma, a French company, and Topotarget, a Danish biopharma company, which both specialize in oncology products. What was the rationale behind the merger?

BioAlliance Pharma's strategy was to dedicate our internal efforts and resources to the development of our oncology pipeline, which was where we saw the most potential. We wanted to drive our key assets and create value in order to accelerate the growth of the company, and the best method for these goals was external growth. We began to look at potential partners with which it would make strategic sense to work together, which was how we identified Topotarget. Topotarget was in a similar position to us and shared our goals for corporate transformation. This fundamental compatibility was what sealed the deal for our two companies.

The merger has proven to be an excellent decision. We now function as a single team, although we maintain a dual presence in both France and Denmark. There has been a lot of synergy: not necessarily in terms of scale or cost savings, given our small sizes, but in terms of portfolio,

expertise and geographic reach. Through Topotarget, we have acquired key oncology expertise, and specifically, a very promising compound, which had already been approved in the U.S. We are now exploring its use for other cancer indications because we believe there is huge potential for this product.

In addition, we acquired a strong presence in the U.S. through Spectrum Pharmaceuticals, which now has the commercial rights to Beleodaq® and Livatag® in the US. Finally, we have enlarged our shareholder base into the Nordics and transformed ourselves more fully into a pan-European company, internationalizing our mentality and employee profile, which we see as a huge advantage. As a means of generating growth, merger and acquisition (M&A) strategy has been extremely successful for us.

Given the success of M&A as a growth driver, will this become an important element of Onxeo's future development?

Given how successful this strategy has proven to be, it makes sense to continue to focus on this method. However, successful M&As require several unique elements; we remain open to suitable opportunities, and are convinced these are efficient levers to sustain growth. Currently, it is too early to make any concrete statements about future transactions.

Fundamentally, a successful M&A needs to be sustained by a clear industrial and corporate logic to a partnership. The corporate leadership teams of both companies must be ready for such an action, and they should be fully supportive and aligned with the vision. Finally, the partnership has to be financially feasible. There are a significant number of similar goals that need to be present for successful partnerships.

We do not have a limited indication or scope for the companies with which we would consider partnership. The key element is that the company must to have an orphan indicator. We are an expert in oncology, so it makes sense for us to focus on that area. In addition, any compound that could be developed in hepatology would also be relevant to us, because we have a strong expertise in that field. However, this aspect is not a requirement but merely an advantage for us.

In general, we are very opportunistic in our search for the best assets.

Since you joined BioAlliance Pharma's executive management in 2011, you have remolded the strategy towards orphan oncology. Given the crowded, competitive landscape of oncology, with Big Pharma players like Novartis and BMS, for instance, that are moving into immuno-oncology, and also other biotech companies, how will

Onxeo differentiate and establish itself?

It is undeniable that oncology is a very populated area, but there is also huge potential in this market given the unmet medical need. And a company has to start somewhere. All Big Pharma companies began as small companies. There are many opportunities for us in the field of oncology, and we have a lot of room to grow. The key objective for me has always been to focus on doing the best work we can because that is our job, and success will come from that. My main concern is that we have the right assets, the right talents, and clear evidence of our products' safety and efficacy.

One of our company's main principles was to de-risk our portfolio profile; our assets should be relatively independent from each other, which is important given how inherently risky a biotech's business model is. Nevertheless, we were also reassured by our strong track record, given that we have successfully brought to market three products, which are currently generating revenues. Hence, we decided to focus specifically on orphan oncology, a field that is broad enough to diversify our risks while still drawing on our expertise. This was also the portfolio in which we saw the most opportunity for valuable growth: high efficacy, less direct competition and better prices.

Focusing on orphan oncology also allowed us to enjoy the advantage of the favorable measures that come with orphan status, in terms of regulatory processes and price. Based on all these considerations, Onxeo's business model positions us well for success within a competitive field.

France is notorious for the complexity surrounding market access issues, especially when it comes to obtaining favorable pricing and reimbursement decisions. How does Onxeo plan to deal with this?

France often faces many criticisms, but I must first point out that there are many advantages for biotechs in the French environment. For instance, the Credit d'Impôt Recherche (the French Research Tax Credit) is a very important financial support for biotech companies, and it is key to R&D companies. In addition, our level of expertise and quality in research and development are extremely strong, particularly in the field of oncology, and we can draw upon this reservoir of knowledge easily.

That said, it is true that market access is a complex issue in France. At Onxeo, we do our utmost to ensure that financial viability is possible, and this means that we exert a significant amount of effort, right from the beginning, in the compilation of a comprehensive dossier that would convince the authorities about the need for a fair price. This includes market research, medico-economic assessments, an understanding of potential generics competition, among other issues. All these are included in our development programme from the very beginning. Long-term planning and

perspective are important.

Finally, I also bring my own expertise and experience to Onxeo, which is probably one of the main reasons I was appointed to executive management. Given my decades of experience working with international pharmaceutical companies on commercialization, I have a strong knowledge of the regulatory and M&A processes, which helps me to navigate Onxeo through the European pricing and reimbursement process.

Onxeo currently has a strong presence in the US, with three partners: Spectrum, Innocutis/Cipher and Dara BioSciences. What are the next steps for Onxeo in terms of international expansion?

We already have offices in Copenhagen, which gives us a strong European footprint and gives us access to Nordic shareholders and academics.

This decision will influence our international expansion strategy. Given the size of the US market, setting up a presence there is always at the back of our minds, and we are still exploring our options. It is a vision for the future, but right now, we are in the process of defining our internationalization strategy.

What is your five-year vision for Onxeo?

There are some very clear milestones for us to achieve over the next five years. First, the data readout from our Phase III trial of the Livatag® program in primary liver cancer is expected in 2017, and the results will constitute a cornerstone for the company. This is a very promising asset with high sales potential.

More generally, we would like to reinforce and enlarge our pipeline. We will also have decided by then our international strategy, including commercial operations.

We are positively opportunistic. I am a strong believer that biotechs need to be very opportunistic – they need to be guided by evidence and strategy, while remaining alert and open to opportunities. As the CEO of a company, you can have your own strategy and plans for the future, but at the end of the day, if you come across a fantastic opportunity, and it is the best option for your company, it is your responsibility to take it.

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