Interview: Bernard Vanhove – CEO & Maryvonne Hiance – Chairman, Effimune, France

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Bernard Vanhove, CEO and Maryvonne Hiance, Chairman of Effimune, an immune regulation biotech, discuss their novel approach to developing immunotherapies, their partnership and commercialization strategies, their perspective on the landscape of immunotherapy as well as the evolution of the French biotech environment, and finally, their mission to position Effimune as a model for public-private collaboration.

Effimune specializes in immune regulation – can you briefly introduce Effimune and highlight what differentiates it from the other cancer biotechs we have seen?

We are an immune regulation company focused on the discovery of novel therapeutic targets and their translation into breakthrough medications.

Our unique approach is that we focus on the immune system, which is at the core of health, instead of specific diseases. The balance of the immune system is very important, and both a depressed immune system and an overactive one can result in a variety of pathologies. This balance is maintained by healthy interactions between effector and regulatory immune cells.

We are developing first-in-class molecules that address potential sources of immune imbalance, which result in pathologies like autoimmune diseases, certain cancers and transplantation rejection. Furthermore, we achieve this not by suppressing the immune system, which is the current standard therapy but by developing solutions to correct the existing imbalance between these effector and regulatory T-cells.

Our research is very focused on the immune system but – or rather, because of this – the potential applications are very broad.

Can you outline your pipeline of innovative products to our readers?

We are still a small biotech, with a staff of fifteen people, but we have done very well in managing to develop three very promising products.

The first and most mature is FR104, which is a first-in-class molecule with preclinical proof of concepts for rheumatoid arthritis, multiple sclerosis and transplantation. This can be fully licensed in the coming month, which means it will exit active development with us while we benefit from milestone and licensing revenues. In 2013, we signed a global option and licensing agreement for this product with Janssen Biotech, which gave Janssen the option to license the product within three months after the end of phase I, which is now approaching. This will give us the opportunity to start a new project.

The second is Effi-7, which is also another autoimmune product that is still in preclinical development.

Finally, we are moving into the promising field of cancer immunology with our third product, Effi-dem, based on our discovery of a novel checkpoint inhibitor. It is still very much in the initial stages of development but it promises to be a very exciting and productive project.

In addition, we also have a dedicated R&D team working significantly upstream to prepare future products and maintain a productive pipeline.

In addition to the 2013 licensing partnership with Janssen Biotech, which funded the development of FR104 up through phase I, Effimune has also raised nearly EUR 15

million (USD 16.5 million) in funding from public and private sources over the past eight years. Compared to other biotechs who have raised tens and hundreds of millions through VCs and IPOs, is Effimune disadvantaged in terms of financing?

We have had many different sources of funding and they have been sufficient for us to generate a productive pipeline. As a biotech, we are also reassured that we have managed to generate revenues of EUR 5.1 million (USD 5.6 million) in 2014, which demonstrates our potential.

We do have further plans to raise more funds in the coming years in order to ensure the development of our pipeline. Immunology is a very competitive domain and our existing projects could be very successful but the time frame for them is longer than we would like. For instance, we would like to have more funds now to develop our third product next year, so we are continuing to explore both public and private opportunities.

Given the success of our partnership with Janssen, we are undeniably very open to further partnerships with Big Pharma. However, while with Janssen, the partnership occurred at the preclinical stage, for subsequent projects, we would like to do it after post-phase II, at the earliest.

We are also seeking pharma partners because they are best equipped to deal with pricing and reimbursement, and market access issues. Our main focus is R&D and therapeutic development, so we do not wish to get entangled in the commercialization process, which can be very complex.

Immunotherapy has been called the breakthrough of the year in 2013 by *Science* magazine, which have resulted in an influx of both Big Pharma but also biotech entrants. How will Effimune differentiate itself from and compete with the others?

Vis-a-vis Big Pharma, as a biotech, we are naturally more flexible, particularly in early clinical development, we are able to take decisions and drive the project forward quicker. But as I mentioned, it would be extremely difficult to commercialize our products ourselves, so we need Big Pharma’s assistance in this area. In this sense, Big Pharma and biotech are very complementary actors and it is not a zero-sum competition.

Vis-a-vis biotechs, I would differentiate ourselves by labeling Effimune as a micro-pharma company instead of a conventional biotech. We do not rely on a specific proprietary technology to build a niche for ourselves. Instead, we focus on the science behind immunology and we utilise the best tools and technology available to produce novel therapies.

Furthermore, very few biotechs already have commercializable products, so we are at a more advanced stage of development. There is the advantage of a proven track record.

Finally, immunology is a vast field with an infinite array of possibilities. Neither Effimune nor any other biotech company has the capacity to do everything and conquer the market. We all have different focuses, and there is space for everyone.

A common complaint of French biotech companies is that France is not as good for biotech development as the US or the UK. For instance, DBV Technologies had to go to the US to obtain sufficient funding. How do you see the French biotech environment and what is your advice to aspiring French biotech entrepreneurs?

To be very fair, France is in an excellent position in terms of seed funding, and I would go so far as to say we are better than most other countries. There is real commitment from the authorities in incubating and assisting new start-ups, and this is not restricted to the central authorities. There are regional funds available as well. Overall access to grants is good and the grants are relatively generous. You can have several millions to co-fund a project.

The gap lies in the later stages of development. Historically, it has been difficult for more mature start-ups to have access to funds. There is a lack of VCs and a lack of VCs with sufficient funding – for more mature biotech companies, they need more money as the later stages of clinical development are more expensive.

That said, the landscape is changing slowly and the market is opening up; the number of IPOs has increased steadily in France and there is now a very active biotech scene on the stock market.

A key thing that remains to be set up is a reference fund in France that can leverage funds abroad to help French biotech companies expand internationally. Currently there are no options available to finance international expansion, but this is important in order to grow the industry overseas. We still need to find a reference funder in France to be able to leverage funds abroad. This would be a critical next step to grow the industry overseas.

Effimune is a spin-off from the Nantes Institute of Transplantation Urology-Nephrology (ITUN), one of the principal European centres for transplantations. We have heard from François Sarkozy that there is "a lack of translational impetus" in France, because "for most researchers the real prize is to work on public research". What is your perspective on this?

This is a very common perception and unfortunately, there is a lot of truth in it. Effimune is proud that we are an exception to this rule, as we are still implanted in the Faculty of Medicine there and we wish to make it our permanent base. We are not simply a biotech company incubated there but

we are rooted within the faculty and we would like to develop Effimune within that scientific community.

Practically speaking, it is very profitable for the company, as we benefit from the expertise and ideas generated there. In turn, we bring dynamism and energy to the institution. Increasingly, public researchers need to be associated with the private sector, whether pharma or biotech, in order to receive public grants, as grant agencies are beginning to prioritize translational research, research that will produce therapies. This is creating a perceptible shift in academia.

Effimune is also actively working to bridge the gap between the public and the private sectors. We are in the process of developing a public-private partnership with the Institut National de la Science et la Recherche Medicale (INSERM; the French National Agency for Science and Medical Research) as a new mode of collaboration. A similar idea had been proposed in the past but it was ahead of its time and there was insufficient public interest. Now, the gap is not as wide as before and public institutions are beginning to realize how mutually beneficial these partnerships are.

When we met with Mr. Jean-Louis Dasseux from Cerenis Therapeutics, which is developing anti-cholesterol therapies, he said his goal was to build Cerenis into the next generation of French success stories along the likes of Pierre Fabre and Servier. Do both of you share that goal for Effimune?

We certainly hope so! We would like to take Effimune as far as possible. We are certainly not hoping to simply build an attractive biotech company for sale and a quick return on investment. Our motivation was to see our projects and our ideas through to completion, to convert our expertise and knowledge into real therapies. This is not possible in the academic world, because once you publish your results, you reach the end. This is why we started Effimune, to take charge of our discovery.

Ultimately, we are doing this because we believe in our approach, the research ecosystem in Nantes and our expertise, and we see the potential in Effimune.

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