Interview: Pierre-Henri Benhamou – Chairman & CEO, DBV Technologies, France

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The Chairman & CEO of DBV Technologies reveals how they have developed a new therapeutic method and new technology in the form of a patch to treat various allergies. DBV

received a "breakthrough" designation from the FDA for the design which meets safety standards that no other products currently being developed do.

DBV Technologies was recently described as a "revolution in immunotherapy": could you please explain to our audience how your ground breaking technology, Viaskin, works?

Viaskin is a new method of immunotherapy and a new technology in the form of a patch that we developed to treat various allergies via epicutaneous administration. This allows the pure protein of allergens, such as peanut, to be placed on unprepared skin to stimulate the immune system by activating antigen presenting cells at the surface of the skin called Langerhans cells. These cells take some proteins and modify their structure in order to amplify their allergenicity. This leads to the exposure of very reactive epitopes that allows the Langerhans Cells to move to the lymph node, activate the lymphocytes there and provoke a reaction. The beauty of this is that you can obtain an immune reaction without any free passage of the allergen, therefore reducing the risk of a severe reaction. This is a very safe approach to desensitization and is particularly important with highly active allergens such as those of peanuts, milk and eggs.

The priority for DBV is to create peanut, milk and egg allergy Viaskins but we also have programs for DHM (dust house mites) and birch pollen. This is a very interesting and brand new approach. The immune reaction often provoked with the application of the patch can have other applications, such as programs in vaccines, immune diseases and inflammatory diseases such as Crohn's disease.

Are there any similar products already on the market or being developed at the moment?

No, there are no treatments for patients other than avoidance of allergens. One needs to understand that peanuts are everywhere and in so many different products. Patients can suffer a severe reaction from a very small amount of the allergen. Recently, there was a case of a young girl who went on a school visit to a biscuit factory and some peanut dust in the air caused her to have a very severe reaction. As such, our approach is very useful because when you have a young child, you want to protect them and treat them in complete safety. There is a company in the US currently working on oral desensitization which uses peanut flour, to be taken orally by the patient, but they have had some safety issues. There are various kinds of milk allergies, the most severe of which have to be desensitized and can be very dangerous and, at the moment, there are no treatments. So we believe our approach is different and we want to continue to develop it with an excellent safety profile.

Recent scientific studies suggest that treating allergies early in life could prevent disease progression or the development of polyallergies: what are the different applications of the treatments in terms of preventing the development of sensitization and anaphylaxis to further allergens?

There is a lot of potential to prevent or treat general allergies because they are extremely common. In the US, statistics show that two percent of young children have a peanut allergy and this means they could have an anaphylactic reaction at any time. Previous measures taken to try and prevent this involved introducing peanut into the diet very early in life; a method that, unsurprisingly, has caused some controversy. The best way to introduce peanut allergens from an early age is via the skin. We are working with the best scientists in the world to use the patch as a vector for prevention against sensitization.

At what stage of the development process are the various treatments at the moment?

We have received a breakthrough designation from the FDA and are the first company working on allergies to be given this designation. We are just starting phase III for our Viaskin Peanut patch

and we hope that, by the end of the year, we will have the first patients in this trial. With our Viaskin Milk, we recently completed a phase 1b study in children, with no safety concerns, and now we are moving into phase 2. In the US, we have a subsidiary company that we are developing very quickly in order to be ready for the launch.

We understand that Sanofi is the CMO for your peanut and milk allergy patch APIs. What is the nature of your collaboration with Sanofi?

We have had a long-term, strategic collaboration with Sanofi for several years. They have extensive expertise in protein extraction and run a very complex process for the manufacturing of natural extracts from proteins in one of their factories in the southeast of France.

In terms of your market strategy, you seem to be focused on the US market where studies suggest that approximately three to five percent of adults and eight percent of children suffer from food allergies. Can you give us an idea of the expected market size and your projected revenue growth?

It is very difficult to evaluate at this stage because there are no treatments currently on the market. There is without a doubt a real blockbuster potential! The predictions for the milk allergy patch are slightly lower but the market for this is worldwide. In countries such as China and Japan, milk allergies are quite common. There are a lot of opportunities for Viaskin to make a real impact because we do not feel that the other products currently being developed meet the same safety standards and safety is, of course, paramount for this kind of treatment.

What is your capacity to respond to demand in the US once you receive approval?

In July we raised over 260 million euros on NASDAQ and six months before I managed to raise more than 100 million euros. The company has plenty of capital so we have the means to develop the infrastructure in the US and we are working very hard on this just now.

We have made the decision to enter the market by ourselves as there is no real expertise in food allergy because there is no treatment. Big pharma companies will not be able to address this any better than us because we have been working on this for more than ten years now. We are going to handle everything ourselves with the only exception being the manufacturing. We are developing our machine, GEN4.0, which is able to produce the patches but we do not want to produce them by ourselves because this is not really part of our know-how.

With such significant investments and the subsequent responsibility to create a return on such investments, how do you remain focused on the core of your company which is

obviously innovation rather than financials?

This is not always easy because, in just one year, we carried out two major fundraisers, which took up a lot of time. However, my goal is to be ready for the launch and the fundraising was, therefore, a crucial part of the program and our success in this arena has meant that we are now ready for the second phase. What we try to do at DBV, is maintain the balance between financial activities and remaining focused on our development, preparing for the launch and our excellent research programs, which I have been very involved in from the beginning.

All your investors over the last few years have been US companies. Why do you think you did not raise such money in France?

Originally, DBV was a very Francophone/French company with some of the best French investors such as BPI (Public Investment Bank) and Sofinnova, the reference investor here, which is now coming to the end of its investment period with us. Around 2012 we started attracting interest from US investors and received several propositions from different pharma companies for the licensing of our main product. However, we chose to do it by ourselves so it was really important to receive considerable financing and it was obvious for us that we could only find enough money for such an ambitious development in the US.

Has this vision of "doing it ourselves" always been a concern for you since the beginning?

This developed progressively because I am, first and foremost, a physician and my vision was really the product and its potential. Our strengths are today twofold: our ability to successfully raise financial support, and our scientific team, as we have the best scientists in the world for allergies. The former president of the American Academy of Allergies and allergist-immunologist in Mount Sinai Hospital, Hugh Sampson, is joining DBV in November because he sees a lot of interesting data to develop here.

Knowing both countries, how do you compare France and the US in terms of environment for the development of Biotech and innovation?

Many people say the French investors in healthcare are not very professional but I would disagree. We have some excellent investors in France and I really enjoyed working with Sofinnova because they understood the story from its genesis. French investors are a lot better than they are made out to be. It is very difficult to generalize because, wherever you go, there are going to be some investors that do not understand what you are proposing but I must say that the people I met in

the US were really impressive.

DBV has become an example of a “super French biotech success story” and you have been at the helm of that process. Looking back, is there anything you might have done differently?

There are probably a lot of things I would have differently! The team has been used to me making a decision and then changing my mind shortly afterwards. But ultimately, and this is the most important to bear in mind, the basis of everything has to be innovation. There are some companies which are modifying pre-existing recipes to create a new product but, in my opinion, the mission of a biotech is to bring a new or dramatic change in the way to treat a particular disease. I feel pleased to believe DBV is doing so in the field of peanut and milk allergies, and generally speaking, in various forms of allergies.

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