Interview: Jean-FranÃ§ois Mouney â?? CEO & Chairman, Genfit, France

Collaboration is in the core DNA of our company

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Genfitâ??s Jean-FranÃ§ois Mouney speaks about responding to high unmet medical needs in inflammatory and metabolic related diseases. With the increase in obesity related diseases, Mouney discusses their lead pipeline product: Elafibranor, the new orphan blockbuster drug aimed at curing NASH; nonalcoholic steatohepatitis and other related diseases.

As an entrepreneur with a background in economics, what prompted you to move to the biopharmaceutcal industry and create Genfit in 1999?

I founded companies focused on fostering innovation. Most of them have been very successful. The first companies I managed were in the field of high performance composite materials dedicated to aeronautics, space, and armaments.

I founded a variety of different biopharma companies and signed agreements with many large international pharmaceutical companies. In 1993 I founded the EurasantÃ© cluster which is now the third largest health cluster in France.. At the time, there was a huge increase in the number of biotech companies emerging in Europe. This was something that had emerged as a major trend in the early 80s in the United States. After the boom of the biotech industry in Europe, we decided to involve ourselves further in the development of biotech companies such as Genfit that were focused on drug discovery. Genfit was incubated for two years at EurasantÃ© and, in 1999, I left EurasantÃ© to become CEO of Genfit.

How has Genfit differentiated itself in comparison to other French biotech companies?

The first day Genfit was incorporated; we attracted four multinational pharma companies â?? Sanofi-Aventis, Merck and UCB Pharma â?? and signed long-term agreements of partnership with them before the inception of the company itself. On that same day, we hired thirty people to start help launch the company and ordered construction of our facilities.

We decided to finance the company with our own revenues instead of working with venture capitalists. Genfit quickly became a very successful and profitable biotech company with more than EUR 100 million in revenue in the first seven years alone. I attributed this success to my initial intuition that the trend of partnerships between biotech and pharma companies was a key change in the future of the pharmaceutical revenue model. After the â??revolution of the genome, we knew technology would be diffused to pharma and biotechnical companies like Genfit and decided to begin to create our own compounds and drugs because of this.

Today, Genfit has a large pipeline of drugs. One of them is in phase-3 and will be entering the market in 2020.

What have been some of the opportunities and challenges you have seen emerge from collaboration with large pharmaceutical companies?

Collaboration is in the core DNA of our company and maintaining a healthy relationship between both parties is key to creating a healthy and long-lasting relationship. It is very important to create a sense of transparency and confidentiality between both partners, the pharma company and the biotech company.

Genfitâ??s expertise in the science of the nuclear receptor is considered to be one of the best in the world, if not, the best in the field of drug discovery and biology based on nuclear receptors. Our second cornerstone is metabolic disorders. These two things made Genfit very attractive to those large pharmaceutical companies, as did our knowhow in collaborations.

What is Genfitâ??s focus in term of strategy?

Genfitâ??s strategy is to develop therapeutic and diagnostic solutions where there is a high medical need, due to a lack of treatment and an increasing number of patients with obesity related diseases worldwide. We see an ever increasing trend in prevalence of obesity-related diseases, and the regular reoccurrence of diabetes as an untreatable disease to certain patients. There has been an acceleration of this trend particularly in emerging countries. In the last fifteen years in India the number of people with diabetes has grown from 15 million to 120 million, with now the same trend occurring in China as well..

In emerging countries, people tend to replicate American or European lifestyles with the access to junk food, soda and less physical activities which ultimately increases the risk of obesity.

Following the strategy to address high unmet patient needs in metabolic and inflammatory diseases, Genfit has been developing a new drug, Elafibranor, which is a first-in-class drug created to treat nonalcoholic steatohepatitis (NASH). It has enormous potential to cure this disease in an environment characterized by obesity and diabetes epidemics.

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What is special about Elafibranor? What makes it different?

To understand Elafibranor, it is important to first understand NASH. NASH (Non-alcoholic steatohepatitis) is a manifestation of metabolic disorder in the liver. It is characterized as an

accumulation of fat, along with inflammation and degeneration of hepatocyctes. Once the disease has taken form it can cause steatosis and nonalcoholic fatty liver (NAFL), then evolve to nonalcoholic steatohepatitis (NASH), and finally cause liver cancer or cirrhosis progressing to liver failure. NASH is highly prevalent among obese patients and those with diabetes. Diabetes is not a cause in itself but 40 percent of people that have NASH are diabetics and 60 percent are pre-diabetic or not diabetic at all. There is a parallel between the increase in obesity, diabetes, metabolic syndromes and the occurrence of NASH. NASH by itself is a different disease from diabetes but is the manifestation of the same risk factors.

NAFLD/NASH is now the second leading cause for liver transplantation in the US and is predicted to become the leading indication for liver transplant in the next few years. Additionally, NASH affects over 10 percent of the European and US population.

Currently, despite the increasing number of patients, there is no suitable treatment for NASH, which is why we have been developing Elafibranor.

Why is Genfit considered to be the partner of choice in offering this drug specifically?

There is another drug from the competition that has also entered phase 3. However, what is important to understand is that the main consequence of NASH is not only liver related disease, but also cardiovascular diseases. Cardiovascular events are actually the most common cause of death among NASH patients. Elafibranor, unlike its competitor, acts not only on the liver but also on the different risks factors of cardiovascular diseases. NASH is a chronic disease, which means adverse side effects can be a major issue for patients.

Elafibranor has been depicted as a first line therapy for the future by quite a few recent studies done by a variety of different institutions. We are expected to capture more than 50% of the potential market thanks to the double efficacy in prevention of cardiovascular related side effects and the treatment of NASH .

Do you have any other sectors that you are focusing on or any other drugs in your pipeline?

In 2016, in addition to Elafibranor in Phase 3, we will be launching clinical development in pediatric NASH, as well as Elafibranor for PBC (Primary Biliary Cholangitis) which is a new disease area. PBC is an inflammatory and progressive degradation of the small bile ducts of the liver that serve to eliminate the toxins, leading to scarring, fibrosis, and cirrhosis.

Pediatric NASH is very important and becomesan increasing concern today . In the US and Mexico, for instance, itâ??s very common to find 13 year old children already diagnosed with cirrhosis mainly due to obesity. Developing a cure for children is more complex because the drug needs to be very safe, which is the case of Elafibranor . We need to understand the evolution of NASH in children as it is different compared to adults.

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Which countries are you aiming for with Elafibranor?

Worldwide. The strategy for Genfit is to control the development of the drug. Even if we have an alliance with other pharma companies we want to co-develop the drug and do not want to leave the development of the drug to anyone else.

In certain countries we might keep the right to commercialize the drug by ourselves but in other countries we might co-commercialize the drug through alliances, or rely upon other companies to fully commercialize it. As Elafibranor has a potential of USD 10 billion a year in revenue, we might not be able to manage it all. We will need to form alliances with very large pharma companies, while keeping some rights of commercialization in certain countries.

My goal is to organize a shift in Genfit, from an R&D biotech company to an R&D and commercial biotech company. We will hire sale forces to control the sales of the drugs in specific and limited territories. But the drug will be commercialized worldwide mainly through alliances.

> It is important to remember that innovation comes with a cost!

What is your opinion on health care and pricing?

It is important to remember that innovation comes with a cost! Elafibranor is going to be a first therapy to address a specific unmet need. This means that people that are not treated by this drug today will very likely require liver transplants. Transplants are very expensive and can cost around USD 700,000 in the US. Thanks to this drug, transplants can be spared, which would ultimately lead to savings in unnecessary and avoidable health expenditures.

In Europe the pressure on price is higher than in other countries. But this is an orphan blockbuster, so we will get high pricing during the first years in order to pay back the cost of innovation, since the priority is to treat the patients with F2 and F3 (severe fibrosis). In ten yearsâ?? time, itâ??s important to be realistic, we then expect that drug prices will be more flexible: we will have to treat more patients, expand to primary care, discuss big volumes of sales, and will have to decrease the price. The market will evolve from specialty care to specialty and primary care .

In a few words, how do you see your company in the next five years?

Genfit is a biotech company that intends to focus on the commercialisation aspect of Elafibranor. I would like to see Genfit consolidatinga strong pipeline with products in different stages: we will for instance enter phase 2 in fibrosis, and will have a few drugs in phase one in the next two years. With those drugs, the goal is to repeat the same success than the one we have had with Elafibranor.

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