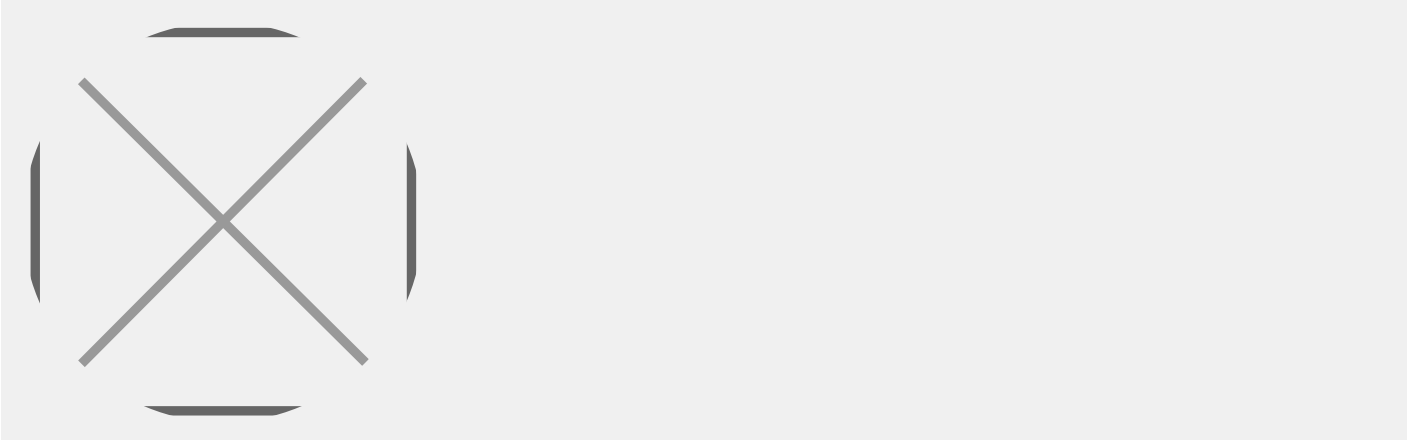
Interview with Brenden Martin, General Manager, Genzyme – Ireland



25.01.2013

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Mr. Martin, you were appointed as Genzyme's GM for UK and Ireland last month after having spent a decade at the organization. Robin Kenselaar, Head of Genzyme EMEA, noted that your appointment came at a "key time for the business." What is your understanding of where this company is going today, and what is your vision for managing this important region?

Let me begin by acknowledging the exciting opportunity I have been given to lead the UK & Ireland affiliate of one of the most innovative and respected biopharmaceutical companies in the world.

When Mr. Kenselaar said that it was a key time for us, he was referring to a number of elements. Firstly, many countries in Europe are drifting in and out of recession. As a result, states are taking an ever more stringent approach in scrutinizing the value of pharmaceuticals and what they contribute to healthcare.

Secondly, it has been 18 months since our acquisition by Sanofi, so we are at the end of a process of synergizing our structures with theirs. We have adopted the best qualities from both organizations and this will be a platform for us to build upon.

Thirdly, we are only now emerging from a three and a half-year difficulty we encountered with supply disruptions in our rare disease business. The problem arose when one of our facilities in North America suffered viral contamination in 2009. In order to protect and ensure long term security of supply to the patients we serve Genzyme was forced to essentially clean out and

sterilize the entire building, thus losing a considerable amount of inventory. We were left with a product shortage, and in some cases we could not deliver products to the patients who needed them. It has taken some time and a huge amount of investment and commitment, but we are very happy to return to full operational capacity once again. We also have an imperative to rebuild confidence and credibility among our stakeholders.

And on top of all that, we are currently pursuing a new endeavor: moving into the treatment of Multiple Sclerosis. We have developed two exciting products, which will address specific needs that have not been met by other medicines.

Locally, the key area of focus for us is improving the knowledge of our drugs among a new audience—the payer—and elaborating on the benefits they bring. I call it a new audience because traditionally, when one is working with rare diseases, one is dealing with a very small community of highly trained clinicians who have a close relationship with their patients. However, things are changing in an ever more fiscally conscious environment, and we and now have to really prove effectiveness and value in order to gain access to the market. Because we do studies in small populations, it is very challenging to produce a level of evidence that is adequate for the purposes of health technology assessment—simply because the statistical data to establish an adequate confidence level in improving life expectancy are difficult to establish. It is quite a task for payers to look at these drugs and see value, because they can be viewed as expensive and the number of people affected so limited.

In our conversation with Kieran Leahy at Takeda, he mentioned that in a small market like Ireland, treating a rare disease might mean looking after a patient population with only 3 or 4 members. Is this a worthwhile business case?

Genzyme is in the business of helping patients. I can go a step further, and note that we are active in one disease area where there has been only one patient identified with the condition in the Republic of Ireland.

For Genzyme, it is not so much a question of whether or not the business case is viable in one region or another; rather, it is a responsibility to work out how we can partner with health systems to provide adequate treatment for affected patients, regardless of their location or scarcity.

Thankfully, our work has been bolstered by European policies and directives, which have devoted attention and funding towards the issue of rare diseases above and beyond support at the national level.

Novo Nordisk’s Owen Treacy explained that one of his biggest challenges is the lack of a comprehensive diabetes registry. If this data is lacking even in a high-prevalence condition like diabetes, surely the situation is even more difficult in rare diseases. Has lack of data

been a challenge for you?

It is indeed a challenge for us—and it is a challenge that leads to very negative complications for the patient. Too often, progressive diseases are not recognized in their early stages and are allowed to develop over time. There is always an issue when we intervene too late.

The treatments we offer at Genzyme get at the root cause of genetic diseases, by immediately replacing missing enzymes. If we can intervene at an early stage, then the chances of our patients being able to move forward and live a normal life are quite high. We put a lot of effort into making sure our patients are diagnosed early—but this can be very difficult, given the nature of these illnesses.

When our drugs enter the approval process, the pharmaceutical regulators ask us to create a registry for the product. Ideally these could be merged with larger registries and data clouds. These archives can be expensive and time-consuming to maintain. I believe, in line with Mr. Treacy, that an emphasis on illness registry, rather than product registry, would be the optimal solution.

Do you believe there is a better framework for treating rare disease in the U.K.?

I think that the healthcare system in England moved towards a better framework in 2005, by creating national centers of expertise to combat rare diseases. When the patients are directed to these centers, they have the benefit of seeing a doctor who is well versed in treating these illnesses and will be able to offer an accurate diagnosis and a good solution.

In Ireland, we have advocated for a similar system. We are very confident that in the first half of 2013, during Ireland's presidency of the E.U., a national plan for rare diseases will be enacted. The plan will see the appointment of a clinical director to take charge of the management of these disorders, and it will also bring more consistency to how patients are treated across the country.

Genzyme has done a lot to improve the local environment for patients in Ireland. For instance, when I started in Genzyme Ireland in 2002, we got involved in setting up the Irish Platform for Patients' Organizations, Science, and Industry (IPPOSI), so that there would be a forum for academics, patients and medical professionals to exchange ideas and information with one another and to work together on priorities. IPPOSI is also an excellent platform for building consensus views on rare disease issues, which can be useful when presenting facts and figures to government bodies. The Department of Health has been of assistance with regards to funding, and has been attentive to the documents and research we produce.

Ultimately, do you think the healthcare system in Ireland is patient-centric?

I do, and I think remarkable progress has been made in recent years. From 1995 onwards, there has been a huge effort to improve our healthcare infrastructure. Mortality rates have gone down

despite an expanding population, and the treatment of cardiovascular disease and cancer has really evolved. I think some of the structures are still a bit old-fashioned, built around the healthcare provider—but I believe that the move towards forming clinical directorates is creating a more patient-centric model. Catching up with international norms and standards has been a considerable task over the past 10 to 15 years, and our officials have done a great deal. From this point forward, we need to refine the current systems and structures.

One example we could borrow from the NHS—is to take advantage of having one overall provider, with common standards. This model promises benefit in terms of clinical research, because you have a very large number of patients all being treated under one umbrella. I think U.K. Chief Medical Officer Prof. Dame Sally Davis has been very proactive in instilling a culture around investigative medicine in the U.K., which we have yet to adopt here in Ireland. There are fewer consultants per capita in Ireland, and they tend to have a higher caseload; this, in turn, makes it more difficult for them to devote time to clinical research. I would conclude that fostering and facilitating clinical research in general is something that Ireland is slightly out of step with, in contrast to other developed nations.

Turning our attention back to Genzyme, what have been the highlights of 2012 for the company, and what is your outlook for next year?

It has been an enormous relief to be able to return to operational normality, and put our supply problems behind us. Naturally, the disruptions harmed our reputation internally and externally—sustainability is a baseline for our service, and in some cases we are the sole producer of medicines patients with very rare illnesses. To have our production capabilities hampered so heavily was a traumatic event for both our small community of patients and our staff. We are very happy to move forward.

We were also pleased to have amalgamated some of our functions and processes with our new parent, Sanofi.

Another highlight was the publication of data regarding our new MS drugs, which is very exciting. When I see the results from these drugs and how they have changed patients' lives for the better, it makes me very optimistic about the future. It is an unusual thing in medicine to see chronic, progressive illnesses stopped in their tracks—and then pushed backwards.

There are a number of major players present in the MS segment—including names like Novartis. Are you confident Genzyme can be competitive in this area?

Yes, I really think we can be. We have always believed at Genzyme that good medicine is good business. I am confident that we will be able operate very effectively in a competitive market.

A number of analysts have observed that, after Sanofi's acquisition of Genzyme, the parent has not imposed its big-pharma culture on the subsidiary. Rather, perhaps the opposite is true: Sanofi has taken a few pointers from the innovative and free-spirited Genzyme. Do you believe that is true?

Thus far, I have seen relatively little change in our culture at Genzyme. The CEO of Sanofi, Chris Viehbacher, had always maintained that the merger would be a mutual learning experience for both companies—and it has been. The types of drugs we produce really promote a lot of motivation and creativity among our staff, so it is important that we are able to act with some degree of autonomy in order to maximize that creativity. I believe, moreover, that our focus on patient-centricity is the key to bringing new and innovative medicines to the market.

With that said, Genzyme is also gaining much from Sanofi. Because of the nature of the conditions we treat, our market is very small, so there were certain processes in operation and communication that needed refinement. Sanofi has been operating on a large scale for many years, and has those processes in place. There has been a good exchange of qualities and ideas, and, having adopted some of Sanofi's conventions, Genzyme now has a much more tangible platform for growth.

What is the significance of the UK and Ireland market for Genzyme?

Whether in manufacturing, marketing or market access, this part of the world is seen as creative, as experimental, and sometimes signposting the way to future sustainability. We have seen some remarkable innovation with cost efficiencies, and health technology assessment, which is driving our approach around the world.

What motivates you to go to work every morning?

I answer that by reflecting on a time when I moved out of the healthcare industry for about 3 years, in the late 1990's. I began working in Executive Search and while I enjoyed most of the day-to-day work that I did, I found it was less rewarding in comparison to the healthcare industry. In healthcare, you definitely feel that you are making an important contribution—particularly in a highly personalized business like Genzyme. For example, I know personally a significant proportion of rare disease patients here in Ireland, having spent time with them and their families at various conferences and events. If one ever looses motivation or meaning, it is very easy to imagine one of those patients and their families and the challenges they have confronted. It can quickly remind you of the significance of our work.

Do you have any final message for our readers?

Good medicine will always be good business, regardless of whether we are in times of austerity or times of plenty. There are still opportunities to manage diseases better, so that patients get the best medicine, at the right time, in the most suitable environment—and their personal and

professional lives are not disrupted too heavily.

For governments to focus on drug prices in isolation is not the answer. You have to look at the challenges faced in a broader context. If we can have an ongoing dialogue with our peers and government healthcare organizations, I think we can all make progress together for the benefit of patients

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