Interview with Olivier Daubry, General Manager, Celgene France

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Only four years Celgene has introduced a number of important products in the French market and is now seen as a preeminent biopharmaceutical company in hematology. As the head of Celgene France's operations, what were the main milestones of the company since its establishment in the French market in 2006?

The history of Celgene has been a unique adventure, based on a true conviction that IMiDs® compounds were a unique opportunity to bring breakthrough innovations for patients in need of a better solution.

In 2006 Celgene France was one of the first countries established in Europe. That coincided with the access to Revlimid for French patients thanks to the ATU system (Autorisation Temporaire d'Utilisation). So it was a huge work to both establish Celgene France on one side and make Revlimid accessible through the ATU system prior to registration. Revlimid obtained a market authorization in June 2007 as a treatment for patients with multiple myeloma after on prior therapy. It is now a leading therapy for this indication in France, and the number one global brand for this indication worldwide.

The second milestone was the market authorization for Vidaza in December 2008 in myelodisplastic syndromes. Vidaza was officially launched in 2009. This was also an important milestone, creating a second pillar in hematology with Vidaza in MDS . At this occasion, we created a second team basically structuring the company and the teams providing the scientific information, around Myeloma and MDS to ensure our focus on patients and to maintain our high level of

excellence and expertise.

The third important milestone was Thalidomide. Thalidomide was available for several years to patients through the ATU process in first line myeloma for elderly patients but also other rare diseases where patients are desperate to have an effective treatment. Thalidomide was eventually officially accessible to patients in October 2009 but within a very strict safety framework.

In France we started with a handful of employees and that number has grown dramatically, but our presence in the country is not represented only through the number of employees. Celgene's particular point is our presence with a high level of R&D and public/private partnerships with haematologists scientific groups. In practice, Celgene sponsors or collaborates to now more than 30 clinical trials and more than 3500 patients are enrolled in clinical trials; this is an important milestone.

A number of local players have also highlighted the advantages of conducting clinical trials in France, but many have also criticized the approval, registration and reimbursement system. What's your assessment of the current legal framework in those areas?

French hematologists community have structured themselves very well in scientific cooperative groups with cutting edge medical publications for many years. They are very prestigious hematologists scientific cooperative groups ,recognized worldwide for the leadership role they play and the treatment paradigm shifts they provide in debilitating diseases such as myeloma, MDS, leukemia, lymphoma, CLL….Such top class scientific medical groups in a country like France is indeed an advantage for working in partnership to conduct clinical trials.

Concerning the regulatory environment, it all depends on transformational science, unprecedented data and clinical outcomes. What we try to do at Celgene is to deliver absolutely breakthrough innovative medicines. We might stop a project if we understand it does not bring a significant clinical benefit that dramatically changes people's lives.

Each time we look at our discovery, we ask ourselves if it will change, in a dramatic way, the lives of the patients. What we pursue every day is to significantly increase the survival and quality of life of patients by altering the natural history of their diseases which translates into better healthcare with better outcomes. Hence we look for science and novel solutions that will bring a very significant shift. This is what Revlimid and Vidaza bring to the patients today, for example.

With this philosophy, our ratio of R&D spend versus revenues in the market is one of the highest , around 30%. The industry-leading performance that we are experiencing today is based on R&D decisions Celgene made five to ten years ago. We believe the R&D decisions that we make today will impact our ability to bring more innovative therapies in the interest of all stakeholders for many years to come. To achieve this balance is very challenging but it is a conscious choice and the

reward to this is that you get absolutely breakthrough innovative medicines and you know they will transform the lives of patients worldwide.

For life-threatening diseases with high unmet medical needs and where patients have used all registered drugs the ATU system allows innovative drugs to be administered in a very controlled process before registration. It is a positive example for early access to innovation.

In France you have also the ASMR system which scores how much the authority perceives the innovation level from 1 to 5 prior to reimbursement. In practice, it is naturally a debate between the industry and the authorities. So it is important that both the industry and authority maintain a dialogue on criteria to assess innovation in order to encourage investment in innovation and fair assessment on one side while still respecting the best use of government spending on the other side.

To invest 30% of your revenues in R&D is a big bet in Celgene's upcoming pipeline. How do you manage your product pipeline and what are Celgene's next big steps in the research arena?

Our immunomodulatory science platform allows us a deep understanding of what blood cancer, solid tumors and immune & inflammatory diseases are about. We explore diseases and we see how much we can discover in the mechanistic understanding to target the best therapies.
What you see today is just a start of this. The first application with Revlimid has been in myeloma in collaboration with the IFM group and we have explored it also in myelodysplastic syndrome with the GFM group. But we are also exploring Non Hodgkin lymphoma, mantle cell lymphoma and chronicle lymphoide leukemia.

Currently Celgene has 20 phase II, 20 phase III and 16 compounds in developments for 25 debilitating diseases in several areas: blood cancer, solid tumors, inflammation and immunology. The later includes programs on oral cytokine inhibitor, oral kinase inhibitor activine Inhibitor and stem cells therapy. For that Celgene has a specific division called Celgene Cellular Therapeutics – which again reflects our immunomodulatory scientific platform as a hallmark that helps us to develop new compounds and indications.

In only four years Celgene created an important network of partners and collaborators in the French market. How strategic these partnerships are for your further development?

Celgene is a company focused on the outer world. It has very close links with the local healthcare providers, the hematologists because of their expertise, and close links to the authorities. We want to be at the top of the science and therefore believe in strong collaboration and partnership with academic hospitals and research groups in our areas of focus so our R&D investment has even more chance to translate into transformational medicine for the patients.

A strong characteristic of Celgene is that we have a very significant proportion of our trials taken as independent trials proposed by the local haematologists scientific cooperative groups such as IFM in myeloma, GFM in myelodisplastic syndromes, GELA group in lymphoma, GOELAMS, or the French CLL group in CLL for example. Those groups are really worldwide recognized experts and they contribute to the development of the drugs in order to deliver better healthcare and the best outcomes for patients in various clinical setting they are facing.

As a result, those partnerships in France play a strategic contribution to the worldwide development of new compounds and R&D activities.

What's your strategy to attract the best talent and to integrate such a fast growing number of people into Celgene France culture?

People and individual employees are at the heart of Celgene development and success. So I try to spend a lot of time in human resources activities as well as business activities. What is critical for is to grow and develop in such a way that, although we integrate people from a variety of horizons, we can still make a coherent group which believes in the same culture and values.

When we interview candidates that want to join Celgene we ask them why they are interest in joining us and most of their answers are towards the same directions: that we are clearly an entrepreneurial company with very unique products; that they can see we strive to make a real impact on patient's lives; they identify Celgene as a place where they can make an impact and where they will see the results of their actions. They also reflect on the level of responsibility, empowerment and autonomy. We are in this business together, so we give a lot of importance to culture and company values. What Celgene wants its people to feel is that they are part of a global company that still holds the feeling of a small company where they do make a difference.

This company has also been built in true courage that allowed us to overcome some great challenges.

Last but not least, this company is all about trust. As a fast growing company, Celgene nurtures high culture, high value, high support, and high challenge momentum in order to make our employees grow with the company – and this is the key of our success.

What are your main ambitions and perspectives for Celgene France in the coming three to five years?

First of all we set our ambitions very high across all functions of our business. Our ultimate ambition, linked to how much data we bring, is to try to make sure that our unprecedented clinical data translates into improved healthcare with better outcomes for greater patient access, because otherwise it will remain just a scientific demonstration. That's why Celgene will continue to work together with local doctors and authorities to make sure that it translates its expertise into the best

treatments patients can get.

To achieve this, my ambition is also to maintain the level of engagement that the team at Celgene France is demonstrating everyday so we can continue delivering our mission.

Finaly, we work hard to possibly increase further our presence in terms of R&D in France, not only to continue the clinical development but possibly to develop more translational medicine partnerships to further develop our presence in the country.

What will be your final message to the readers of Pharmaceutical Executive in France and worldwide?

I’m very proud to be part of Celgene and changing the course of human health through bold pursuit in science. We have the challenge of a fast moving and fast growing organization: we learn by doing, we construct and move forward in the same time. So we have a high beat organization where managerial skills and quality of each individual employee plays a key role. But this is a unique and a very exciting and rewarding moment for everyone.

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