Interview: Pasquale Frega â?? Vice-President & General Manager, Celgene Italy

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Pasquale Frega, General Manager for Celgene Italy, discusses the companyâ??s rapid growth and imminent entry into immunology, the business and regulatory environment for innovators in the country and the characteristics of the Italian market that make it especially promising to Celgene.

Mr. Frega, to start off, Imnovid, Celgeneâ??s newest oral treatment for Multiple Myeloma has just been approved for reimbursement by AIFA. Can you tell us about the potential of this treatment in the Italian market?

The potential of this product is very clear; thanks to its clinical development and positioning it is set to address a high unmet need in treating patients who have not improved after well established first- and second-line treatments have been administered. There are roughly two thousand patients in Italy who are currently left with no medical options at that stage, and pomalidomide has been shown to have a significant impact on patientâ??s progression-free survival, overall survival and quality of life. One of the common complaints among both companies and patients however is that after receiving approval at a national level, even for innovative drugs such as Imnovid, we still need to go through another access barrier at regional level. This is delaying patient access, in spite of specific legislation exempting innovative drugs from requiring regional approval. However, there is certainly a need for this treatment in Italy so its potential is clear.

Celgene is also expanding its business beyond oncology and hematology into Inflammation & Immunology, a new area for the company. How do you expect these immunology treatments to impact your business in Italy?

Inflammation & Immunology is one of the best examples of Celgeneâ??s capacity for innovation and of the way it seeks to create value for its patients and the organization. When I joined Celgene three years ago Inflammation & Immunology was only briefly mentioned in my introduction, while today our immunology pipeline is one of the most exciting globally. We have completed the development of

apremilast, which is now launched in Europe, and is serving an unmet medical need for patients with psoriasis and psoriatic arthritis. This is a well served market for patients, however, our product is a bridge between oral drugs with limited efficacy and biologics which carry a very high cost and are limited to severe patients.

Besides this we are very proud to have acquired a new therapy for Crohnâ??s disease which has proven life-changing for patients. It was created at Tor Vergata University in Rome and is now in phase three development. Finally, Celgene has acquired Receptos, bringing a new and exciting late-stage drug, Ozanimod, into our portfolio for the treatment of MS and IBD (Inflammatory Bowel Disease). All of this combines to make the promise of the immunology area just as significant as our traditional core areas of oncology and hematology.

What are you personally most excited to bring to Italian patients?

Our portfolio addresses forty-five rare diseases in total, and I am following one drug in particular as it targets Mediterranean anemia, which is more prevalent in Italy than in other, especially Northern-European, countries. This is now in phase three development, and it is one of our most exciting projects for me because it relates closely to the countryâ??s needs.

Receiving authorization for market access and reimbursement is a challenge for innovators in Italy, even when that drug targets unmet needs and has no comparator. How have you experienced this in your dealings with AIFA?

We do have a very good relationship with AIFA, as we are able to leverage our scientific capabilities effectively, which has built up a mutual respect between us for the value of what we do. The issues come from the way the system is designed. We had hoped for a reform of the drug agency to be formally announced, however this is currently still being discussed. The timelines for product approval in particular need to be reduced. AIFA has long suffered from being understaffed, but in a positive development they have received funding for the hiring of a large number of new employees which should improve their own capabilities significantly, with the extra costs being paid by the Pharma Industry.

How do you ensure your products still receive market-access despite the flaws in the system?

We donâ??t have any secret explaining our success, rather it is inherent in what we do. We are the only company in Italy which has three innovative-status drugs as recognized by AIFA. No other company has more than one drug of this status, and this is why we are successful. If you have truly innovative drugs and can clearly communicate their value to AIFA, then they are approved for reimbursement more quickly. For this we have our business model to thank, which leads us to invest more than 30% of our revenues into R&D, exclusively in areas of unmet needs.

Around the world, the importance of patient groups is increasing. How are you approaching patient groups in Italy?

This is an area in which we still need to improve, as the Italian system is quite limiting in the way it allows companies to work with patient groups. Unfortunately, in general there is still a very limited role for patient associations in the decision-making process. Our hope is that the government changes the way in which it approaches patient associations and includes them more prominently in the decision-making process, of which they are after all the most important stakeholder and therefore need to be heard. We want to do more in this area, but for this to happen we need support from the national authorities.

At the opening of Celgeneâ??s new Italian headquarters last year, you highlighted the introduction of significant new therapies as key to doubling your revenues by 2018. The end of 2015 is in sight, and with two new therapies introduced this year, what progress has been made towards this goal?

There were two specific commitments made, the first was to double our number of employees by the end of 2015, and the second was to double our sales by the end of 2017. In terms of employees, we had committed to move from around 100 in 2014 to 220 by 2015. That goal has been achieved. In terms of sales we are also performing according to plan, so we are on track to achieve both of those goals.

What are the unique characteristics of the Italian market which make the country so promising to Celgene?

I think that the Italian market is especially significant for Celgene because we have a large number of lead investigators playing an important role in the development of new drugs. In fact, Italy is number one for Celgene in Europe in terms of clinical studies and patients recruited into those studies. This is due to a combination of the quality of the research centers here, the high need for access to innovative drugs, as well as the capacity of Celgene to leverage that expertise with our high level of R&D and our promising pipeline.

The scarcity of resources makes it increasingly difficult to access the Italian market without the ability to demonstrate real innovation, so I think that the innovation model is the only one which will see real success in the country over the next few years. We are well positioned to demonstrate our excellence in that respect. Just this year we have received five approvals from the EMA, which is a record. No company has ever received five approvals in twelve months, in fact the previous record of three approvals was set in 2013 by Roche and Celgene, so we are breaking our own records.

After working in the pharmaceutical industry throughout Europe, in Paris, London, Stockholm and Milan, how would you say innovation is being received in Italy?

I would say that it is extremely well-received by the scientific community. However, as noted there are currently still barriers which are posed by the system, rather than by peopleâ??s willingness to embrace innovation. We do see this evolving in a positive manner however, as specific legislation is set to ease access to clinical development resources, 2016 will be an important year for this. Looking at the publication of global scientific literature Italy is second after the United States, showing that not-withstanding regulatory barriers the quality of productivity of researchers is indeed very high and this remains a key attraction to companies such as Celgene when evaluating investments.

Where do you see potential areas of collaboration with public or academic institutes?

We are very committed to providing these institutes with the support they need. We are also very keen to collaborate in terms of education. Most diseases we work with require a huge amount of educational effort, from the diagnosis to the therapy. To address this, we have multi-level collaboration with academic centers from early stage research to investigator-driven trials to R&D trials.

What are your priorities for Celgene Italy in 2016?

Most important is clearly to continue to bring the innovation Celgene is renowned for to the Italian market. We have two main challenges in this regard. First, is to serve the psoriasis and psoriatic arthritis patients with apremilast, which we expect to launch in Italy next year. We have also had another important innovation in Revlimid, our flagship product, which can now be used to treat newly

diagnosed patients with very promising results and limited side-effect. This is significant because it can provide chemotherapy-free treatment, unlike current first-line options. These will by my priorities for the new year, and success here will continue to build on our performance in the country.

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