# Interview: Fabrizio Greco â?? General Manager, AbbVie Italy

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*Fabrizio Greco, General Manager at AbbVie Italy, discusses the successful launch of the companyâ??s new Hepatitis C treatment, how AbbVie is seeking to position itself as a partner to the authorities, and where the companyâ??s next generation of growth drivers will be found.*

**To start off, we are approaching the end of 2015, AbbVieâ??s third year as its own company. How would you characterize AbbVieâ??s performance in the Italian market this year?**

It has been a positive year. We had the new launch of our innovative all-oral HCV treatment in 2015, and that has made it a challenging, but very rewarding year for AbbVie Italy. We also continued the development of our current therapies to ensure their compatibility with the market and to safeguard the delivery of our solutions to patients.

**With the approval by AIFA for Viekirax and Exviera granted in May, how has AbbVie joined the fight against Hepatitis C in Italy?**

I would say that we started a number of years ago, both from a commercial standpoint and from a manufacturing standpoint.

Here I would like to highlight the role of AbbVie Italyâ??s manufacturing site in the delivery of the HCV treatment. In Italy we employ more than 1.300 people, and the company is headquartered in

the Lazio region, in Campoverde di Aprilia. Here we also have a production site which was established 1963, and is approved by AIFA, The Brazilian National Health Surveillance Agency (ANVISA) and the U.S. FDA amongst others. The site also received numerous quality, safety and environment awards.

Our production is characterized by the highest standard of quality. The reason behind this lies with our integrated corporate strategy, which is designed to combine an innovative approach with the technical strengths that we have developed over the years. Due to the high standards of quality, and speed of production, the Campoverde manufacturing site has been chosen as the global production site for one of the three active ingredients in our revolutionary treatment to eradicate Hepatitis C. The AbbVie interferon-free therapy against hepatitis C is an important research milestone that can improve the lives of 160 million patients worldwide. All these elements position our manufacturing site as one of the highest performing and most competitive in the AbbVie manufacturing landscape.

Meanwhile we have continued to partner with our different stakeholders to understand the best way to get the treatment to the market while maximizing the access patients would have to the treatment even before the official reimbursement approval was handed down from AIFA. To do this we worked together with AIFA to create one of AbbVieâ??s largest compassionate use projects worldwide. We had a great number of patients treated prior to reimbursement through this compassionate use program, and that has been very much appreciated by our stakeholders.

With the official approval in May, we have started to deliver our treatment to a wider number of patients. The entire roll-out, from the initial compassionate use program to the official launch has been carried out very smoothly, in no small part thanks to the team we have here at AbbVie, who have worked tirelessly to ensure its success.

**With an estimated 1.2 million people in Italy afflicted by the disease, does this treatment represent a real breakthrough in the countryâ??s efforts to eradicate it?**

It is certainly a breakthrough. The innovative therapy, treating people with genotype I, the most common type of HCV, and genotype 4, combines three direct acting antiviral agents, each of which is characterized by a different mechanism of action and by distinct and non-overlapping resistance profiles. It also targets hepatitis C in a different viral lifecycle phase, achieving cure rates of 95-100%. We are not the only company with a therapy on the market of course. I think that together with other therapies which have been approved we can confidently say that these treatments are game-changers in the fight against HCV.

**Globally Humira currently accounts for 60% of AbbVieâ??s revenues, however the patent is set to expire next year. Do you see the HCV treatment taking Humiraâ??s place in AbbVieâ??s portfolio over time?**

It will be a complement in our portfolio. We do not see it replacing Humira, as Humira will continue to be a key pillar for AbbVie alongside new therapies under development. We have a number of very promising indications on the way, with some already approved and some hopefully soon to be approved. So anything that we are developing will be complementary to Humira, and build upon our existing portfolio to further strengthen it.

**Besides the Hepatitis C treatment, AbbVie currently has seven products submitted for registration globally, and thirteen in phase three. With so many new treatments on the way, how do you see your portfolio evolving in 2016?**

The biggest development in our portfolio is going to be oncology. We already have one molecule, which is set to receive approval next year. Many of these new treatments fall into the hematology

area.

Besides this we have other molecules which have either been developed internally or in collaboration with external partners, and which we look forward to adding to our portfolio over the coming years. We are tackling diseases where there is a significant patient need for more and better solutions, with our focus being on hepatitis C, immune-mediated conditions, cancer and more. Our scientists are working to advance a pipeline of specialty medicines that demonstrate both strong clinical performance and economic value. Our expertise in both small molecules and biologics gives us the flexibility to find and pursue the best solution in areas such as hepatitis C, immunology, oncology and neuroscience. AbbVieâ??s oncology research is focused on the discovery and development of targeted therapies that work against the processes cancers need to survive. By investing in new technologies and approaches, AbbVie is breaking ground in some of the most widespread and difficult-to-treat cancers, including glioblastoma multiforme, multiple myeloma and chronic lymphocytic leukemia. AbbVieâ??s oncology pipeline includes multiple new molecules in clinical trials being studied in more than 15 different cancers and tumor types.

**With these new drugs on the horizon, market access must be high on your agenda. With the compassionate use program as an example, how is the company developing a market access strategy to deal with Italyâ??s complex regulatory environment?**

This was indeed a good example of our determination to partner with the authorities. The negotiation of the new HCV treatments was quite challenging because of the prevalence of the disease amongst the population. While we were discussing this, we realized that there were many patients who knew that a treatment was on the way, but who could not yet obtain access to it. Some of these people also could not afford to wait for approval. As a result, we agreed with AIFA that we needed a way to get the therapy to those patients with the most urgent need of it. To do this, we drafted a protocol establishing a framework for getting the therapy to them prior to approval. This also clearly showed the benefits the treatment could bring to patients, not only from a social perspective but also economically.

This brings me to the need to, as an industry, develop not only effective, but also sustainable therapies. In our discussions with the authorities it was important for us to see the situation from each otherâ??s perspectives, and to show that curing people with HCV would also bring economic benefits. This effort has led to the first dedicated fund for innovative drugs in Italy, amounting to half a billion euros, which has been largely set aside for the HCV therapies as the strong economic benefits these can bring to society has been publicly recognized by the government.

**These efforts are very much in line with AIFAâ??s vision for the creation of a sustainable system. How would you define your relationship with Italyâ??s central regulatory body?**

I would say that it is a very cooperative relationship. All AbbVie agreements with the health authorities in Italy reflect our commitment with governments, medical-, and advocacy organizations to help address the unmet medical needs of patients. By offering our treatments, along with support tailored for patients, AbbVie is determined to meaningfully contribute to addressing the burden of a range of invalidating diseases. We continue our ongoing collaboration with AIFA and the different stakeholders involved in market access regulatory activities to guarantee availability of our treatment in Italy as quickly as possible.

**We have heard many different views on the current system, but some have said that when companies offer truly innovative drugs, it is still possible to get a fair price for them. Do you agree?**

I believe that we need to find a way to achieve a meaningful compromise between delivering access to the largest number of patients possible and rewarding investments in innovation. To achieve this balance, we need to change the way in which we manage the pharmaceutical spending, as the current governance is not sustainable. Especially around hospital drugs, which is where we will see the most innovation over the next few years, current funding is insufficient. Finding a way to merge different budgetary silos, currently blocking the shift of savings from one area to another, will be pivotal to this process. It is estimated that a patient who is cured of HCV today can generate ten thousand euros in savings over the next two years, meaning that the cost of therapy can be significantly reduced if you can transfer those savings to the pharmaceutical budget, in order to help fund more deliveries of the therapy.

**In Europe AbbVieâ??s manufacturing facilities are located in Italy, Germany and Ireland. As you mentioned the facility in Campoverde di Aprilia is now set to begin production of a critical part of the new HCV treatment. How will the fact that Italy was chosen as one of the countries to produce AbbVieâ??s most promising product impact your commercial operations in the country?**

There is of course no direct impact, however the fact that we are perceived a key player in the pharmaceutical industry does help us in our operations. A country which is seen to be favoring innovation and which is creating an attractive environment for innovation also helps attract investments.

The local authorities also appreciate our efforts. Italy is currently the second, and perhaps soon it will be the first exporter of pharmaceuticals in Europe. AbbVie Italy plays a role exporting in more than 110 countries. An internal study has shown that each direct employee we take on creates six indirect jobs as a result of peripheral operations supporting our presence here. When you consider that we have 1300 direct employees in the country, it is clear that we have a significant on the local economy. Representing such a company, means that we are perceived as an important player in the creation of innovation and development in the territories where we operate.

**The opportunities for growth in the market are clearly many for AbbVie, but surely a well qualified and experienced team will be crucial in realizing them. In a highly competitive sector, how do you retain your most promising staff?**

I believe a first key element is sharing the vision and culture of our company. We need to ensure that our people are engaged and share a common mission to positively impact patientsâ?? lives. The best way to attract and retain talent is to ensure that talented individuals have many different opportunities to gain new experience, and to create an environment in which innovation and risk is rewarded. In the last three years we have been nurturing a biotech spirit at the company, moving towards that pioneering mentality which can make a difference. A global biopharmaceutical company with a biotech spirit is what we stand for, and it is an excellent combination which can really help propel our organization to new heights.

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