Valentino Confalone â?? VP & General Manager, Gilead Sciences Italy

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Gilead Sciencesâ?? vice president and general manager for Italy, Valentino Confalone, outlines the companyâ??s tumultuous pandemic journey in one of the first global epicentres; the role that Italy played in the early studies of remdesivir as a treatment against severe COVID-19 disease; how Gilead is working to eliminate viral Hepatitis by 2030; and the potential of its HIV pipeline. In addition, Confalone dives into the past, present and future of oncology and CAR-T in Italy.

Can you begin by commenting on Gileadâ??s footprint in Italy, a country where the company has been present for just two decades?

Even though it is relatively young, Gilead is one of the biggest pharmaceutical companies in Italy. Our footprint in the country is threefold, on one side, we have a traditional commercial presence conducting the usual affiliate work around market access and medical affairs, for which we employ around 240 people. We also have a vast footprint of indirect manufacturing, making Italy a key cluster for third-party production for the global organization, which includes, for example, API production for our chronic Hepatitis C virus (HCV) treatments, and for the new generation of oncology products.

The third pillar is clinical trials due to the extensive network of universities and researchers present in the country; we have trials for all key therapeutic areas, including virology, oncology, haematology and CAR-T. With 38 active trials and 57 hospitals involved, the country is leading the way in the development process of many of Gilead therapies.

Gilead has been a pioneer in terms of palliative care for patients with severe COVID-19. Almost two years in, what can you share about the companyâ??s journey bringing forward treatments that address COVID, as well as the overall impact of this pandemic on your operations?

2020 and 2021 have been very interesting and complex years for the industry and the company as the COVID-19 pandemic delayed diagnosis and treatment in important areas where Gilead is present such as HIV, Hepatitis C, and oncology. Some ambitious goals, such as the elimination of viral Hepatitis by 2030, have been negatively impacted.

On the positive side, since Gilead focuses on infectious diseases, we had the opportunity to make a difference in the fight against COVID-19 through our remdesivir product. The company has always had a strong impact on the communities it serves, but that comes with a big responsibility, which was not always easy to manage in the first couple of months of the pandemic due to the limited availability of the product. However, we managed to deliver the products through a compassionate use program for the first six months, providing it for free from April until October 2020. After that, with the joint procurement agreement signed with the European Commission (EC), the situation eased, and we were able to meet demand.

From a business perspective, remdesivir offset what Gilead lost in other therapeutic areas, although the company never thought of the product as a business opportunity, rather choosing to price it below what would have been considered a reasonable price from a cost-effectiveness point of view, so that everybody could have access; it was one of the reasons why Gilead was able to sign the joint procurement agreement (JPA) with the EC. It was an intense period, but we managed to ensure continuity of supply for patients in need.

Remdesivir was put under the spotlight at the start of the pandemic because of the way it was presented to different regulatory authorities for emergency use authorisation with what some considered a very high price. What are your reflections on that part of the story?

Especially in the beginning, we faced challenges related to discrepancies in the data available at the time to the WHO, and to the US and European authorities. Fortunately, very recent data has confirmed the benefits of remdesivir even for patients with less severe disease. Indeed, questions were raised in the months following the JPA about the effectiveness of the product, but subsequent data from trials proved that it was the correct decision.

In some ways, the case of remdesivir resembles what happened with sofosbuvir, where initial concerns were raised about the price tag but history proved that the product was not only incredibly valuable, but also correctly priced since it saved health systems millions by helping to prevent Hepatitis C patients from progressing to liver failure. Even the Italian Ministry of Health has publicly expressed that sofosbuvir was one of the best investments they have made in decades due to the clinical and overall economic benefit; there is data showing that the investment is recovered in six years.

Since Italy was one of the first epicentres of the pandemic, the country served a key role in understanding the value of remdesivir. There were many Italian centres involved in the clinical trials run by both Gilead and external parties such as the Italian Medicines Agency (Agenzia Italiana del Farmaco â?? AIFA).

To what extent did the success of Gilead HCV treatments, a drug that pioneered the value-based pricing discussion, change the conversation about value-based treatments in Italy?

On far too many occasions, the discussion has revolved around price, failing to consider the amazing innovation that these therapies represent; HCV drugs are eliminating the disease, curing millions of patients. We still believe that we can get rid of Hepatitis C by 2030, a goal set by the World Health Organization and shared by the Italian authorities; over 400,000 patients have been treated so far and we are well on our way to achieving that goal in the country.

The Italian government has dedicated EUR 72 million to perform Hepatitis C screenings and we are working with patient associations, regions, and the scientific community to make sure that all parts of the country benefit from the program. On paper, there are around 240,000 patients who are yet to be diagnosed and treated and there are a significant number of people that can benefit and avoid progressing to cirrhosis and hepatocellular carcinoma.

Moving to HIV, another area of interest for the company, there are between 130,000 and 250,000 people in Italy living with the virus. How does this compare to European standards and how is Gilead tackling the issue?

Italy does have a high prevalence of HIV, and it remains a big policy issue, but it is not far from the European average. The challenge is that awareness of the disease within the young population continues to decrease, thus creating the need for prevention measures, diagnosis and quick access to treatment.

Countries are working towards the 90-90-90 targets proposed by UNAIDS, which call for a scale-up of HIV testing so that 90 percent of people with HIV are aware of their infection, 90 percent of people diagnosed receive treatment and 90 percent of those treated adhere and have undetectable levels of HIV in their blood. The early diagnosis and access to treatment in Italy remains relatively low so there is an effort to be made to ensure that people avoid infection and receive treatment if needed.

Looking at Gileadâ??s pipeline, lenacapavir, the companyâ??s potential first-in-class HIV-1 treatment, stands out. What role is Italy playing in the development of the asset?

There are clinical trials open for lenacapavir in Italian centres, particularly for the long-acting formulation.

At a global level for HIV the company is focusing on long-acting new molecules like lenacapavir, which could result in patients receiving an injection every six months, and on a potential cure along with Gritstone, with whom we are applying the concept of immuno-therapy to HIV. The combination of Gileadâ??s virology expertise and Gritstoneâ??s machine learning capabilities present a good opportunity to finally develop a cure; currently, Italy is not involved in the early stages of the program as it usually gets involved in from phase II onward.

Clinicians in the country recognize that clinical trials are a great opportunity to obtain early access to innovative solutions, making Italy a great destination for global drug development programs, but the overall system must improve in the number of patients enrolled in studies; it is a question of reducing bureaucratic hurdles such as redundant ethical committees that must approve the protocols in every centre.

Gileadâ??s experience with remdesivir during the pandemic could be a turning point in this regard because it proved that one single committee was sufficient and effective; we were able to get trials approved with the same requirements and level of scrutiny in a matter of weeks rather than a year.

In 2019, Italyâ??s AIFA decided to approve reimbursement of Gileadâ??s CAR-T therapy for adults with large b-cell lymphoma. What can you tell us about your experience in securing the agreement?

The agreement Gilead reached with AIFA was a consequence of a collaborative process that was completely focused on data and finding joint solutions. We openly discussed AIFAâ??s needs from the beginning and, for the first time ever in any country, we reached a payment-at-result agreement where the company gets compensated only after the treatment is proven to have worked. After two years, the data has confirmed the results of the clinical studies and the agreement is working nicely for both parties.

Obviously, it is a complex agreement to manage with a lot of data to collect; the registry is run by AIFA, treatment centres are in charge of data collection and input, and we only receive crucial data in order to ensure that the agreement has been fulfilled. The qualification process for centres is also interesting; there were 43 requests from the regions to qualify centres, which is a huge number considering the small patient population, and we have qualified 22 centres and we aim to add ten more in 2022. There is a lot of appetite for developing the skills and the know-how on CAR-T. However, centre selection could be improved by increasing the coordination between the regions, AIFA and private companies.

In my view, the key for such complex treatments to become sustainable is to make sure that while clinical trials hopefully prove they are effective in more indications so a larger number of patients can benefit in the end we also move from autologous CAR-T toward allogeneic CAR-T, and that is the real challenge for the industry.

The EMAâ??s hospital exemption (HE) rule allows for unlicensed, developmental advanced therapy medicinal products (ATMPs) to be used to treat patients under certain conditions. Is Gilead taking a particular approach to HE in Italy?

There was concern about the development of academic CAR-T and the potential for inappropriate use of hospital exemptions, but we are in a completely different situation after a few years of debate on the topic between the scientific community and national authorities. Everybody agrees that it would be a waste of resources to have academic centres focusing on the same indications that are already available with approved products; hospital exemptions should be used only when there is no alternative.

There are many opportunities to experiment with cell therapy for new indications and that is where centres with capabilities are focusing on; it even creates potential for partnerships. This is the approach that has been taken in the last 18 months.

What is your perspective on recent developments around the increase of Italyâ??s health budget, the proposals of tax breaks to ease of doing business, and new rules for market access, pricing and transparency?

It is a major topic for the industry and the country in general. There has been a shift in the Italian populationâ??s perspective on health, seeing it not as a burden to the public budget but rather an investment for the future. This approach has reversed a trend of investment reduction in the health sector.

The country is looking at three main items: the modernization and digitalization of hospitals, more funds for primary care support after it was shown that it can play a crucial role in emergency situations, and an increase in pharmaceutical spending, especially at the hospital level, to ensure funds for innovative therapies.

However, there is still work to be done to change the current payback system that together with access, represents a disincentive for innovation.

Is there a final message you would like to share with our international audience?

I would like to close with one of the learning we obtained from the pandemic, that is, that government and industry cannot achieve ambitious health goals alone. We need to work together to solve the important medical problems of today and must maintain open communication.

As a company, Gilead has made the impossible possible, redefining what possible means by bringing transformative treatments to patients. Our goal is to bring at least ten new treatments to patients in the next ten years which requires a collaborative approach with all stakeholders.

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