Frederico Silva â?? General Manager, Gilead Sciences Middle East

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Frederico Silva outlines the highlights of his two years heading up Gilead Sciencesâ?? relatively young Middle-East affiliate, how Gilead has pivoted to serve evolving healthcare needs during the COVID-19 pandemic, and its commitment to inter-stakeholder collaboration in increasingly important markets such as Saudi Arabia.

In what is your first general management role at Gilead, you have taken on the responsibility for 12 countries in the Gulf region and Levant. Can you outline the career journey that has taken you to this position and what your responsibilities and priorities are today?

I started out in pharma with Gilead as a medical representative over 16 years ago in my native Portugal. After working through various roles in marketing, sales, and business leadership, I took charge of Gileadâ??s most important business unit in the country. Following that experience, I moved to Spain where I had the huge responsibility for launching the companyâ??s HCV portfolio;

Following Spain, I was given an international assignment at Gileadâ??s European headquarters in London before taking on the general manager position in the Middle East in 2019. It is extremely exciting to be able to help bring Gileadâ??s latest innovations to patients in the region as well as

support local authorities to advance the healthcare sectors alongside other industry partners. I am also very passionate about being responsible for the development of my colleagues and ensuring that Gilead is one of the Best Places to Work in the Middle East.

Gileadâ??s leadership team in the Middle East have three key objectives. The first is to enhance access to all of Gileadâ??s currently available treatments in HIV, hepatitis, COVID-19, and antifungals. Additionally, we are working internally and with the health authorities to bring our latest innovations to market, particularly in oncology, specifically cell therapy and treatment for breast cancer. Thirdly, we aim to grow our footprint in the Middle East even further, particularly in Saudi Arabia, where we established a scientific office this year. Saudi is a critical component to accelerating the development of our plans.

What was the level of maturity of Gilead in the Middle East when you arrived in 2019 and how conducive was the existing infrastructure to achieving these three objectives?

Gilead has only been present in the region since 2014 and so it is a rather young affiliate, although our medicines have been available here for much longer through our distribution partners. We have a very innovative and pioneering portfolio and for 30 years have been working to create breakthrough medications that were thought to be impossible, particularly in life-threatening diseases. We are making these breakthrough products available to patients via key local partnerships, such as our partnership with Cigalah in Saudi.

What were your first impressions of this heterogeneous region in terms of healthcare systems and levels of economic development, having previously spent your entire career in Europe?

It has been an amazing experience. I took on the role in December 2019 before moving my family out in June 2020, amid the COVID-19 pandemic. The pandemic meant that travel was restricted, making it a particularly challenging time to take on a new function, especially a multi-country one.

Our product portfolio is well recognized by health authorities in the region. This was augmented by the experience of being able to launch a new antiviral therapy during the pandemic as a treatment option for SARS-COV infections. It has been very rewarding to experience collaborating virtually with authorities in multiple countries to address challenges and being able to introduce this product for the benefit of patients here. Additionally, the move has been smoother than I had anticipated for my family. I have high hopes that these positive experiences will continue, on both a professional and personal level.

Given the large amount of noise around Veklury (Remdesivir) and its impact on COVID-19, what was your experience of bringing this product to the Middle East at such a critical time? What kind of communication initiatives did you have to undertake to ensure that expectations for the drug were reasonable?

All of us at Gilead were humbled by the possibility of making a difference so early in the pandemic. Veklury has demonstrated that it shortens recovery times for hospitalized patients with COVID 19, thus easing the burden on healthcare systems. Additionally, recent real-world data demonstrates that Veklury reduces mortality for some hospitalized patient cohorts.

It is important to point out that Gilead has been focusing its R&D efforts on virology for over 30 years, particularly on the treatment and prevention of HIV and HCV, giving us a deep understanding of viruses. Our R&D team has been working for a long time on emerging viruses and looking at potential therapies for future viral threats. Therefore, we were able to pivot quickly to help in the global fight against COVID-19, which was well appreciated by stakeholders in the Middle East.

We took bold steps, such as ramping up production of our COVID-19 treatment. Manufacturing timelines have come down from 12 to six months and we have expanded our manufacturing network, both internally and through working with partners, including industry peers. This is a good showcase for our collaborative approach to what has been an unprecedented crisis.

Gilead has engaged with health authorities across the region at an early stage, making the product available and ensuring that it could be supplied without interruption. Moreover, we collaborated extensively with the healthcare community, sharing information, and supporting the public health response to the pandemic.

Finally, an important facet of Gileadâ??s approach was the 1.5 million vials of the drug that we donated globally. Within the region, we donated over 25,000 vials in the first few months of the pandemic.

Was Veklury given emergency use authorisation in Saudi Arabia and across the region, which is a mechanism less recognised in this part of the world? How challenging has it been to square the circle between accessibility and commercial viability in the Middle East where there are big economic disparities between countries?

We engaged early on with the health authorities in the region to establish a regulatory pathway in most of the Middle East countries to allow the availability of Veklury and secure uninterrupted supply. We also collaborated with healthcare providers, the medical community and clinicians to share information and support the public health response to this pandemic.

We received emergency use authorisation from several regulatory agencies in the region as the pandemic accelerated the development of this mechanism. Very early on, Gilead received seven conditional approvals, full marketing authorisation in the UAE, and in Saudi. These emergency use authorisations ensured that the product has been broadly available to those in need.

As part of our commitment to ensuring Veklury is available for patients globally, Gilead set a single government list price and is in regular discussions with governments around the world to accelerate access to the medicine. Gilead also entered into voluntary licensing agreements with nine generics manufacturers to further expand the supply of remdesivir to 127 countries that represent nearly all low-income and lower-middle-income countries.

Saudi Arabia is an increasingly important market for global biopharma not just because of its size, but because of its regulatory influence across the region. How would you encapsulate the significance of Saudi to Gilead, and how are the companyâ??s operations being influenced by the Vision 2030 national plan?

Saudi is a country with immense potential, which led us to establish a legal entity there to make our operations more robust. The governmentâ??s support for the strategic development of industries like biopharma coupled with the growing local demand for new medical products and improving access

to innovation makes Saudi a particularly attractive investment destination for companies like Gilead.

Vision 2030 is an incredible strategic program aiming to transform the country into a vibrant society, thriving economy, and ambitious nation by 2030. Life science is a highly strategic sector within this vision and Saudi is looking to increase the industryâ??s contribution to GDP and employment. A lot of work is being done to localise manufacturing and build R&D capabilities in the country.

Gilead has been actively engaging with the Ministry of Health, The Ministry of Investment, the Saudi FDA, and other stakeholders to contribute to this Vision. I hope that we can become even more of a strategic partner in the future, building on this strong collaboration.

The Saudi FDA is recognized as one of the leading regulatory agencies in the region and its recent admission to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) reinforces this position. The SFDA is also adopting procedures and mechanisms to ensure early access to innovative medicines. The Saudi FDA and other authorities are also advancing in other areas, such as the protection of innovation, helping not only to create better access to innovation, but also encouraging more investment and reducing the barriers to expanding our footprint here. They can count on Gilead to be part of this growth story.

Gilead has long been a disruptor in terms of business models for innovation; with Sovaldi being a game-changer in terms of the way regulators and payers look at how medicines fit into their economic and efficiency frameworks. How does this play into your operations in the region, particularly in Saudi?

This therapy was truly disruptive in terms of changing the lives of patients, the way that patients were treated, and the way that systems address innovation. Whenever disruptive innovation is brought forward in impactful disease areas such as Hepatitis, most stakeholders embark on a journey into uncharted territory. This of course comes with challenges, but at the end, thousands of patients in the region, and potentially millions worldwide, have been cured of their disease through our innovations and partnerships.

Sovaldi has been approved and priced by the Saudi FDA since 2014 and since then we have worked intensively with health authorities in Saudi and across the region to facilitate access to the drug and other Sovaldi-based medications. As a few examples, we have partnered with authorities throughout the Middle East on elimination programs, public awareness campaigns, medical education, and local data generation. All in all, this was a tremendous success story for patients and an important learning opportunity for all stakeholders in the region.

I also want to recognise the extraordinary and challenging role that health authorities play, because they have finite budgets and need to prioritise and provide access to innovation. Here, Gilead has demonstrated, and will continue to demonstrate in the future, that we are strongly committed to finding the right balance between the value that our medicines have and making sure that they are accessible to patients in every country. There are several examples of how we have done so in HIV, as well as for Veklury.

The Saudi Ministry of Healthâ??s public policy strategy includes a focus on HIV; what do you see as Gileadâ??s role in alleviating this infectious disease?

Gilead has long been a leading innovator in both the treatment and the prevention of HIV, with a strong tradition of driving HIV research forward. We are committed to continuing to operate in this field with more community collaborations to raise awareness and reduce stigma. In HIV alone, Gilead has already brought forward 11 medicines, with a constant focus on greater efficacy and enhanced safety. This has been particularly well appreciated by the Saudi authorities.

One of our breakthrough innovations was the first single tablet HIV regimen, which helped treat HIV with just one pill once a day. Following on from this, we brought forward several modified and improved products. Gilead will continue this journey while working on continuing to add more innovative HIV treatment options, as a new therapeutic class for heavily-treatment experienced people living with HIV and long-acting injectables aimed to control the HIV virus with few injections per year, that can be most suitable for some patients.

We are also partnering with the Ministry of Health, the National AIDS Program and the Saudi Medical societies, to address different challenges, seeking to improve the HIV care pathway in the Kingdom. This demonstrates the institutional commitment in KSA to continue the journey towards improving the lives of people living with HIV.

Globally, one of Gileadâ??s objectives is to enhance its oncology franchise. Do you have plans for your CAR-T solutions to be part of the oncology therapies introduced in Saudi Arabia?

We already have innovations in oncology, particularly in CAR-T and in the treatment for breast cancer. Gilead is looking to bring even more innovation into this space. Our CAR-T technologies are managed by Kite Pharma, so it is not fully under my remit, but I am working in close collaboration with the Kite team to bring these therapies to the region.

The Ministry of Investment and the Ministry of Health are doing a tremendous job of creating the right ecosystem to bring these technologies to the Kingdom.

Is Gilead involved in clinical trials in Saudi?

To support the transformation as highlighted in Vision 2030 into practice, we began a three-year project to build capacity in clinical research and leverage research capabilities in the region, including in Saudi. This program has been rolled out in collaboration with the government, public health organisations, and several reputable international universities such as Harvard and Stanford. We believe in the importance of creating the right environment and the critical mass to boost the regionâ??s clinical research footprint.

Gilead has been very active in supporting local data generation which would be an important tool in the future health-related decision-making processes.

The Saudi pharma market is changing rapidly, with the centralisation of public procurement via NUPCO and the intention to ramp up private participants both in insurance and hospital infrastructure. Where do you see the market moving in the next five years and how will this influence Gileadâ??s operations?

The Saudi government is looking to draw from experiences and best practices in Europe and the US to enact and accelerate the goals of Vision 2030. It has been particularly interesting to see the evolution from international reference pricing discussions to recent value-based discussions and HTA that is expected to potentially be enacted in Saudi in the near future.

This evolution is a major step towards securing access to the most advanced innovations while minimizing the burden on the healthcare system. However, this is a journey that has just started and in order to reach the desired outcome, a joint effort and close collaboration between all stakeholders, along with policies conducive to increasing patient access to innovation, are critically needed. This can only be achieved through effective contribution from all concerned stakeholders with proactive communication leading to full alignment on the outcome.

We are fully committed to supporting this common journey.

What message would you like to send to your counterparts in the region and globally about Gileadâ??s Middle East franchise?

Gilead Sciences is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. This becomes possible through collaboration with governments, health authorities, the public and the healthcare industry. The good level of partnership between the public and private sectors allows the growth and development of the biopharmaceutical sector and ultimately better serve the people who need these medicines. That is why we continue to get out of bed every morning: passion for our work.

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