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About 34 of 38 million people living with HIV globally are between Intercontinental and the Global Patient Solutions (GPS) region

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Gilead Sciences' Jacopo Andreose PhD is a 20+ year pharma veteran and is today responsible for setting company strategy, planning and execution for over 150 countries across Asia, Russia/CIS, Latin and Central America, the Middle East, and Africa. In an exclusive conversation, Andreose outlines how Gilead was able to roll out its COVID-19 antiviral to emerging markets so quickly; why the firm is prioritising covering unmet needs in his region; the importance of Gilead's access work in low- and middle-income countries; and the potential impact of the company's global move into oncology.

Can you tell us a little bit about your background and what brought you to Gilead?

I have been in the pharma industry for over 20 years. I started in medical at Abbott, where I stayed for about 13 years moving from medical to commercial in Italy, the Nordics, and then eventually in global strategic roles. After Abbott, I moved to BMS where I stayed for a couple of years in general management before moving to GSK and ViiV Healthcare, where I stayed for about seven years before joining Gilead in May 2020, at the beginning of the pandemic.

Therefore, for several months I worked as a virtual leader with a virtual team. We just had a debrief session and one of the topics was about transitioning back to face-to-face leadership after people have become used to this efficient, but sometimes impersonal way of managing the organisation. At the same time, Gilead's Intercontinental region has been successful also, as a virtual organisation. The region in its current format was created just before I joined, so it is relatively new for Gilead. It was put together by my manager, the Chief Commercial Officer, taking different parts of the globe from different experiences and different constructs in Gilead. Therefore, I am the first head of Intercontinental at Gilead.

Looking at Gilead's financial results, the company seems to be very focused on the US. How does it view its intercontinental portfolio and what is Gilead trying to achieve with it?

Obviously, the US and Europe remain critical markets for Gilead, but part of the reason why Intercontinental was created, is to increase our focus and presence outside of the US and Europe. While there is growth potential in our markets, they also represent areas of high disease burden and unmet patient need. If you think about the therapeutic areas where we are most active, the largest patient pool and therefore the highest unmet needs from a medical standpoint are in the Intercontinental region. For example, about 34 of 38 million people living with HIV globally, are between Intercontinental and the Global Patient Solutions (GPS) region, which became part of my organisation in May 2021 and covers about 100 primarily low- to middle-income countries across Africa and Asia. Between Intercontinental and GPS there are about 160 markets and that is where the highest burden of diseases is for HIV, but also for hepatitis and other disease areas we are working in. Thus, there are relevant unmet needs and disease burden that we are trying to address in those countries

Among these markets, are there some that Gilead is prioritising?

If we think of patient burden, the countries that we prioritise are the ones where the unmet needs are the greatest. Just to give you a couple of specific examples, in the GPS space, South Africa and India are markets that we look at with great interest. You might remember that back in April-May 2021, India had a significant rise in COVID-19 infections, especially with the Delta variant being extremely severe from a burden of illness standpoint and the impact on the healthcare system. We enhanced our support to voluntary license partners in terms of stepping up their capabilities to fill

the unmet needs of Indian patients. At the same time, we donated branded medicines to cover the short-term needs of the Indian government and also donated our antifungal drug, because in addition to COVID, hospitalised patients in India were at significant risk of mucormycosis, which is a deadly infection that created a significant challenge for the healthcare system. That is just to give you an example of how we can support those markets, especially in moments of need, like during the pandemic, but in general, we are looking at these markets with great interest because of the burden of illness.

One particularity of these markets is that the healthcare infrastructure is not always straightforward. This perhaps requires companies to be more proactive in bringing more robust solutions. What elements would you say are important when working with low- and middle-income governments in order to be effective?

Voluntary licensing has been a very important model for operating in these markets because it gives you scale and in some cases, it gives you speed, as we have favoured non-exclusive voluntary licensing with several manufacturers. If we stick to the COVID-19 example, we have about nine partners across India, Pakistan, and Egypt to bring our COVID-19 treatment more rapidly and more broadly across multiple countries. Just to remind you, remdesivir is a COVID-19 antiviral and the main utilisation is for hospitalized patients, although we recently had approval in the U.S. and other countries for outpatient use as well. Of the 11 million patients that have been treated to date around the world, about 7 million are because of the voluntary license agreements in low-middle income countries, through our partners, so it shows that the voluntary licensing model, while not always the right solution in all therapeutic areas, can be extremely effective in certain cases, to allow you to build scale and high-quality medicines at affordable prices in those markets.

What about other solutions like differential pricing based on the population’s income? Is that something Gilead has implemented?

Yes, especially for HIV and hepatitis C we have looked at the burden of disease as an important element to evaluate what the right strategy for the market is, but also the country’s ability to pay. Those are all elements that we take into consideration when we look at access models.

When we look at remdesivir, it seems incredible that Gilead has taken it to emerging markets so quickly. What other factors would you say are critical if you want to go quickly into markets which are more unstructured internally?

What has been a critical factor, both in the countries where Gilead has a direct presence and where we have distributor networks, is early engagement with regulatory agencies. In the early days of the pandemic when data on the medicine were still emerging from clinical trials, relationships with governments and especially regulatory agencies were instrumental to inform initial discussions and help contextualize the data, which later led to several approvals, either on the model of the US emergency use authorisation, special import permits, or full approval, as was the case in Japan, Taiwan and other countries that approved a full marketing authorisation early on.

Going back to voluntary licenses, for some it may be difficult to understand why they can be granted in some places and not in others. What would you say is the ideal situation for going into a voluntary license deal?

I think it should be evaluated based on some of the criteria I mentioned before. The ability of a country to pay is linked to its gross national income (GNI), but at the same time, we should not only look at financials, but also the burden of illness, inequality, and other elements. Therefore, if you look at the 127 countries where we have granted the voluntary license agreement for COVID-19, which was very much covering the same type of geographic footprint as previous voluntary license agreements for HIV and Hepatitis C, you will see a very strong consistency across those criteria.

You mentioned HIV, an area where Gilead has a strong background. Where do we stand today with respect to HIV?

I have been working in the HIV area for 22 years, starting in the medical organization, and then in the commercial space. It is a therapeutic area that I am passionate about and being a part of the progress that has happened over these 20 plus years compared to, the middle and late 80s or even early 90s when breakthrough medicines were not available, has been extremely rewarding.

We have made strong progress and Gilead is a fundamental player in the discovery, development and commercialization of innovation in HIV. For example, in 2006 Gilead launched the first complete single-tablet regimen, then moved into the integrase inhibitor space, which again has been relevant from both an efficacy and tolerability level, making things easier for patients. As we

were discussing before, we are not just making things easier for patients in the developed world, but also making the same high-quality and more tolerable medicines available on a larger scale in the countries with the highest burden of disease. And then if you think about the future of HIV, while the cure will remain the key objective and something that Gilead is also working on, in the shorter term one of the potential new chapters, if approved, are long-acting medicines. Long-acting medicines can be transformational for treatment, but also equally important for the prevention of HIV.

In some countries there has been a certain level of denial about HIV. Is that progressing at all?

Luckily, yes. I will give you one example from my trip to the Middle East a few weeks ago. We had the sixth edition of a standalone meeting fully dedicated to HIV, with many key stakeholders from different countries in the Middle East, including Saudi Arabia. For the first time, to my knowledge, we were able to involve very courageous patients in a discussion panel and this shows just how much progress has happened in the Middle East, where stigma remains high, as it does in many countries in the world, including the most developed ones. But yes, there was a time when countries were in denial and this is still a high priority for the HIV community, that stigma is reduced in terms of legislation if there is legislation or employment practices that are discriminatory against people living with HIV. I think the road is still quite long, but incredible progress has been made.

We are a provider of medicines, which is our main role, but we also have long, established experience in the field, and knowledge on how we can support the delivery of HIV care, from diagnosis to ongoing engagement with healthcare systems. Linkage to care and adherence to treatment is also something that is extremely important when you are talking about a chronic disease that requires continuous treatment. Gilead is really trying to play an important role in all these areas.

I would like to touch briefly on Russia and Ukraine. As an American company, perhaps forced into an embargo, what decisions have been made to ensure essential medicines are getting to patients in those countries?

When it comes to Ukraine, we are present through a distributor and unfortunately, especially at the beginning of the invasion, operations were significantly disrupted, including the ability to bring the medicines that Gilead is providing to patients through this distributor into Ukraine. The situation for refugees has been better and we have been able to reach the countries around Ukraine, especially Poland, the Czech Republic, and Romania. We have been coordinating with Gilead's organizations from those countries, who were able to support either the governments directly or humanitarian organisations, to provide life-saving medicines to patients in need. For Ukraine and Russia, the burden of disease in some of our therapeutic areas, especially HIV, is very high. Ukraine, I believe is the second-highest, just below Russia, when it comes to the number of people living with HIV in Europe. We keep working with both our distributors and humanitarian organisation to ensure that now that things are at least more stable in the parts of the country less impacted by the war, that supply is secured. We are also sending support through donations, including an employee donation program.

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When it comes to Russia, as a company we are committed to patients no matter where they are, especially for the underserved populations in the therapeutical areas we cover. Therefore, our position is to maintain our organisation in Russia, but only for essential activities linked to access to medicines. In addition to that, we are also committed to donating any profits coming from Russia to humanitarian help for Ukraine.

Gilead has been investing heavily in oncology, a new area for the company. Can you tell us about that?

It is a very exciting new chapter for Gilead. We have made a significant investment in this area over the last five years, first with the Kite acquisition, a very exciting company in the cell therapy space. Kite also plans to expand in the Intercontinental region after being in the US and in Europe for several years. Therefore, we are going to see cell therapy made available in our markets with some important filings coming already this year and next year. Then, in 2020, came the acquisition of Immunomedics, a company working primarily in solid tumours with a portfolio that has the potential to expand into multiple areas within oncology.

First, an antibody-drug conjugate that has been approved by the FDA and EMA and now has been filed in a number of Intercontinental markets. And there is more to come, so we are building up resources and capabilities to make sure we can serve patients also in these disease areas where the unmet need is huge. Especially, I should mention, that the first indication for our ADC is triple-negative breast cancer, which is one of the most aggressive forms of breast cancer and one where women of colour and mixed-race are also disproportionately represented. Therefore, the Intercontinental region is extremely important from that standpoint and we are building capabilities in oncology, which comes from a mix of enhancing internal talent, but also looking outside and an understanding also from a go-to-market model of what the difference is with respect to virology.

If you are in a market like the US or Europe, finding talent to build the oncology franchise is probably straightforward. Is it more challenging in markets that have a smaller pool of talent?

I have been in the Middle East recently and in Brazil and other markets where we started building an oncology team. There is a lot of excitement for Gilead because it has the feel of a start-up. Some people who have been in more established oncology companies for some time feel the excitement of building something from the ground up. Secondly, because they know we have innovative therapy both in haematology, including cell therapy as well as in solid tumours on the market, as well as an exciting pipeline. Therefore, people who know this, see we may not have a huge portfolio, but our treatments are potentially transformative. And then number three, our track record in virology in our markets makes us a credible player and therefore an attractive future employer. The net result is that we have been able to attract people with very strong experience and significant potential in critical roles in some of these key markets.

You mentioned at the beginning of the interview that you began leading virtually during the pandemic. What are your thoughts on the way we will be operating from now on, particularly in emerging markets?

Regions like Intercontinental and GPS, even before the pandemic, needed to have a mix of virtual connections and physical presence, because you cannot be in Seoul at the same time as in San Paolo or London. Clearly, technology helped before COVID and will continue to play an important role even after countries re-open to travel post-pandemic. That is the efficiency of technology; it allows you with a click of the mouse to be in a meeting on the other side of the world. At the same

time, I feel the need for human contact, I feel I can give more to the team when I am physically present in the countries. We have already opened a new phase in which we are looking at more face-to-face and therefore higher engagement. When I do market visits, in addition to engaging with the local team I'm keen to meet customers, whether that is treating physicians, patient associations, or government officials. I think it is an important part of the way I can support the local team in being successful. As importantly, I want to meet with local employees that I usually do not see on Zoom calls, to make sure I get a better understanding of the needs of the business, but also, that they get more visibility to myself, and the rest of the leadership team that is travelling with me.

What are your thoughts on the talent of the future?

The talent of tomorrow is very digitally connected and likes flexibility in the workplace. I am not very much of a social media person, but I see that employees are using these tools more and more. At the same time, when I do market visits, I see gen-Zers and millennials are equally keen on human interactions as people from previous generations. In that sense, I do not think people will be fully motivated by only being remote, or by not coming back to the office and not having any team interaction. It seems like the new generation wants more flexibility and a lot of people during the pandemic enjoyed the ability to work from home. Even though we encourage people to go back to the office, there is also an increasing need for flexibility, whether that be flexibility about location or flexibility about working from home and not being in the office every day. There are cultural differences in different parts of our geography, so it is very difficult to generalize across our many countries.

You have been at Gilead International for about two years. What would you like to achieve in the next two years?

Clearly, our financial objectives are important, and ideally achieving those ahead of time, which is something that we have been able to do in the last couple of years. As we were saying in the beginning, we want to become an even stronger contributor to Gilead, while the US and Europe will remain hugely important. But we want to increase diversification and that is one of the elements we can provide. Again, access and impact on public health are important for me, and therefore seeing our medicines more broadly available, either directly through Gilead, or to our partners in distributor markets, or through our partners in those markets covered by voluntary license

agreements. That is also something that will remain high up as a priority for me and will keep me engaged and motivated and that is what I want to see two years from now. And then, something we did not speak about that much, but Intercontinental has already been highlighted internally as an exporter of talent. We have a number of high visibility appointments, but also many people not only at VP or Executive Director levels that have moved to bigger roles across different parts of the Gilead organisation. This is something that will continue to make me proud: our ability to export our diverse dynamics. That is one of the great assets that Intercontinental builds: diversity of thinking, because when you are dealing with such a diversity of cultures and business models, it really tests your muscles in a different way than some of the more traditional markets and that is why the talent we develop is in high demand and I believe will be more and more successful in the years to come.

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