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Our goal is to work together with the broader community to help end the HIV epidemic for everyone, everywhere

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After positions at Novartis and Merck, Bettina Bauer, a trained scientist, joined Gilead in 2019 as VP and general manager of its German affiliate. Today, as the VP of the company's global commercial strategy and operations for HIV, COVID-19, and emerging viruses, she discusses the company's strides in HIV prevention and cure research; its access initiatives, including voluntary licensing agreements; Gilead's approach to global HIV clinical trials, and preparedness for future health threats.

Can you start by giving us a brief introduction of your background and what brought you to your current role at Gilead?

Throughout my career I have learned that change is helpful and often also necessary to develop yourself and to keep growing. This is one of the drivers I have for myself. The other is that, because I am a trained scientist and have done research myself, it is important to me to bring innovation to patients.

Based on these criteria, Gilead was a natural choice. I was attracted to Gilead because of its proven track record of bringing innovation to patients. When I was at school in the 1980s and HIV

appeared, I remember how catastrophic the impact was on patients. Today, thanks in part to companies like Gilead, the virus can now be suppressed in most cases. Tremendous progress has been made, and with effective treatment the virus can be kept below detectable levels, which also means patients cannot pass it on to others through sex, helping to prevent the spread of the virus.

Gilead also has a long history of working with the communities it serves, and is driven to achieve broader access to care, and to improve public health. When I was country Head in Germany, I saw Gilead's community efforts at the beginning of the outbreak of COVID-19 first-hand. It became critical to work with all stakeholders to see what we could do as a new health threat was emerging. Again, it was Gilead's expertise in virology, but also its pandemic preparedness that made the difference.

Speaking of COVID-19, Gilead developed an antiviral treatment for people hospitalised with COVID-19 which has now been made available to 13 million patients in more than 170 countries worldwide. If you think that the pandemic began just three years ago, this is a very impressive achievement.

In my new role as vice president on the global team, responsible for the commercial strategy and operations for HIV, COVID-19 and emerging viruses, I can help people impacted by viruses around the world, making sure the right strategies are in place so that our innovations reach patients.

Many companies began working on HIV and then decided to abandon it while Gilead has continued to pursue the area. What is driving this continued interest in HIV?

The short answer is that we are not done yet. There are many things still to be done to contribute to the overarching goal of ending the epidemic for everyone, everywhere. For 35 years, Gilead has been a driving force in the evolution of HIV treatment. For example, we developed the first single tablet regimen, which reduced the pill burden on people living with HIV.

Innovation has continued and now we believe we need to go further to ultimately have treatments in place that allow patients to benefit from demonstrated long-term safety and efficacy profiles. Moreover, we are not only active in treatment but have also pioneered the first therapy to prevent transmission. All this progress has been transformative for both treatment and prevention.

However, we believe we need to go further to ultimately end the HIV epidemic. That is why we are continuing to focus on HIV and making major investments to expand options for HIV treatment and prevention. We are also actively pursuing research that could one day potentially lead to a cure.

Another critical issue is that we do not want any patient to be left behind. At the end of the treatment algorithm, we are also committed to developing several long-acting investigational options, to make sure we are addressing the preferences, and also the different needs of a diverse set of individuals and communities around the world.

Looking at the status of HIV in both developed and emerging countries, what would you say are the gaps that still need to be filled?

So much progress has been made in the last 35 years, but what makes me frustrated is that even in developed countries, so many people do not have access and there are still many underserved patients and populations. The highest incidence is in sub-Saharan Africa, Eastern Europe, and Central Asia and HIV remains, despite available options, a global health issue that needs to remain high on the agenda. Only through continued dialogue and partnerships, can we solve it; medications are only one piece of the puzzle, especially if you think about stigma, discrimination, and the reasons why people do not have access or use all of the options available to them.

We know that HIV impacts key populations unequally, for example in 2019, gay and bisexual Black men accounted for 26% of all new HIV diagnoses in the United States, due in part to intersectional stigma and discrimination based on race and sexual orientation. Transgender people are 49 times more likely to be living with HIV than the general population. For some women, gender-based violence can drive disparities in HIV infection rates and prevent women living with HIV from accessing care. These inequalities continue to hold back efforts to end the HIV epidemic and Gilead is working with policy makers and advocates to highlight these inequities and find positive solutions to address them.

There are also an estimated 6 million people 50 years and older living with HIV globally, with this number is expected to steadily grow. This is a positive consequence of improvements in HIV treatments and increasing rates of treatment uptake. As people living with HIV are at risk of accelerated ageing, increasing the likelihood of multiple comorbidities, services and access to treatments that better manage that are essential.

Some countries have only just begun reporting HIV cases while others seem to still be in denial about it, potentially making collaboration rather challenging…

We support policies that allow for equitable access and that try to keep HIV high on government agendas, addressing these underserved populations and allowing for equitable access to healthcare. One part is testing and linkage to care, because to be able to report data, you need to test and know a person's HIV status. This then also allows people to be directed into care, making sure they get the support they need.

We take our responsibility very seriously as one of the stakeholders and partners in helping end the epidemic for everyone, everywhere. We can only do this in partnership with other key stakeholders. Dialogue with the communities involved as well as with governments is important to see what can be achieved beyond medication alone.

You mentioned some of the geographies where HIV is prevalent. How does Gilead work in these areas, particularly considering that in many of these countries healthcare systems are not always so robust and budgets are often deficient?

To explain our approach in the different geographies, I can say that we do recognise that the greatest need for HIV treatment is in low- and middle-income countries. We put innovative programmes and partnerships in place to expand global access to our medicines, and advance global health equity.

In 2006, Gilead first began licensing its intellectual property to generic drug manufacturers to sell high-quality, high-volume, low-cost versions of our HIV medicines in resource-limited countries. In 2011, Gilead also became the first pharmaceutical company to join the Medicines Patent Pool. By 2021, HIV medicines were made available to an estimated 16.5 million people living with HIV in resource-limited countries around the world through organisations that benefited from licensing agreements with Gilead.

However, medicines alone cannot solve the impact of HIV. Thus, we partner with health systems and multidisciplinary stakeholders around the world to strengthen care for people living with HIV, through education and partnerships. Specifically, to address the challenges in Eastern Europe and Central Asia, we partner with the Elton John AIDS Foundation, including through a ground-breaking initiative called RADIAN, which we launched in 2019.

In addition, in many developed countries, only 75 percent of people living with HIV have access to HIV treatment. We advocate for policies that enable more equitable broad and uninterrupted access to treatment and prevention, and for expanded screening, testing and the linkage to care.

We partner with organisations to drive policy change and we want to tackle the gaps in HIV care. You may have heard of Fast Track cities, for example, which work to concentrate advocacy, policy and resources to demonstrate that we can have an impact through coordinated efforts against HIV, particularly in cities around the world.

You mentioned voluntary licensing. From your standpoint, has the experience been productive?

We have been involved in voluntary licencing to generic manufacturers since 2006, when we provided the first licence for HIV. Additional licence agreements followed in 2014, for hepatitis C, and then in 2020 for our COVID-19 treatment. Through our COVID-19 voluntary licence programme, we have made our treatment available to more than 8 million people in low- and lower-middle-income countries to date. We have a very serious commitment to this, but having said this, voluntary licencing is often only one piece of the access puzzle. Again, we are involved in dialogue with governments; we work with communities, and we work with other stakeholders to make sure we expand access and strengthen healthcare systems to equip them to address the need.

Are there any takeaways from the COVID-19 experience that could be applied to other parts of the company's portfolio such as HIV?

We were able to act in the COVID-19 space because Gilead has a dedicated team that has continuously and for many years been researching emerging viruses, and also antiviral therapeutics to ensure we are well-placed to respond to emerging and future viral threats.

Our decades-long commitment to collaborative partnerships around the globe was also critical to making new treatments available for COVID-19. We invest in virology innovation and this will help enable a rapid and effective response to the next global health threat. Our scientists continually work to invent new small molecules and biologics, and they generate an expansive library, and this library can be accessed and tested against new pathogens or new targets as they emerge.

Coming back to HIV, long-acting prevention options have the potential to help people stay protected from HIV and provide new options alongside daily oral therapies. In HIV cure research, we think a multi-pronged approach is needed to achieve the goal of curing HIV and this is why we need different agents, probably in a combination. We are driving discovery and development of latency reversing agents, immune modulators, genetically engineered effector antibodies and

therapeutic vaccines to explore the potential for combination therapy. Together we are working to deliver a functional cure, or long-term viral remission, in the absence of any antiviral therapy.

For most companies, COVID-19 had an impact on commercial operations. What can you tell us about Gilead and the future of the company's commercial teams?

Our approach has always been collaborative and focused on dialogue, and that remains true. Of course, when the global pandemic started, we were all challenged and we had to urgently find new ways to work with key stakeholders, and support awareness and continued understanding of our medicines. Part of our work is to ensure the continued dissemination of scientific knowledge and to do this we participated in large-scale virtual medical conferences and targeted online engagements during the pandemic.

Now the impact of COVID-19 has changed, some of our customers and healthcare professionals have become more selective about meetings in person. We understand the challenges, and we respect their preferences, so we are quickly evolving our approach to meet customers where and when they want to hear from us.

Beyond the business model, there were also the geopolitical consequences of COVID. We saw pressure on economies and an impact on healthcare and because we actively participate in public dialogue to ensure that HIV remains a political priority, we had to make sure that dialogue continued.

What does patient centricity mean to Gilead in the field of HIV, specifically with respect to clinical trials?

To make sure that our science is person-centric and inclusive, in our clinical trials we include populations that stand to benefit the most. In addition, for Gilead it is important to bring the community voice directly into the research progress, from programme planning to clinical trial execution. Specifically for HIV, our research programme is designed to address the unmet needs of those disproportionately impacted by HIV and those that have historically been underrepresented in clinical studies.

We have several large-scale global HIV clinical research studies, both in prevention, and in cure, and they include a robust community engagement component. We have a dedicated community

accountability group that consists of HIV advocates, but also community leaders. They counsel us throughout the research process, from the clinical trial design and recruitment strategies to looking at real world data and participant-reported outcomes. We believe that engaging with the community in the process not only leads to better science, but it brings greater trust and engagement throughout the trial, and it helps scientists to better address the experiences of the populations we serve. A current example is our ongoing engagement with the International AIDS Society to help develop guiding principles to consider for person-centred care.

Is there anything else you would like to share with PharmaBoardroom's global audience?

Our goal is to work together with the broader community to help end the HIV epidemic for everyone, everywhere. We are proud of the progress that has been made in the development of effective treatments, helping people living with HIV. At the same time, not everyone living with HIV has access to treatment and we are driven by developing people-centric innovations to address the remaining unmet needs, and also the evolving needs of people living with HIV. Only two out of three people living with HIV globally are virally suppressed, so closing the HIV treatment gap must be a top global priority.

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