The Evolution of HIV Innovation

Issue

An estimated 1.2 million people in the United States aged 13 and older are living with human immunodeficiency virus (HIV), and approximately one-in-seven are unaware that they have HIV.ⁱ HIV is a virus that attacks immune cells, making a person more vulnerable to other infections and diseases.ⁱⁱ Despite ground-breaking treatments that have slowed the progression and burden of HIV, treatment rates remain low – only 64 percent of those diagnosed with HIV are receiving medical care.ⁱⁱⁱ Moreover, the virus disproportionately impacts certain populations, particularly racial and ethnic minorities, youth, and people residing in the south-eastern Unites States.^{iv} Although currently no cure for HIV exists, innovative treatment options can help people living with HIV (PLWH) experience long, healthy, and productive lives and these same medicines can prevent HIV transmission.

ViiV Healthcare's Commitment to HIV Innovation

ViiV Healthcare (ViiV) is a global specialist HIV company established in November 2009 by GlaxoSmithKline (GSK) and Pfizer, with Shionogi joining the joint venture in 2012. ViiV is the only pharmaceutical company solely focused on combating, preventing, and ultimately curing HIV and AIDS, and our goal is to leave no patient behind. We strive to make HIV a smaller part of people lives by delivering advances in treatment and care for PLWH and for people who are at risk of becoming infected with HIV. Beyond developing innovative therapies, ViiV works with communities affected by HIV to address enduring disparities in HIV care and outcomes. ViiV has a long-established track record of proactively supporting numerous public campaigns to address HIV stigma, challenge social prejudice, and eliminate discrimination experienced by people living with and affected by HIV.

ViiV is proud of the scientific advances in the treatment of this disease since the Centers for Disease Control and Prevention (CDC) first established cases of a rare lung infection, later termed acquired immunodeficiency syndrome (AIDS), in a Morbidity and Mortality Weekly Report on June 5, 1981.^v Since the approval of azidothymidine (AZT) in 1987, the first antiretroviral therapy (ART) developed by a heritage GSK company, there have been major advancements HIV medicine. These advances in have transformed HIV from a terminal illness to a manageable chronic condition. In the early days of the epidemic, fewer than 50 percent of PLWH



Source: https://fight.org/hiv-medications/

were expected to survive the first year after diagnosis, whereas today PLWH can expect to live an average lifespan.^{vi} Thus, the scientific community has been able to focus on improving treatment regimens and care for PLWH, helping to reduce side effects and significantly reduce pill size and the number of pills required to a single, once-daily, fixed-dose tablet combining multiple drugs that suppress the virus to undetectable levels. ViiV pioneered the development of several new medicines and combination treatments for PLHIV. This includes antiretroviral medicines for treatment naïve (never undergone treatment), switch (changing medication) and highly treatment experienced (limited remaining options) populations. The innovation has continued with pre-exposure prophylaxis (PrEP) for the prevention of HIV. Further, the first long-acting complete regimen for the treatment of HIV is currently under review by the US Food and Drug Administration (FDA) and will be the newest revolutionary treatment for HIV and offer monthly injections as an alternative to daily oral regimens.

Viral Suppression and Treatment as Prevention

These significant advances have not only improved adherence and patient health outcomes but have also led to the scientific breakthrough that HIV treatment offers the added benefit of preventing onward transmission when a patient achieves sustained viral suppression." Viral suppression is defined as having fewer than 200 copies of HIV per milliliter of blood in one's body and means that the viral load is so low

that effectively there is no risk of transmitting the virus to others.^{vii} Viral suppression is the ultimate goal in

HIV treatment, however, only an estimated 53 percent of PLWH have achieved viral suppression.^{viii} The National Institutes of Health (NIH) and the CDC have endorsed treatment as prevention.^{ixx} Further, the National Institute of Allergy and Infectious Diseases (NIAID) supported research that demonstrated when PLWH achieve and maintain viral suppression, there is no risk clinically of transmitting HIV to their HIVnegative sexual partner.^{xi} The remarkable advancements in HIV treatment reaffirms the need to continue to bolster scientific innovation in HIV.

The HIV Care Continuum

The HIV Care Continuum is a public health model that quantifies success in each stage of HIV treatment from diagnosis to achieving viral suppression. The continuum is based on the prevalence of HIV in the US. Prevalence is the number of people living with HIV at a given time, regardless of when they were infected or whether they have received a diagnosis Despite innovative treatments, gaps remain between diagnosis and treatment, particularly for minority and LGBTQ populations and people living in the South. Supporting PLWH from diagnosis to viral suppression is key to health and wellness, and also to preventing new transmissions, yet only 56 percent of those diagnosed have achieved viral load suppression.xii Treating to viral load suppression saves state Medicaid programs an estimated \$1 million per treated patient by preventing an average of 2.65 transmissions over 50 years.xiii This can only occur, however, if PLWH are diagnosed, have access to medical care, receive treatment, and remain adherent to their prescribed therapy.



Conclusion

HIV remains one of the greatest public health challenges of our time. Since the 1980s, however, there have been remarkable scientific advances in the treatment of HIV. Forty years of data has revealed a clear path to progress in achieving optimal patient health among PLWH, preventing further transmissions, and ending the HIV epidemic. ViiV is proud to be at the forefront of HIV innovation. Now is not the time for complacency. ViiV Healthcare remains committed to discovering the next generation of HIV medicines and working with policy makers, the HIV advocacy community, and PLWH to ensure access to innovative, patient-centered treatments and to ensure that no PLWH is left behind. It is the mission of ViiV Healthcare to see the end of the HIV epidemic in our lifetime

* For HIV, Treatment is Prevention, Dr. Francis Collins, NIH Director's Blog, posted January 22, 2019

Accessed September 1, 2020.

¹ HIV Surveillance Report, Supplemental Report 2020:25(1), Estimated HIV Incidence and Prevalence in the United States 2014-2018, CDC. https://www.cdc.gov/hiv/statistics/overview/index.html. Accessed September 1, 2020.

[#]What is HIV? www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids. Accessed September 28, 2020.

[&]quot; HIV.gov, "HIV Care Continuum," https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum

^{iv} HIV.gov "Standing Up to Stigma" https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma

^v MMWR: Epidemiologic Notes and Reports, CDC. https://www.cdc.gov/mmwr/preview/mmwrhtml/june 5.htm. Accessed September 1, 2020.

vi Mortality Trends: Toward a New Definition of AIDS. TheBodyPro. https://www.thebodypro.com/article/mortality-trends-toward-newdefinition-aids. Accessed on July 16, 2020. ^{vii} HIV Treatment as Prevention, CDC. <u>https://www.cdc.gov/hiv/risk/art/index.html</u>. Accessed September 1, 2020.

viii CDC, Division of HIV/AIDS Prevention. https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-prevention-and-care-outcomes-2018.pdf. Accessed November 2, 2020.

^{ix} HIV Treatment as Prevention, CDC. <u>https://www.cdc.gov/hiv/risk/art/index.html</u>. Accessed July 16, 2020.

https://directorsblog.nih.gov/2019/01/22/for-hiv-treatment-is-prevention/. Accessed September 1, 2020.

xi NIAID, https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable. Accessed September 1, 2020. xii CDC, Division of HIV/AIDS Prevention. https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum (slide 26).

xiii Skarbinski, et al. JAMA Intern Med. 2015;175(4):588-596. doi:10.1001/jamainternmed.2014.8180. Published online February 23, 2015.