



## **ViiV Healthcare's Position on Continuous Innovation in Prevention, Testing, Treatment & Care of HIV**

ViiV Healthcare is a company 100% committed to HIV, and we are always looking to move beyond the status quo and find new ways of navigating the challenges of the HIV epidemic. While tremendous progress has been made over the past 30 years, the HIV landscape is constantly changing. We are using our heritage and expertise to refine our approach and map an HIV free future, leaving no patient behind. We are a patient-centric company with patients at the forefront of all our decisions.

We will work in partnership with all stakeholders and policy-makers in order to

1. Focus on key affected populations
2. Focus on most impacted geographies
3. Support priority interventions with meaningful partnerships.

By working in conjunction with key stakeholders, we can achieve better outcomes for people impacted by the disease through expertise-sharing, synergy of partnerships, innovative R&D, and ensuring that the care provided supports PLHIV to lead healthy and full lives.

### **The Issue**

Over the past few decades, ongoing innovations in the field of HIV have transformed the once fatal illness into a chronic condition. With lifelong access to HIV treatment, people living with HIV (PLHIV) today can expect a life expectancy comparable to those without the condition.<sup>i</sup>

However, it is clear that further innovation in treatments and services is urgently needed in order to prevent the HIV epidemic from accelerating ahead of efforts to manage it.<sup>ii</sup> In 2015, of the 36.7 million PLHIV globally, an estimated 60% knew their HIV status, 46% were on antiretroviral therapy, and 38% had achieved viral suppression, UNAIDS concluded in their 2016 Gap Prevention Report 'efforts to reach fewer than 500,000 new HIV infections by 2020 are off-track'.<sup>iii</sup> Over the next 10 years, most of the current PLHIV will require antiretroviral treatment (ART).<sup>iv,v</sup>

Progress also remains to be made in ensuring that the impact of HIV on quality of life is minimised. This issue will continue to become particularly acute as PLHIV age and co-morbidities develop, both related to HIV and otherwise.

Significant advances in combination therapy have been instrumental in improving the quality of lives and life expectancy for PLHIV. However, in the absence of a cure, sustained investment and innovation is required to address the evolution of HIV as it develops resistance to current treatment options and also to continue to focus on advances to improve adherence and quality of life for PLHIV. Treatment innovation is therefore fundamental to future efforts to combat HIV. However, innovation will also need to occur across the care continuum.

The UNAIDS 90-90-90 strategy, which sets out targets to end the HIV epidemic by 2030, has built expectations of continued innovations into its projections and the strategy warns that without this progress, we may see a progressive expansion of the HIV burden globally.<sup>vi</sup> It is clear that innovation will need to come in all forms.

Firstly, there is a need for continued innovation in the delivery of existing interventions.<sup>vii</sup> Diagnostic and therapies already at our disposal are not always being appropriately deployed. For example, in 2014 only 32% of children living with HIV were being prescribed treatment.<sup>viii</sup> Treatment as prevention represents a further case study of a key innovation that could be one of the most powerful elements of HIV response strategies; however, this has yet to be implemented to full effect in most countries.<sup>ix</sup>

Secondly, new tools must be developed that can respond to the changing needs of the epidemic.<sup>x</sup> As the existing population of PLHIV increases and ages, due to the reduction in mortality rates, treatment strategies will need to adapt to the realities of a lifetime of living with HIV, including managing and treating multiple co-morbidities. Furthermore, diagnostic and therapies will also need to be developed that meet the needs of those populations that are currently not adequately served by existing treatments.

Additionally, as the virus mutates and develops resistance to current ART, new medicines need to be developed in advance and be readily available to patients with limited treatment options. Achieving this will require sustained innovation and investment in order to maintain a healthy R&D pipeline for new HIV therapies with novel mechanisms of action. As seen with the global crisis posed by antimicrobial resistance to existing antibiotics, reduction in sustained investment and innovation could result in a serious shortage of available therapies for future use with potentially grave consequences.

Finally, it is clear that innovation will be required at each step of the pathway in order to reach the 2020 UNAIDS targets of 90-90-90.<sup>iii</sup> Currently there is an estimated gap of 10.9 million PLHIV who know their status in order to reach the first 90 and a gap of 12.7 million PLHIV on antiretroviral treatment to reach the second 90 and 13 million to reach the third 90,

## ViiV Healthcare's Position

In the coming years, innovation in treatments and care need to continue to deliver significantly better outcomes for PLHIV, and society as a whole. The HIV community must ensure that the global public policy environment continues to incentivise the development of new and better treatments and care for PLHIV.

In particular, the points below should be considered by all HIV stakeholders:

- Much progress has been made in the 30 years of the HIV epidemic, through the investment in and use of innovative treatments. However, the recent UNAIDS Gap Prevention report showed progress towards the 90-90-90 goals in 2015 was actually 60-46-38. The report itself summarises targets for 2020 are 'off-track'.<sup>iii</sup> If we hope to get 'back on track' we need to continuously innovate.
- Research and development in new treatments to meet unmet medical needs for PLHIV (both naïve and treatment experience) remains a cornerstone of innovation in the field. The key to ensuring innovation that delivers improved patient and societal outcomes is in maintaining open access for patients to a wide range of therapeutic options. This allows physicians to tailor treatment regimens specific to the needs of individual patients, whilst also enabling the development of the real world clinical data and evidence that contributes to innovation.<sup>xi</sup> It has also become clear, however, that to meet the goal of ending the AIDS epidemic that there is an urgent need that innovation must go beyond medicines: from prevention, through diagnosis, access to treatment and throughout the whole care continuum.
- ViiV Healthcare is committed to research and innovation that includes, but is not limited to, novel HIV drug development. Innovations in treatment regimens, drug delivery methods, HIV diagnostics, dosage regimens, adherence, preventative and support measures are all equally relevant and require sustained investment in order to improve patient outcomes.
- Collaboration between stakeholders is key for continued innovation. Only by working together with patients, academic institutions, patient advocacy groups, not-for-profit organisations in the healthcare community and other pharmaceutical and biotechnology companies, will we be able respond to the demands of an evolving epidemic. Fixed-dose co-formulations is but one example of excellent collaboration that has improved patient adherence, outcomes and reduced drug resistance.<sup>xii</sup>
- Pricing and reimbursement policies should reflect the value that innovation delivers for PLHIV and society as a whole.<sup>xiii</sup> This not only includes the impact on quality of life for PLHIV, but the wider impact to the economy as well as the preventative impact of reducing onwards transmission. Innovation that results in better treatment for PLHIV should be considered as a cost-effective, long term investment by all stakeholders, including governments and national health systems.

- Research into care approaches and HIV treatment regimens should be designed to demonstrate how well PLHIV can lead full and productive lives whilst minimising the societal and economic impact of HIV. In order to better measure this, PLHIV should be included in the development of 'implementation science' investigating innovative strategies to engage PLHIV along the whole care continuum as well as research into products. All stakeholders should take into consideration patient insights, patient reported outcomes, information about unmet needs and expectations that can add value and ultimately deliver improved care.
- Clinical trials of HIV treatment regimens, for example, should be designed, with the involvement of patient groups or representatives, to demonstrate beyond efficacy and safety, how well PLHIV can lead full, active and productive lives, thereby minimising the societal and economic impact of HIV.
- ViiV Healthcare looks to partner with external stakeholders around innovative approaches to continue to fund and invest in research, treatment and care. For instance, ViiV Healthcare collaborates with the Medicines Patent Pool (MPP). The MPP is a United Nations backed organisation founded in 2010 to increase access to HIV treatment and to help spur new innovation worldwide. ViiV Healthcare first began discussions with the MPP in early 2010, which in 2013 resulted in a partnership that granted the MPP a voluntary licence to its intellectual property for paediatric formulations. In 2014, ViiV Healthcare extended its voluntary licensing programme with MPP to Tivicay (dolutegravir), including its paediatric formulations (which are under development).<sup>xiv</sup>

## Conclusion

As a specialist HIV company, ViiV Healthcare is focused on continuing to improve health outcomes for PLHIV and society. Until a cure is found, ongoing research and development will continue to play a crucial part in tackling the HIV epidemic, providing options that deal with the different needs associated with managing a chronic disease.

ViiV Healthcare is focused on finding new medicines to improve outcomes for PLHIV. This includes understanding how best to prevent and treat the disease and careful monitoring of how the virus evolves resistance to treatment. We develop drugs with novel mechanisms of action in order to provide new treatment options for PLHIV who may be resistant to, or unsuitable for, existing treatments. However, in addition we are also committed to innovation across the care continuum and recognise innovation across this spectrum is vital to reaching the UNAIDS 90-90-90 strategy and ending the epidemic by 2030.

ViiV Healthcare is committed to partner with external stakeholders to develop innovative approaches to fund and invest in research, treatment and care. Establishing an environment that fosters innovation requires a collaborative response from all stakeholders including the governments, payers and national health systems, and industry. Uncertainty in investing and supporting innovation in HIV may, in the



short term, lead to a decline in the quality of treatment options and the number of patients able to access treatment. In the longer term, disinvestment risks undermining, and potentially undoing, the progress made to date in increasing treatment coverage, reducing mortality from HIV and reducing the spread of HIV.<sup>xv</sup>

ViiV Healthcare is committed to finding a cure for HIV. However, without the incremental improvements that come from innovations through continued investment in research and development and collaboration across stakeholders, we are unlikely to ever reach that goal.

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<sup>i</sup> NHS Choices. What is the life expectancy for someone with HIV?.

<http://www.nhs.uk/chq/Pages/3106.aspx?CategoryID=118&SubCategoryID=126>. Accessed July 2016.

<sup>ii</sup> WHO. Innovation and new technologies needed to accelerate HIV response. Opening Remarks.

[http://www.who.int/dg/speeches/2011/hiv\\_20110609/en/](http://www.who.int/dg/speeches/2011/hiv_20110609/en/). Accessed July 2016.

<sup>iii</sup> UNAIDS. Prevention Gap Report. 2016. <http://www.unaids.org/en/resources/documents/2016/prevention-gap> last accessed July, 2016

<sup>iv</sup> WHO. Innovation and new technologies needed to accelerate HIV response. Opening Remarks.

[http://www.who.int/dg/speeches/2011/hiv\\_20110609/en/](http://www.who.int/dg/speeches/2011/hiv_20110609/en/). Accessed July 2016.

<sup>v</sup> UNAIDS. The Gap Report. 2014. <http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport> last accessed July, 2016

<sup>vi</sup> UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic. 2014.

[http://www.unaids.org/sites/default/files/media\\_asset/90-90-90\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf) Accessed July 2016.

<sup>vii</sup> WHO. Innovation and new technologies needed to accelerate HIV response. Opening Remarks.

[http://www.who.int/dg/speeches/2011/hiv\\_20110609/en/](http://www.who.int/dg/speeches/2011/hiv_20110609/en/). Accessed July 2016.

<sup>viii</sup> UNICEF fact sheet. <http://data.unicef.org/hiv-aids/paediatric.html>. Accessed July 2016.

<sup>ix</sup> AIDSMAP. HIV treatment as prevention. Press Release. <http://www.aidsmap.com/HIV-treatment-as-prevention/page/1270646/>. Accessed July 2016.

<sup>x</sup> WHO. Innovation and new technologies needed to accelerate HIV response. Opening Remarks.

[http://www.who.int/dg/speeches/2011/hiv\\_20110609/en/](http://www.who.int/dg/speeches/2011/hiv_20110609/en/). Accessed July 2016.

<sup>xi</sup> The Value of Innovation in HIV/AIDS Therapy. Boston Healthcare. <http://www.phrma.org/sites/default/files/pdf/2014-bha-report-hiv-aids.pdf>. Accessed July 2016.

<sup>xii</sup> Kauf TL, Davis KL, Earnshaw SR, Davis EA. Spillover adherence effects of fixed-dose combination HIV therapy. *Patient preference and adherence*. 2012;6:155-164. doi:10.2147/PPA.S28482.

<sup>xiii</sup> The Value of Innovation in HIV/AIDS Therapy. Boston Healthcare. <http://www.phrma.org/sites/default/files/pdf/2014-bha-report-hiv-aids.pdf>. Accessed July 2016.

<sup>xiv</sup> The Medicines Pool Patent Project. <http://www.medicinespatentpool.org/current-licences/>. Accessed July 2016.

<sup>xv</sup> UNAIDS. The Gap Report. 2014. <http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport> Accessed July 2016.