

Bictegravir/emtricitabine/tenofovir Alafenamide for the Treatment of People Living with HIV

An expert interview with Josep Mallolas¹

1. HIV-AIDS Unit, Hospital Clínic de Barcelona, Barcelona, Spain

DOI: <https://doi.org/10.17925/ID.2022.1.1.12>



Josep Mallolas

Dr Josep Mallolas is currently head of the HIV-AIDS Unit of the Hospital Clínic de Barcelona, and senior consultant of the Infection Service of the same hospital. He is an associate professor of medicine and co-director and professor of the Master of AIDS at the University of Barcelona Faculty of Medicine. In addition, he is a principal investigator in numerous clinical and translational research studies, being a researcher at Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS) within the Infectious Diseases and AIDS-HIV team.

Keywords

HIV, AIDS, real-world, treatment-naïve, bictegravir, TAF, integrase inhibitor

Disclosure: Josep Mallolas received honoraria as speaker or for AB from Gilead, ViiV, MSD and Janssen.

Acknowledgements: Medical writing assistance was provided by Katrina Mountfort, freelancer, and funded by Touch Independent Medical Education.

Review process: This is an expert interview and as such has not undergone the journal's standard peer review process.

Compliance with ethics: This article is an opinion piece and does not report on new clinical data, or any studies with human or animal subjects performed by any of the authors.

Data availability: Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study/during the writing of this article.

Authorship: The named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship of this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval for the version to be published.

Access: This article is freely accessible at touchINFECTIOUSDISEASES.com. © Touch Medical Media 2021

Received: 29 October 2021

Published online: DD Month 2022

Citation: *touchREVIEWS in Infectious Diseases*. 2022;1(1):12–3

Corresponding author: Josep Mallolas, HIV-AIDS Unit, Hospital Clínic de Barcelona, 170, 08036, Barcelona, Spain. E: authorone@uni.com

Support: No funding was received for the publication of this article.

As a result of prolonged virologic suppression, improved clinical outcomes and longer survival, patients with HIV are exposed to anti-retroviral agents for decades. Despite advances in anti-retroviral therapy, many people living with HIV and taking long-term anti-retroviral therapy have a high symptom burden.¹ Bictegravir is a potent integrase strand-transfer inhibitor (INSTI) with a high barrier to resistance.² The single-tablet regimen of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF; Biktarvy®, Gilead Sciences, Inc., Foster City, CA, USA) has been shown to be safe and effective in a number of clinical studies.^{3–5} The real-world Bictegravir single tablet regimen (BICSTaR) study is designed to evaluate the effectiveness and safety profile of B/F/TAF in routine clinical practice in people living with HIV.

In an expert interview, Josep Mallolas discusses the B/F/TAF regime and the BICSTaR study.

Q. Could you tell us a little about bictegravir/emtricitabine/tenofovir alafenamide and its mechanism of action?

B/F/TAF is the smallest integrase strand inhibitor-containing single-tablet regimen, and is indicated as a complete regimen for both treatment-naïve and virologically suppressed patients. B/F/TAF has demonstrated high virologic suppression rates and non-inferior efficacy compared with dolutegravir, elvitegravir/cobicistat and protease inhibitor-based regimens, regardless of baseline viral load and CD4 count.

Q. What were the aims and design of the BICSTaR study?

To evaluate the effectiveness and safety of B/F/TAF in treatment-naïve and treatment-experienced people living with HIV in a real-world setting. In this analysis we report pooled 12-month effectiveness and safety data for 1,135 people living with HIV receiving B/F/TAF in routine clinical care across Europe, Canada and Israel.

Q. What were the real-world efficacy and safety findings from this study?

B/F/TAF demonstrated effectiveness and persistence at 12 months. Furthermore, the results were consistent across key populations (females, older individuals and individuals presenting late for HIV care), without emergence of resistance to the components of B/F/TAF. Regarding safety, there were no new or unexpected safety findings. Additionally, we observed statistically significant improvements in quality of life and reductions in the frequency of several bothersome symptoms in treatment-naïve participants. In treatment-experienced individuals, treatment satisfaction following a switch to B/F/TAF improved after 12 months of follow-up, despite the fact that it was

already high at baseline. In this real-world cohort of people living with HIV with a high prevalence of comorbidities (and in the setting of a global pandemic), the results continue to support the use of B/F/TAF in clinical practice. These findings were presented in a poster at the European Aids Conference, 2021.⁶

Q. What were the strengths and limitations of this study?

This is a real-world data setting, where the conditions under which patients receive the study drug are more representative of the general population compared with the narrow patient populations included in

randomised controlled trials (RCTs). With this study, and after RCTs have already demonstrated efficacy, we can measure effectiveness, which reflects whether the drug works in routine clinical practice. The main limitations of the study are the single-arm, non-comparative study design and the limited number of treatment-naïve patients enrolled.

Q. What questions remain unanswered and what future studies are planned?

It is important to explore the longer-term real-world use of B/F/TAF and this is why the BICSTaR study has been extended in Germany, Canada and France for a further 3 years. □

1. Cihlar T and Fordyce M. Current status and prospects of HIV treatment. *Curr Opin Virol.* 2016;18:50–6.
2. Tsiang M, Jones GS, Goldsmith J, et al. Antiviral activity of bictegravir (GS-9883), a novel potent HIV-1 integrase strand transfer inhibitor with an improved resistance profile. *Antimicrob Agents Chemother.* 2016;60:7086–97.
3. Wohl DA, Yazdanpanah Y, Baumgarten A, et al. Bictegravir combined with emtricitabine and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV.* 2019;6:e355–63.
4. Stellbrink H-J, Arribas JR, Stephens JL, et al. Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV.* 2019; 6: e364–72.
5. Gallant J, Lazzarin A, Mills A, et al. Bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection (GS-US-380-1489): a double-blind, multicentre, phase 3, randomised controlled non-inferiority trial. *Lancet.* 2017;390:2063–72.
6. Mallolas J. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) for the treatment of people living with HIV (PLWH): 12-month (12M) effectiveness, persistence, and safety in a multi-country cohort study. Presented at: EACS, Virtual & London, 28, October, 2021. #PE2/57.