

# Consistent Weight/Body Mass Index Change by Race, Sex, and Ethnicity After Switching From Tenofovir Disoproxil Fumarate to Tenofovir Alafenamide on a Protease Inhibitor–based Regimen

Keith Dunn,<sup>1,\*</sup> Erika Van Landuyt,<sup>2</sup> Shubin Sheng,<sup>3</sup> Jiyun Cai,<sup>3</sup> Donghan Luo,<sup>3</sup> Amanda Gibson,<sup>1</sup> Bryan Baugh<sup>4</sup>

<sup>1</sup>Janssen Scientific Affairs, LLC, Titusville, NJ, USA; <sup>2</sup>Janssen Research & Development, Beerse, Belgium; <sup>3</sup>Janssen Research & Development, LLC, Titusville, NJ, USA; <sup>4</sup>Janssen Research & Development, LLC, Raritan, NJ, USA.

\*Presenting author.

## INTRODUCTION

- The US Department of Health and Human Services recognizes that certain antiretroviral therapy (ART) regimens may be associated with weight gain
  - Recent data have shown greater weight gain among patients switching from a tenofovir disoproxil fumarate (TDF)–containing regimen to a tenofovir alafenamide (TAF)–containing regimen, especially in the setting of an integrase inhibitor (INI)<sup>1-3</sup>
- Moreover, ART-associated weight gain appears to disproportionately affect Black or African American, female, and Hispanic patients<sup>1</sup>
- In the phase 3 EMERALD study, treatment-experienced, virologically suppressed patients switching from a boosted protease inhibitor (bPI)–based regimen to darunavir/cobicistat/emtricitabine/TAF (D/C/F/TAF) experienced a median weight change of +1.8 kg at Week 96, indicating a small weight increase in the overall population<sup>4</sup>
  - Similar changes in weight were observed in treatment-naïve patients receiving D/C/F/TAF over 96 weeks<sup>5</sup>
- This post hoc analysis evaluated changes in weight and body mass index (BMI) in EMERALD patients based on race, sex, and ethnicity

## OBJECTIVE

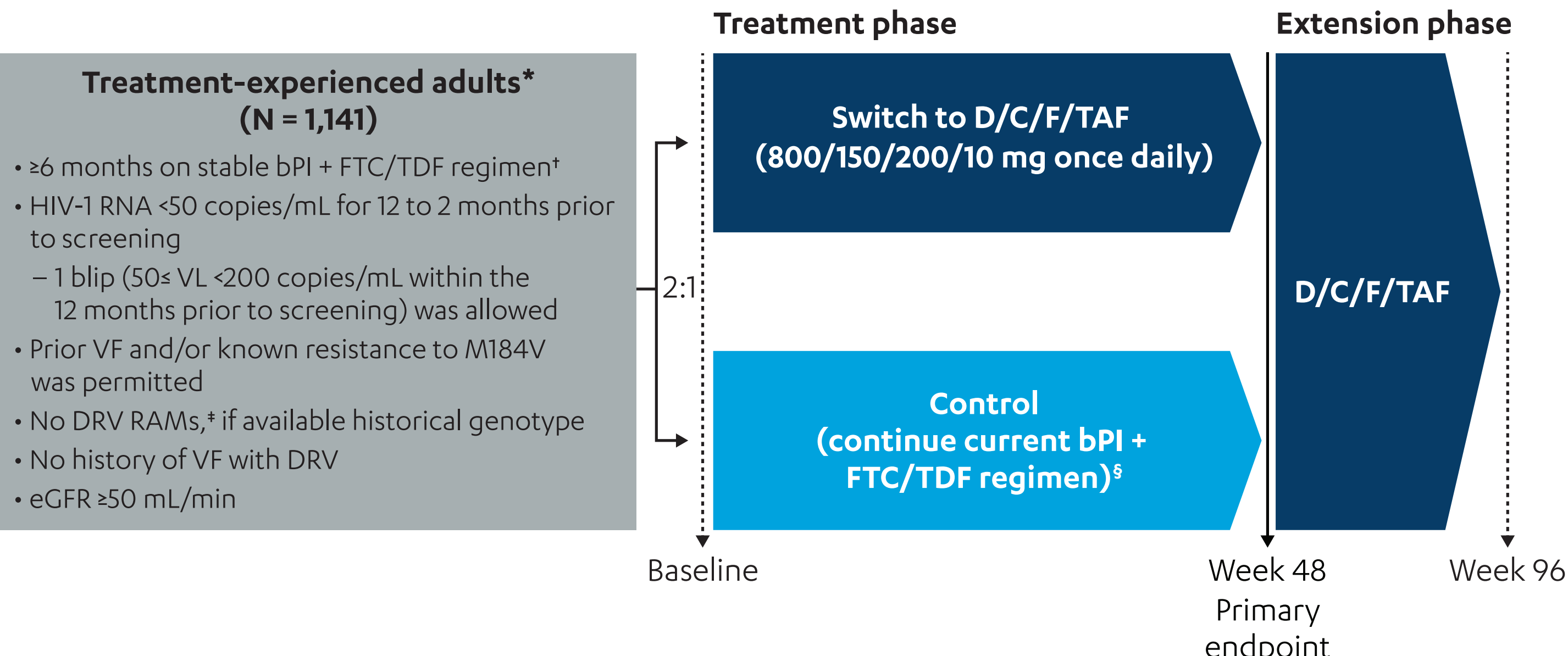
- To evaluate changes in weight and BMI from baseline in EMERALD patients according to race, sex, and ethnicity at Weeks 48 and 96

## METHODS

### Study Design

- The EMERALD (ClinicalTrials.gov Identifier: NCT02269917) study design<sup>4,6</sup> is summarized in **Figure 1**

Figure 1. Study design.



FTC, emtricitabine; HIV-1, human immunodeficiency virus-1; VL, viral load; VF, virologic failure; DRV, darunavir; RAM, resistance-associated mutation; eGFR, estimated glomerular filtration rate; IAS-USA, International Antiviral Society–USA; ATV, atazanavir; rtt, ritonavir; COBI, cobicistat; LPV, lopinavir. \*Patients were stratified by bPI at screening prior to randomization. Prior experience with multiple antiretroviral drugs was allowed, and there was no restriction on the number of non-DRV prior VFs. †Prior use of boosted DRV was allowed. ‡IAS-USA DRV RAMs. †bPI was ATV with rtt or COBI, DRV with rtt or COBI, or LPV with rtt.

### Analyses

- In this post hoc analysis, changes in weight and BMI from baseline were assessed at Weeks 48 and 96
- Results were evaluated in subgroups based on race (Black or African American/White/other), sex (male/female), and ethnicity (Hispanic/non-Hispanic)

## RESULTS

### Patients

- As reported previously, baseline demographics were similar across treatment arms<sup>6</sup>
- Median weight and BMI were generally similar across subgroups and treatment arms at baseline (**Table 1**)
  - Both median weight and BMI were higher for Black or African American patients than for those in comparator race subgroups
  - Males had a higher median weight but lower median BMI than females

Table 1. Baseline Weight and BMI Based on Demographic Subgroup\*

|                                            | Control (N = 378)           | D/C/F/TAF (N = 763)         |
|--------------------------------------------|-----------------------------|-----------------------------|
| <b>Weight, median (IQR), kg</b>            |                             |                             |
| <b>Race</b>                                |                             |                             |
| Black or African American                  | 81.8 (71.4; 94.3) (n = 82)  | 82.9 (71.6; 93.6) (n = 155) |
| White                                      | 76.1 (67.6; 86.0) (n = 282) | 76.9 (68.0; 88.5) (n = 573) |
| Other                                      | 64.7 (56.0; 79.2) (n = 12)  | 70.3 (59.0; 76.7) (n = 29)  |
| <b>Sex</b>                                 |                             |                             |
| Male                                       | 78.2 (69.0; 87.9) (n = 313) | 79.0 (70.1; 90.0) (n = 623) |
| Female                                     | 69.4 (59.5; 86.7) (n = 65)  | 68.8 (58.0; 82.8) (n = 140) |
| <b>Ethnicity</b>                           |                             |                             |
| Hispanic                                   | 74.6 (65.0; 85.7) (n = 59)  | 75.5 (67.0; 87.5) (n = 111) |
| Non-Hispanic                               | 77.2 (68.1; 88.4) (n = 317) | 78.0 (68.9; 89.5) (n = 649) |
| <b>BMI, median (IQR), kg/m<sup>2</sup></b> |                             |                             |
| <b>Race</b>                                |                             |                             |
| Black or African American                  | 27.4 (23.9; 30.2) (n = 82)  | 27.8 (24.8; 32.3) (n = 155) |
| White                                      | 24.5 (22.3; 27.9) (n = 282) | 24.9 (22.4; 28.4) (n = 572) |
| Other                                      | 25.0 (22.6; 25.7) (n = 12)  | 24.2 (22.8; 26.2) (n = 29)  |
| <b>Sex</b>                                 |                             |                             |
| Male                                       | 24.7 (22.5; 28.0) (n = 313) | 25.3 (22.7; 28.5) (n = 623) |
| Female                                     | 25.7 (23.2; 30.2) (n = 65)  | 26.9 (22.8; 31.2) (n = 139) |
| <b>Ethnicity</b>                           |                             |                             |
| Hispanic                                   | 24.8 (22.4; 29.3) (n = 59)  | 26.1 (23.7; 28.7) (n = 111) |
| Non-Hispanic                               | 24.8 (22.6; 28.2) (n = 317) | 25.3 (22.5; 29.2) (n = 648) |

IQR, interquartile range. \*n values indicate the number of patients in each subgroup with available weight data.

### Outcomes

- Among patients in the Black or African American, female, and Hispanic subgroups switching to D/C/F/TAF, median change from baseline in weight ranged from 1.3 to 1.7 kg through Week 48 and was 2.0 kg through Week 96 (**Figure 2**)
- Across the same subgroups, median change from baseline in weight through Week 48 in the control arm ranged from 0.0 to 0.7 kg
- For patients in the Black or African American, female, and Hispanic subgroups switching to D/C/F/TAF, median change from baseline in BMI ranged from 0.5 to 0.7 kg/m<sup>2</sup> through Week 48 and from 0.7 to 0.8 kg/m<sup>2</sup> through Week 96 (**Figure 3**)
- Median change in BMI through Week 48 in the control arm ranged from 0.0 to 0.2 kg/m<sup>2</sup> across the same subgroups

Figure 2. Median (IQR) change in weight based on demographic subgroup.

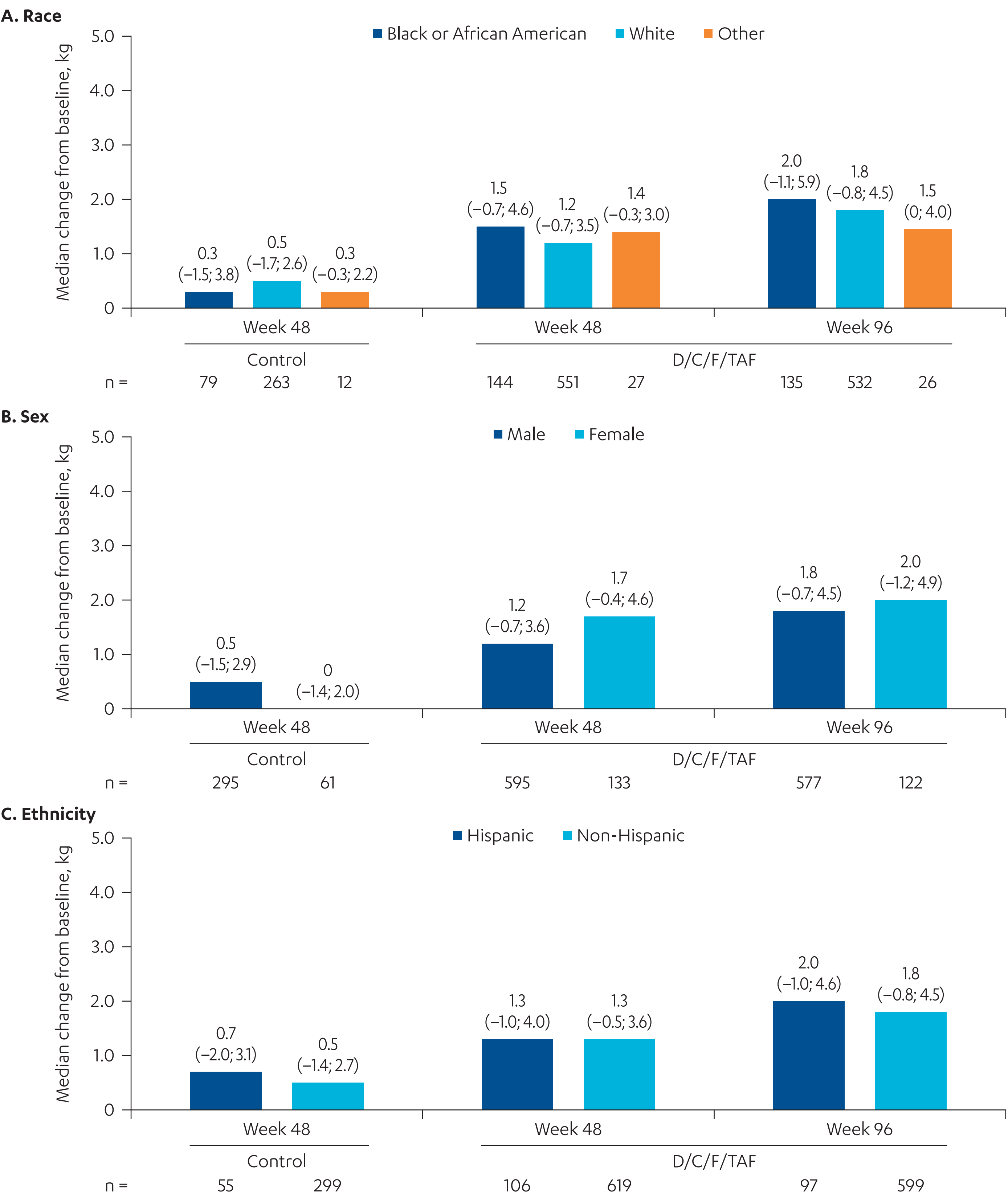
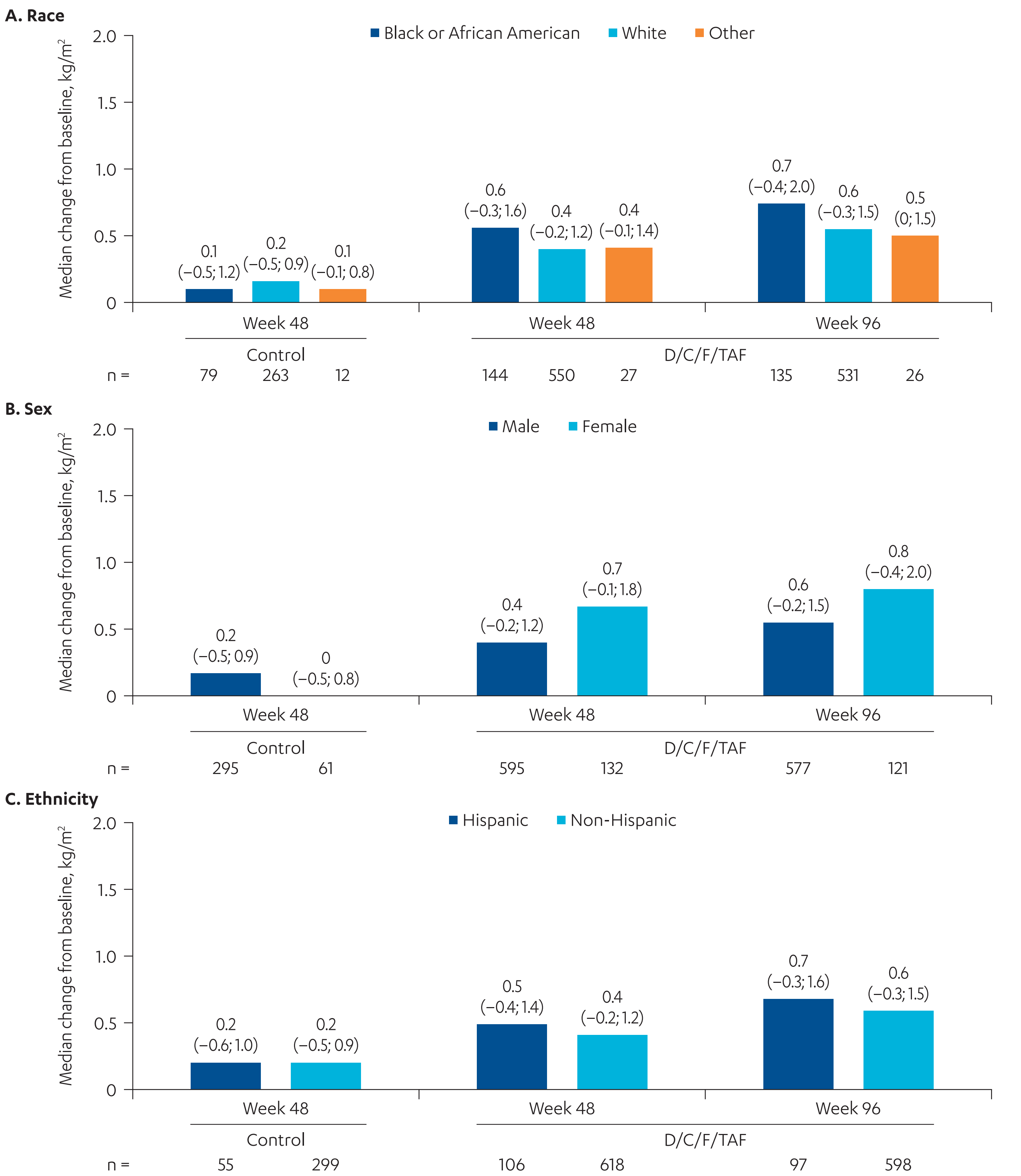


Figure 3. Median (IQR) change in BMI based on demographic subgroup.



## CONCLUSIONS

- Across demographic subgroups, including race, sex, and ethnicity, consistent and relatively small changes in weight (≤2.0 kg at Week 96) and BMI (≤0.8 kg/m<sup>2</sup> at Week 96) were observed when switching from TDF to TAF in the background of a bPI
- Consistent with other data, small but numerically higher changes in weight and BMI were observed among Black or African American, female, and Hispanic patients with HIV-1
- Further studies should investigate outcomes in these subgroups when switching to regimens implicated in ART-related weight gain (ie, INI + TAF)

### REFERENCES

- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 29, 2021.
- Pajella FJ, et al. Weight gain among PWH who switch to ART containing INSTIs or TAF. Presented at: Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual.
- McComsey GA, et al. Weight change in suppressed people with HIV (PWH) switched from either tenofovir disoproxil fumarate (TDF) or abacavir (ABC) to tenofovir alafenamide (TAF). Presented at: IDWeek; October 21-25, 2020; Virtual.
- Eron JJ, et al. *Antiviral Res*. 2019;170:104543.
- Orkin C, et al. *AIDS*. 2020;34(5):707-718.
- Orkin C, et al. *Lancet HIV*. 2018;5(1):e23-e34.

### ACKNOWLEDGMENTS

Medical writing support was provided by Melanie Chen, PharmD, and Caryn Gordon, PharmD, of Cello Health Communications/MedErgy, and was funded by Janssen Scientific Affairs, LLC.

### DISCLOSURES

This study was sponsored by Janssen Scientific Affairs, LLC. KD, EVL, SS, JC, DL, AG, and BB are employees of Janssen and may be stockholders of Johnson & Johnson. KD, EVL, AG, and BB contributed to the analysis and interpretation of the data. SS, JC, and DL contributed to the statistical analysis and interpretation of the data. All authors contributed to the drafting of this poster and approved the final version. If you have any additional questions or would like to request a copy of this poster, call +1-800-JANSSEN (+1-800-526-7736) or go to [www.janssenMD.com](http://www.janssenMD.com).



An electronic version of the poster can be viewed by scanning the QR code. The QR code is intended to provide scientific information for individual reference. The PDF should not be altered or reproduced in any way.