Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) for the Treatment of People Living With HIV: 24-Month Analyses by Age, Race, Sex, Adherence and Late Diagnosis in a Multi-Country Cohort Study

Introduction

B/F/TAF is a guideline-recommended single-tablet regimen for the treatment of HIV-1 infection that can contribute to long-term treatment success in people living with HIV1

BICSTaR is a large, ongoing, multi-country, prospective, observational study that has enrolled 2,380 ARV treatment-naïve (TN) and treatment-experienced (TE) people in Europe (France, Germany, Ireland, Italy, the Netherlands, Spain, UK), Canada, Israel, Japan, Taiwan, South Korea and Singapore

Methods

In this planned analysis with a data cutoff of April 8, 2021, pooled 24-month effectiveness and safety data are presented for people receiving B/F/TAF in routine clinical care from France, Germany, Ireland, Italy, the Netherlands, Spain, UK, Canada, Israel, Japan, Taiwan, South Korea and Singapore

We describe data both in the overall population and in key groups related to sex, age, race, treatment adherence level, late diagnosis and prior use of TDF (for weight only)

"With exception of individuals with a late diagnosis, key group analyses were restricted to the TE group due to the small numbers in the TN group.

Study Design

BICSTaR

N = 1,076

Cutoff for analysis: April 8, 2021

24 months

24 months study outcomes included:

• CD4 cell count, BMI,* kg/m2

• Change from Baseline in CD4 cell count at 24 months – Overall Population

• Missing = Excluded analysis (n = 628)

• Discontinuation = Failure analysis (n = 732)

• Primary resistant mutation(s) at baseline: - NNRTI / NRTI / INSTI -

• Late presenters: CD4 < 350 cells/µL and/or 2 AIDS-defining events at baseline

• Late presenters: CD4 < 350 cells/µL, and/or 1 AIDS-defining event at baseline

Key Safety Data Through 24 Months

By sex (TE)

- TE group: 24% of people with a late diagnosis

- TN group: 11% of people with a late diagnosis

- TE group: 7% of females

- TN group: 5% of females

- People with < 50 years of age

- People ≥ 50 years of age

- People with other races*

- People with ≥ 90% adherence

- People with ≥ 99% adherence

Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>39 (36, 41)</td>
<td>39 (36, 40)</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>76 (66, 87)</td>
<td>74 (65, 83)</td>
</tr>
<tr>
<td>BMI, kg/m2</td>
<td>25 (22, 28)</td>
<td>24 (21, 27)</td>
</tr>
<tr>
<td>White</td>
<td>88%</td>
<td>85%</td>
</tr>
<tr>
<td>Black</td>
<td>9%</td>
<td>10%</td>
</tr>
<tr>
<td>Asian</td>
<td>3%</td>
<td>2%</td>
</tr>
</tbody>
</table>

*Population with weight and BMI data available at baseline and 24 months; †Calculated as changes from baseline to 24 months for each individual

Persistence

Participants reaching 24 months and still receiving B/F/TAF

118 (14%) of participants discontinued B/F/TAF through 24 months for any reason

18% of TN participants (n = 120)

27% of TE participants (n = 126)

Weight (kg) – Overall and Key Groups

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>By sex (TE)</th>
<th>By age (TE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (Q1, Q3)</td>
<td>69 (63, 73)</td>
<td>65 (58, 76)</td>
<td>75 (68, 83)</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>+6.1† (5.4)</td>
<td>+0.5 (4.2)</td>
<td>+1.2† (0.6)</td>
</tr>
</tbody>
</table>

* Population with weight and BMI data available at baseline and 24 months

Baseline (n = 104)* TDF, NRTI, PI, INSTI

118 (14%) of participants discontinued B/F/TAF through 24 months for any reason

By adherence (TE)

93% of people with ≥ 99% adherence

96% of people with ≥ 99% adherence

By race (TE)

94% of Black race

96% of people of other races*

By age (TE)

95% of people < 50 years

96% of people ≥ 50 years

By sex (TE)

97% of females

95% of males

By late diagnosis (< 350 cells/µL) (TN)

96% with late diagnosis

98% without late diagnosis

By adherence (TN)

99% with adherence

97% without adherence

Impact of adherence on late diagnosis

Change from Baseline in CD4 Cell Count at 24 Months – Overall Population

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>24 months</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (Q1, Q3)</td>
<td>424 (384, 484)</td>
<td>661 (610, 851)</td>
<td>+238</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>+48</td>
<td>+176 (12.3)</td>
<td>+86.5†</td>
</tr>
</tbody>
</table>

*Calculated as changes from baseline to 24 months for each individual participant

References


3. By age (76, 87) (n = 720/838) / 62 (7%) ‡

4. By race (TE) (66, 86) (n = 154/182) / 15 (16%) 89 (15%) 61 (17%) 43 (13%)

5. By sex (TE) (68, 88) (n = 120/135) / 15 (16%) 89 (15%) 61 (17%) 43 (13%)