

Errata to the Sponsor Briefing Document
Pulmonary-Allergy Drugs Advisory Committee (PADAC)
November 8, 2022

Note: Page number reflects the number at page bottom within document. Please see next page for corrected figure.

Errata to Sponsor Briefing Document

- Table A1, p.101

Age group	
12-<18 years	BDA MDI 80/180 modelled hazard ratio (95% CrI) [Events] “0.836 (0.497, 1.178) [83]” should read as “0.782 (0.497, 1.178) [83]”

- Figure 9, p.39

Sex	
Male	BDA 160/180 hazard ratio (95% CI) “0.613 (0.441, 0.850)” should read as “0.618 (0.444, 0.862)”
Female	BDA 160/180 hazard ratio (95% CI) “0.805 (0.648, 0.999)” should read as “0.796 (0.640, 0.989)”
Age group	
≥12 - <18	BDA 160/180 (95% CI) “(0.536, 3.869)” should read as “(0.537, 3.871)”
≥18 - <65	BDA 160/180 (95% CI) “(0.550, 0.834)” should read as “(0.549, 0.834)”
Race	
White	BDA 80/180 hazard ratio (95% CI) “0.801 (0.658, 0.975)” should read as “0.810 (0.667, 0.984)”
Black or African American	BDA 80/180 hazard ratio (95% CI) “0.921 (0.540, 1.572)” should read as “0.947 (0.580, 1.548)”
Other	BDA 80/180 hazard ratio (95% CI) “0.611 (0.287, 1.301)” should read as “0.572 (0.272, 1.204)”
Smoking Status	
Never Smoker	BDA 160/180 hazard ratio (95% CI) “0.765 (0.622, 0.941)” should read as “0.760 (0.617, 0.936)”
Region 2	
USA	BDA 160/180 hazard ratio (95% CI) “0.831 (0.594, 1.163)” should read as “0.878 (0.623, 1.237)”
Non-USA	BDA 160/180 hazard ratio (95% CI) “0.703 (0.567, 0.871)” should read as “0.684 (0.552, 0.847)”
Severe Exacerbations (last 12 months)	
1	BDA 160/180 hazard ratio (95% CI) “0.724 (0.586, 0.893)” should read as “0.719 (0.582, 0.887)”
>1	BDA 160/180 (95% CI) “(0.544, 1.107)” should read as “(0.542, 1.110)”
Maintenance therapy at baseline (GINA 2020)	
Low dose ICS-LABA or medium dose ICS ^d	BDA 160/180 hazard ratio (95% CI) “0.591 (0.411, 0.850)” should read as “0.603 (0.417, 0.872)”
Medium dose ICS-LABA or high dose	BDA 160/180 hazard ratio (95% CI) “0.808 (0.608, 1.074)” should read as “0.803 (0.608, 1.069)”
High dose ICS-LABA	BDA 160/180 hazard ratio (95% CI) “0.787 (0.576, 1.074)” should read as “0.766 (0.561, 1.047)”
Baseline FEV₁	
<60% PN	BDA 160/180 hazard ratio (95% CI) “0.746 (0.558, 0.998)” should read as “0.751 (0.561, 1.005)”
≥60% PN	BDA 160/180 hazard ratio (95% CI) “0.723 (0.573, 0.912)” should read as “0.713 (0.565, 0.901)”

Figure 9 Subgroup Analysis of Time to First Severe Asthma Exacerbation During the Randomized Treatment Period, Cox Regression Forest Plot, Efficacy Estimand (Full Analysis Set; BDA 160/180 ≥12 and BDA 80/180 All Ages) – MANDALA



^a Comparison for BDA 160/180 vs AS MDI 180 mcg is in subjects 12 years and older.

^b Subgroup analysis by race was not prespecified.

^c Prior to randomization.

^d With or without an additional LTRA, LAMA, or theophylline.