

**ERRATA SHEET
TO THE ARTHRITIS ADVISORY COMMITTEE
BRIEFING MATERIALS**

NINTEDANIB SOFT CAPSULES

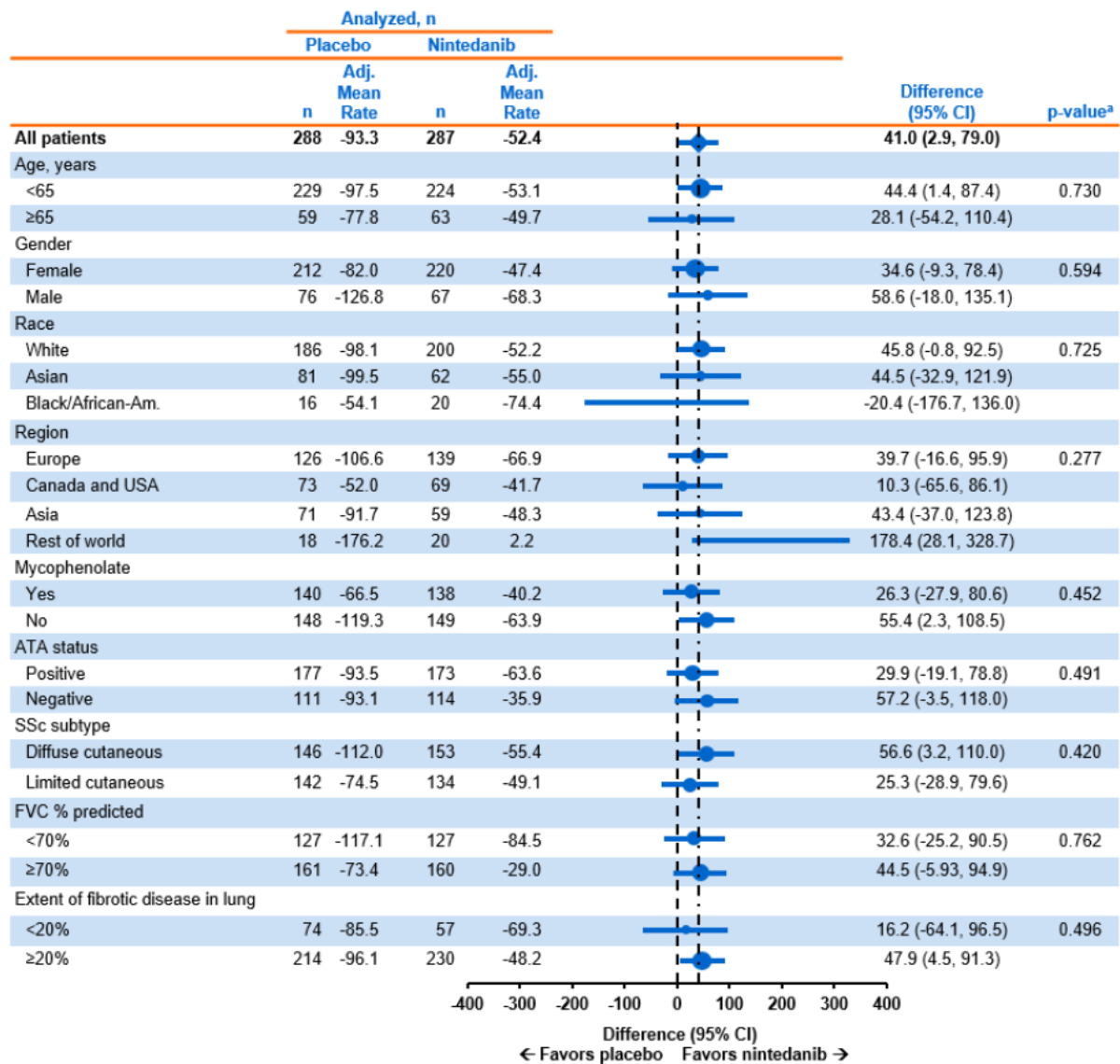
INDICATION: Treatment of systemic sclerosis-associated interstitial lung disease

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AVAILABLE FOR PUBLIC RELEASE

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Figure 14 of the briefing materials contains errors. The graphical display of the point estimates and 95% confidence intervals for the subgroups of age ≥ 65 years and male gender was incorrect. These errors have been corrected in Figure 1 below.



^a treatment-by-time-by-subgroup interaction

The subgroup of patients with mycophenolate use at baseline comprised patients who took mycophenolate mofetil and sodium; however, 3 patients who took mycophenolic acid were allocated to the subgroup of patients without concomitant mycophenolate use at baseline, based on an incomplete specification in the trial statistical analysis plan detected only after database lock. This was later confirmed as not having an influence on the interpretation of the results of this subgroup.

Figure 1 Forest plot of the rate of decline in FVC [mL/year] over 52 weeks in subgroups in the SENSICIS trial (corrected) - TS