

SECTION A - Clarifications of the CONFIRM data:

A3. If available for each study arm and the overall trial population, for previous adjuvant therapy and previous advanced disease therapy, please provide the proportion of patients who received previous endocrine therapy with an anti-oestrogen (AO) only, aromatase inhibitor (AI) only and both an AO and AI (as in the 'Adjuvant therapy' and 'Advanced disease therapy' rows in table B6 on p47 of the submission).

Response to A3: **XXXXXXXXXXXXXXXXXX**

A4. If available for each study arm and the overall trial population, for previous adjuvant therapy and previous advanced disease therapy, please provide the baseline characteristics (as in Table B6 of the MS) and the findings for overall survival (OS), time to progression (TTP) and overall response rate (ORR) for patients who received previous endocrine therapy with an AO only, AI only and both an AO and AI.

Response to A4: **XXXXXXXXXXXXXXXXXX**