

Safety

- Any TEAE leading to dose delay occurred in 5 (33%) pts with low mSWAT and 6 (40%) pts with high mSWAT
 - Drug-related TEAE dose delay occurred in 1 (7%) and 4 (27%) pts, respectively
- Any TEAE leading to dose reduction occurred in 2 (13%) pts with low mSWAT and 1 (7%) pts with high mSWAT (all drug-related)
- Any TEAE leading to study drug discontinuation occurred in 1 (7%) pts with low mSWAT and 4 (27%) pts with high mSWAT
 - Drug-related TEAE leading study drug discontinuation occurred in 1 (7%) and 3 (20%) pts, respectively
- Only 1 TEAE resulting in death was reported in the high mSWAT group; the death was not drug-related
- Peripheral edema occurred in 11 (73%) of pts for both the low and high mSWAT groups; in the primary analysis, peripheral edema was the most common TEAE⁶