SINGLE-PILL COMBINATION OF TELMISARTAN 80 MG/AMLODIPINE 5 MG PROVIDES SUPERIOR BLOOD PRESSURE REDUCTIONS TO AMLODIPINE 5 MG IN HYPERTENSIVE PATIENTS WHO WERE UNCONTROLLED ON AMLODIPINE 5 MG MONOTHERAPY

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Objectives To investigate the efficacy and safety of the single-pill combination of telmisartan 80 mg plus amlodipine 5 mg (T80/A5 SPC) versus amlodipine 5 mg (A5) in hypertensive Asian patients who were uncontrolled on amlodipine 5 mg (A5) monotherapy (NCT01103960).

Methods Design and Methods After a 6-week open-label run-in period with amlodipine 5 mg monotherapy, patients, who failed to respond adequately to A5 (defined as seated DBP ≥90 mm Hg), underwent double-blind randomisation with 160 and 164 patients assigned to receive either T80/A5 SPC or A5 monotherapy daily. The primary endpoint was change from baseline in mean seated trough DBP after 8 weeks of randomised treatment. Treatment groups were compared using an Analysis of Covariance (ANCOVA) model including treatment, country and the baseline measurement as a covariate.

Results In the full population (n=314), seated trough mean±SE BP reductions (mm Hg) with T80/A5 vs A5 from baseline to week 8 were −16.2±1.5 vs −11.7±1.3 for SBP (p<0.001) and −12.4±0.95 vs −10.2 ±0.93 for DBP (p=0.007). T80/A5 provided DBP goal attainment (<140/90 mm Hg) in 64.5% vs 45.3% with A5 alone (p=0.007) and DBP response rate (<90 mm Hg or ≥10 mm Hg reduction) was 80.0% vs 65.5% (p=0.0017). The incidence of related AEs (including peripheral oedema) was low and similar in both treatments group.

Conclusions In Asian patients T80/A5 SPC provided superior BP reductions and goal rate achievement versus A5 monotherapy after 8 weeks of treatment, T80/A5 was well-tolerated and had a safety profile comparable to A5 monotherapy.