

SUPPLEMENTARY FIGURE 1 Trial design

*The 24h-urine collection and 8-point plasma profile from Day –1 to Day 1 could be performed at home depending on the patient’s experience, at the investigator’s discretion. †12 patients were not eligible for randomisation as follows: 10 patients did not meet the inclusion/exclusion criteria, 1 patient could not be randomised within the prespecified time-window, and 1 patient could not be randomised due to the maximum target for the female cohort being already achieved. ‡At least one-third, but no more than two-thirds, of participants to be female; §at least 6 participants to be <15 years of age. PK, pharmacokinetics; PD, pharmacodynamics.

SUPPLEMENTARY FIGURE 2 Arithmetic mean concentration-time profiles of empagliflozin in plasma (a, linear scale, sensitivity analysis for 5 mg dose excluding 2 physiologically implausible values; b, linear scale, individual empagliflozin concentrations of affected patient)

a) The mean empagliflozin plasma concentration for the 5 mg dose group at 48 h post dose was not calculated as only 3 participants values were available at this time point. b) One participant had 2 implausible high empagliflozin plasma concentrations at 8 h and 48 h postdose while the remainder of the plasma concentrations of this patient were within the expected range.

SUPPLEMENTARY FIGURE 3 Mean changes from baseline in micturition volume (including 95% confidence intervals) on Day 1 and Day 2 (adjusted for baseline micturition volume)