# Baseline Characteristics of Patients Enrolled in the Ongoing Phase 3 Randomized, Double-Blind, Active-Control Trial of Sparsentan for the Treatment of Focal Segmental Glomerulosclerosis (DUPLEX)

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- FSGS often follows a progressive course to chronic kidney failure<sup>1</sup> and has a profound negative impact on patient QOL and long-term survival<sup>2-4</sup>
- Sparsentan is a novel single molecule Dual Endothelin Angiotensin Receptor Antagonist (DEARA) being investigated for the treatment of FSGS<sup>5</sup>
- The ongoing Phase 3 DUPLEX study is examining the long-term antiproteinuric and nephroprotective efficacy and safety of sparsentan compared with an active control, the ARB irbesartan, in adults and pediatric patients with FSGS

## **Objective**

 To report the blinded and aggregated baseline characteristics for all patients enrolled in the DUPLEX trial

#### **DUPLEX Study Design**

- Ongoing, global, Phase 3, multicenter, randomized, double-blind, parallel-group, active controlled study (the final patient visit in the double-blind period is anticipated early 2023; EudraCT number: 2016-005141-23; US ClinicalTrials.gov identifier: NCT03493685)
- Double-blind period of 112 weeks followed by open-label extension up to 156 weeks
- Primary efficacy endpoint is the slope of eGFR over ~2 years of randomized treatment
- Surrogate efficacy endpoint is the proportion of patients achieving UP/C ≤1.5 g/g and a >40% reduction from baseline of the double-blind period in UP/C at Week 36
- Patients receiving RAASi underwent a 2-week washout prior to randomization
- Patients were randomized 1:1 to sparsentan (2-week titration to the target dose 800 mg/day) or irbesartan (2-week titration to the target dose 300 mg/day) stratified by screening eGFR and UP/C<sup>1</sup>

### **Patient Key Inclusion and Exclusion Criteria**

- Male or female aged 8-75 years (US/UK) or 18-75 years (outside US/UK) weighing ≥20 kg; biopsy-proven FSGS lesion or documentation of a genetic mutation in a podocyte protein associated with FSGS; at screening: UP/C ≥1.5 g/g, eGFR ≥30 mL/min/1.73m<sup>2</sup>
- Patients with a known secondary cause of FSGS were excluded
- 1. Target dose for patients weighing 20 kg-≤50 kg at screening is sparsentan 400 mg/day and irbesartan 150 mg/day.

## **Baseline Characteristics of Patients Enrolled in DUPLEX**

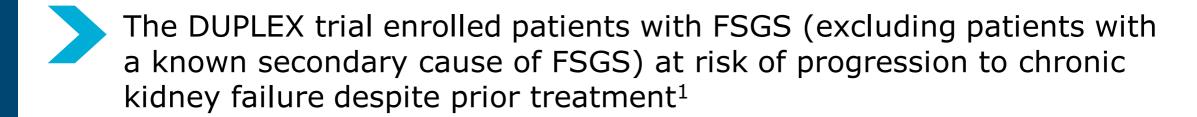
|  | Patients <sup>a</sup><br>(N=371) |
|--|----------------------------------|
| Age at informed consent, years, median (IQR)       | 42 (27.0, 56.0)                  |
| Age group 9 years to <18 years, n (%)              | 35 (9.4)                         |
| Female, n (%)                                      | 171 (46)                         |
| Race, n (%)  |                                  |
| White  | 276 (74)                         |
| Asian  | 50 (13)                          |
| Black or African American                          | 29 (8)                           |
| Other  | 22 (6)                           |
| Not Hispanic or Latino, n (%)                      | 281 (76)                         |
| Documented history of nephrotic syndrome, n (%)    | 112 (30.2)                       |
| History of hypertension, n (%)                     | 238 (64.2)                       |
| Systolic / diastolic blood pressure, mmHg, mean±SD | 131.9±14.9 /<br>83.8±10.5        |
| BMI, kg/m², mean±SD                                | 27.7±5.9                         |
| Serum creatinine, µmol/L, mean±SD                  | 124.5±49.3                       |
| Serum albumin, g/L, mean±SD/median (IQR)           | 34.9±7.4 /<br>36.0 (30.0, 40.0)  |

|   | Patients <sup>a</sup><br>(N=371) |
|---|----------------------------------|
| UP/C, g/g, median (IQR)                   | 3.0 (2.2, 4.6)                   |
| Nephrotic range UP/C, n (%)               |                                  |
| >3.5 g/g in adults (age ≥18 years)        | 124 (36.9)                       |
| >2.0 g/g in pediatrics (age <18 years)    | 34 (97.1)                        |
| eGFR, mL/min/1.73m², mean±SD/median (IQR) | 63.8±30.3 /<br>55.0 (41.0, 80.0) |
| eGFR, mL/min/1.73m², n (%)                |                                  |
| ≥90                                       | 70 (18.9)                        |
| ≥60 - <90                                 | 98 (26.4)                        |
| ≥45 - <60                                 | 79 (21.3)                        |
| ≥30 - <45                                 | 101 (27.2)                       |
| ≥15 - <30                                 | 23 (6.2)                         |
| Pre-treatment RAASi use, n (%)            | 271 (73)                         |
| Baseline medication use, n (%)            |                                  |
| Non-RAASi antihypertensive medications    | 222 (60)                         |
| Lipid-lowering medications                | 217 (58)                         |
| Diuretics                                 | 133 (36)                         |
| Immunosuppressive agents                  | 92 (25)                          |

<sup>&</sup>lt;sup>a</sup>The interim analysis set included all patients who were randomized and received at least one dose of double-blind study medication.



DUPLEX is the largest randomized controlled trial to date in FSGS



At baseline, the patients enrolled in DUPLEX had a similar proportion of patients with chronic kidney disease stages 1 to 4

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#### Disclosures

- HT: Consultant to and/or member of a data monitoring committee for Akebia, Chemocentryx, Goldfinch Bio, Inc., Natera, Otsuka, Travere Therapeutics, Inc., and Walden.
- JR: Consultant to and Research Grants from Travere Therapeutics, Inc.,
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