

FORM254

FSGS Novel Therapies (FONT II)

Semi-Annual Follow-up Starting with Month 24 (Form # 254)

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1. Participant ID Number PID		2. Alpha Code ALPHCD		3. Visit Number CPEVENT / VISIT_NUMBER / SUBEVENT_NUMBER		4. Date of Visit (dd/mmm/yyyy) VISDT																								

F263.3 a. Has the participant died since their last visit?(0 = no, 1 = yes)___DTHNY
 b. Date of death..... (dd/mmm/yyyy) ___ ___/___ ___/___ ___ DTHDT

F263.4a. Primary cause of death	MDVT1, MDCLLT1
F263.4b. Secondary cause of death	MDVT2, MDCLLT2

5. a. Does the participant have kidney failure?(0 = no, 1 = yes) ___ESRD
 b. If yes, patient’s ESRD treatment modality __ESRDRX
 1 = hemodialysis
 2 = peritoneal dialysis
 3 = kidney transplant
 4 = untreated (refusing dialysis)
 8 = not applicable
 9 = unknown
 c. Date of ESRD onset..... (dd/mmm/yyyy) ___ ___/___ ___/___ ___ ESRDDT

6. a. Has the participant been pregnant since the last visit?(0 = no, 1 = yes, 8 = not applicable)
 ___PREG1
 b. Is the participant currently pregnant?(0 = no, 1 = yes, 8 = not applicable) ___PREG2

7. a. Since the last visit has an SAE or hospitalization related to the study medication occurred?(0 = no, 1 = yes) ___EVENT1
 b. Date of event? (dd/mmm/yyyy) ___ ___/___ ___/___ ___ EVENTDT1
 c. Diagnosis? EVENTDX1

Since the participant’s last visit, did any of the following occur?

8. a. Cardiovascular event?.....(0 = no, 1 = yes) ___EVENT2
 b. Date of event? (dd/mmm/yyyy) ___ ___/___ ___/___ ___ EVENTDT2
 c. Diagnosis? EVENTDX2

FAX COMPLETED FORM TO FONT STUDY DESK
UMich (734) 232-2353 NYU (212) 263-4053

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Since the participant's last visit, did any of the following occur, continued...

9. a. Thromboembolic event?(0 = no, 1 = yes) ___EVENT3
b. Date of event? (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___EVENTDT3
c. Diagnosis?EVENTDX3
10. a. Malignancy?(0 = no, 1 = yes) ___EVENT4
b. Date of event? (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___EVENTDT4
c. Diagnosis?EVENTDX4
11. a. Infection with hospitalization?(0 = no, 1 = yes) ___EVENT5
b. Date of event? (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___EVENTDT5
c. Diagnosis?EVENTDX5
12. Is the participant currently involved in another clinical trial?..... (0=no, 1=yes, 9=unknown)___OTHTRL

200. Date this form completed.....(dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___

201. Username of person completing this form.....