

FORM231

FSGS Novel Therapies (FONT –II)

Study Exit Before Randomization Form (Form # 231)

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1. Participant ID Number
PID

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2. Alpha Code
ALPHCD

B		
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3. Visit Number
CPEVENT /
VISIT_NUMBER /
SUBEVENT_NUMBER

Please respond with a code of “1=Yes” to any new exclusion criteria detected during baseline. Other items can be left blank.

- 5. Participant is moving out of the area? __MOVING
- 6. Participant/guardian no longer wants to participate?..... __PTOUT
- 7. Participant’s personal physician no longer wants the patient to participate? __PHYOUT
- 8. FONT-II Study Team no longer thinks the patient should be enrolled? __FSGOUT
- 9. Age – Pt ≥ 52 at time of randomization?..... __OLDAGE
(before randomization, database will confirm patient has not yet reached 52st birthday)
- 10. a. GFR <40 ml/min/1.73m² at screening (B01);
GFR <30 ml/min/1.73m² prior to randomization (B02)? __LOWGFR
- b. Date of blood draw for Serum Creatinine measurement that determined
 ineligibility..... (dd/mmm/yyyy) ____ / ____ / ____ __DRAWDT1
- 11. a. Hematocrit < 27%? __LOWHCT
- b. Date of blood draw for Hematocrit measurement that determined
 ineligibility..... (dd/mmm/yyyy) ____ / ____ / ____ __DRAWDT2
- 12. a. Screening or Run-In protein to creatinine ratio(s) ineligible?..... __PCRAT
- b. Date of last urine collection that determined
 ineligibility..... (dd/mmm/yyyy) ____ / ____ / ____ __COLDT
- 13. Biopsy ineligible? __INBIOP
- 14. Currently participating in another therapeutic trial?..... __OTHTRL
- 15. Pregnant? __PREG
- 16. Breastfeeding? __BRSTFD
- 17. Currently menstruating female who does not practice abstinence and refuses to use
two forms of birth control? __BIRCON
- 18. Transplant recipient? __TXRCPT
- 19. History of malignancy?..... __MALIG

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UMich (734) 232-2353 NYU (212) 263-4053

- 20. Uncontrolled hypertension?.....__HIGHBP
- 21. Diabetes Mellitus, Type I or II?.....__DIABET
- 22. a. Hepatic disease (serum ALT/AST levels more than 2.5x the upper limit of normal)
__LIVERD
- b. Date of blood draw that for ALT/AST levels that determined
ineligibility (dd/mmm/yyyy)..... __ __ / __ __ __ / __ __ __ __DRAWDT3
- 23. Hepatitis B?__HEPB
- 24. Hepatitis C?__HEPC
- 25. HIV?__HIV
- 26. SLE or multiple sclerosis?.....__SLEMS
- 27. Significant GI disorder detected?__GID
- 28. Solitary kidney?.....__SOLKID
- 29. Reflux nephropathy?.....__REFNEP
- 30. Allergic to both ACEi and ARB?__ALGARB
- 31. Treated with cyclosporine in the past 30 days?.....__TRTCYC
- 32. Treated with tacrolimus in the past 30 days?.....__TRTTAC
- 33. Treated with azathioprine in the past 30 days?__TRTAZA
- 34. Treated with mycophenolate mofetil in the past 30 days?__TRTMYC
- 35. Treated with rapamycin in the past 30 days?.....__TRTRAP
- 36. Treated with sirolimus in the past 30 days?.....__TRTSIR
- 37. Treated with cyclophosphamide in the past 30 days?__TRTCPP
- 38. Treated with levamisole in the past 30 days?__TRTLEV
- 39. Treated with chlorambucil in the past 30 days?__TRTCHL
- 40. Treated with methotrexate in the past 30 days?.....__TRTMET
- 41. Treated with nitrogen mustard in the past 30 days?__TRTNIT
- 42. Treated with rituximab with in 90 days prior to randomization?__TRTRTX
- 43. Treated with study medication galactose?.....__TRTGAL
- 44. Treated with study medication adalimumab?.....__TRTADA
- 45. Abnormal pap smear (more than CIN1) was untreated or no follow-up pap smear
to indicate normal?__ABNPAP
- 46. Other?__OTHER

- 200. a. Form Completed By(Print name) _____
Q200a is not entered into database
- b. "Username" of person completing this form _____
- c. Date this form completed.....(dd/mmm/yyyy) ____ / ____ / ____