CAST

OPEN LABEL TITRATION

Affix Patient I.D. Here

COMPLETE THIS FORM WHEN EVALUATING EACH DRUG/DOSE LEVEL TRIED DURING OPEN LABEL TITRATION

1 Date of evaluation: DATE12 ___/___/___ (mo dy yr)

STUDY DRUG FOR EVALUATION

2 ☐3 Moricizine DRUG12

☐1 Dose 1 ☐2 Dose 2 ☐3 Dose 3 DOSE12

3 Date this drug/dose level started: ___/___/___ (mo dy yr) DTSTRT12

4 Was patient hospitalized or kept in hospital to start titration on this drug?

☐1 yes HOSP12 ☐2 no If yes, for how many days? ___

ECG OR HOLTER INFORMATION

5 Heart rate: HR12 ___ bpm PR interval: 0.PR12 ___ secs

QRS duration: 0.QRS12 ___ secs QT interval: 0.QT12 ___ secs

RESULTS OF EVALUATION ON THIS DRUG AND DOSE (Check all that apply)

6 ☐1 (1) Successful suppression.

If checked, date of Holter: DTSUPH12 ___/___/___ (mo dy yr)

☐1 (2) Lack of suppression (but not proarrhythmia)

If checked, was lack of suppression documented?

☐1 yes ☐2 no

If documented, date of Holter: DTLACK12 ___/___/___ (mo dy yr)

VPD's/hour: ____.__

☐1 (3) Disqualifying VT (Complete VT form, CAST 21)

☐1 (4) Proarrhythmia (Complete Adverse Symptoms form, CAST 08)

☐1 (5) Disqualifying ECG effect (Complete Adverse Symptoms form, CAST 08)

☐1 (6) Recurrent MI (Complete Recurrent MI form, CAST 20)

☐1 (7) Congestive heart failure (Complete New or Worsened CHF form, CAST 19)

☐1 (8) Other intervening event

☐1 (9) Other adverse clinical symptoms (Complete Adverse Symptoms form, CAST 08)

☐1 (10) Resuscitated cardiac arrest (Complete Death or Cardiac Arrest form, CAST 23)

☐1 (11) Death (Complete Death or Cardiac Arrest form, CAST 23)

☐1 (12) Other investigator concern, specify

_____

☐1 (13) Patient refusal for evaluation

☐1 (14) Physician refusal for evaluation

7 Code (number in parentheses) of primary result RESULT12 ___

SUBSEQUENT TREATMENT

8 ☐1 Continuing titration

NEXT12 ☐2 Restarting titration because of event. If checked, complete:

Specify event: _____

New baseline: VPD's/hr NEWVPD12 ___.__ LVEF 0.__ NEWEF12

VPD runs/hr (≥ 120 bpm) RUNSHR12 ___.__

Date of confirming call to CC: __/__/__ (mo dy yr)

Person at CC: _____

Code number: ___

☐3 Withdrawn before completing titration, date DTWTHD12 __/__/__ (mo dy yr)
Complete TELENT, CAST-74

- ☐1 Patient refusal to continue
- ☐2 Physician refusal to continue
- ☐3 Beyond 90 days WHYWTH12
- ☐4 Death or cardiac arrest
- ☐5 Verified disqualification
- ☐6 End of Study

☐4 Completed titration. If checked, indicate eligibility:

- ☐1 Main study (≥ 80% suppression)
- ELG12 ☐2 Substudy (0-79% suppression)
- ☐3 Neither - (Complete TELENT, CAST 74)

If Main study or substudy, was patient randomized?

☐1 yes ☐2 no

If NO, reason:
- ☐1 Patient refusal
- ☐2 Physician refusal
- ☐3 Patient death (before randomization)
- ☐4 Other,

specify: _____

☐5 Completed titration; randomized on earlier drug/dose level based on prospective new baseline

STUDY DRUG ASSIGNED

9 Indicate next drug/dose level or drug/dose level chosen for randomized trial:

CAST Therapy

ASNDRG12 ☐3 Moricizine

ASNDOS12

☐1 Dose 1 ☐2 Dose 2 ☐3 Dose 3

Name of person filling out form _____ Code Number ___