Reference #: _____

CitAD

Safety Report
(SR-1)

Purpose: Report any serious adverse events occurring during and one month after the 9-week treatment period. A serious adverse event is defined as any adverse event that results in a life-threatening adverse experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, and/or death.

When: **Within two working days** of learning of such an adverse event.

Completed by: CitAD certified study physician and study coordinator.

Information obtained from: Patient, caregiver, and medical records of the patient.

Instructions: Use a separate form for each serious adverse event episode. Narrative in section E should be completed by a study physician. Fax Safety Report (SR) to the CC at (443) 287-5797. Call CC at (443) 287-3170 to confirm receipt of fax. The original form should be retained in the clinic center files.

For updates, complete a new SR form. In the update, complete sections A, B, and F entirely, and sections C, D, and E, only with updated items. Do not update by crossing out items from previous safety reports. Fill out the current date in item 4 (do not use date of initial SR form). Indicate that the form is an update to a previous Safety Report in section B. Fax Safety Report updates to CC. Follow local guidelines regarding reporting serious adverse events and updates to your IRB or review board.

A. Clinic, patient and visit identification

1. Clinic ID: ____ ____ ____ ____

2. Patient ID: C ____ ____ ____ ____

3. Patient four-letter code: ____ ____ ____ ____

4. Date form completed:

____ ____ – ____ ____ ____ – ____ ____
day month year

5. Visit ID: n ____

6. Form revision date:

1 1 – a u g – 0 9
day month year

B. Safety Report information

7. Type of Safety Report:

Initial Safety Report . . . . . (1)

12. ____

Update to a previous Safety Report . . . . (2)

8. Initial Safety Report number *(see section G of the initial Safety Report distributed by CC):*

____ ____ ____

9. Date of initial Safety Report:

____ ____ – ____ ____ ____ – ____ ____
day month year

10. Number of updates including this report: ____ ____

11. What item(s) of the previous SR form is/are being updated or changed *(specify):*

_____

_____

12. Is additional information expected:

Yes (1) No (2)

C. Participant information

13. Age: ____ ____ ____ years

14. Gender:

Male . . . . . (1)
Female . . . . . (2)

15. Weight: ____ ____ ____ pounds

16. Height: ____ ____ inches

17. Date study treatment started:

____ ____–____ ____ ____–____ ____
day month year

18. Dose of study medication at time of serious adverse event *(check only one):*

Not on study drug . . . . . (1)
1 capsule/day . . . . . (2)
2 capsules/day . . . . . (3)
3 capsules/day . . . . . (4)

D. Adverse event data

19. Date clinic center was notified or became aware of event:

____ ____–____ ____ ____–____ ____
day month year

20. Serious adverse event:

a. Event

_____

b. Date of original onset:

____ ____–____ ____ ____–____ ____
day month year

c. Date study drug last taken before serious adverse event:

____ ____–____ ____ ____–____ ____
day month year

d. Date resolved:

____ ____–____ ____ ____–____ ____
day month year

21. Event considered serious because *(check all that apply):*

a. Resulted in death . . . . . (1)
b. Was life-threatening . . . . . (1)
c. Required hospitalization or prolonged hospitalization . . . . . (1)
d. Resulted in disability or incapacity. . . . (1)
e. Required intervention to prevent permanent impairment . . . . . (1)
f. Other . . . . . (1)

_____
specify

22. Change in study treatment due to adverse event *(check only one):*

No change . . . . . (1)
24. ⌐
Terminated . . . . . (2)
Dose reduced . . . . . (3)

If study treatment is terminated, a Treatment Termination form should be completed and entered.

23. Did the adverse event resolve after study treatment was terminated or dose reduced:

Yes . . . . . (1)
No . . . . . (2)
Unknown . . . . . (3)

24. Relationship of serious adverse event to study treatment *(check only one):*

Not related . . . . . (1)
26. ⌐
Possible . . . . . (2)
Probable . . . . . (3)
Definite . . . . . (4)

25. Based on the list of side effects in the drug package insert, is the adverse event:

Expected . . . . . (1)
Unexpected . . . . . (2)

26. Hospitalization information:

a. Patient hospitalized

Yes (1) No (2)

27. ⌊__⌋

b. Date admitted:

____ ____–____ ____ ____–____ ____

day month year

c. Date discharged:

____ ____–____ ____ ____–____ ____

day month year

27. Treatment for adverse event *(include dates):*

a. None . . . . . (1)

b. Medications *(specify)* . . . . . (1)

c. Other treatment *(specify)*. . . . . (1)

28. List any tests, including dates, and results of the tests, related to serious adverse event:

29. Concomitant medications *(list all drug names patient was taking at time of adverse event):*

a. Medication 1

b. Medication 2

c. Medication 3

d. Medication 4

e. Medication 5

f. Medication 6

g. Medication 7

h. Medication 8

i. Medication 9

j. Medication 10

k. Medication 11

l. Medication 12

30. Are any of the concomitant medications thought to be associated with the adverse event:

( ) Yes (1) ( ) No (2)

34. ___

31. Suspect medication #1:

a. Medication

_____

b. Indication

_____

c. Dose

_____

d. Frequency

_____

e. Route of administration

_____

f. Dates of administration

_____

32. Suspect medication #2:

a. Medication

_____

b. Indication

_____

c. Dose

_____

d. Frequency

_____

e. Route of administration

_____

f. Dates of administration

_____

33. Suspect medication #3:

a. Medication

_____

b. Indication

_____

c. Dose

_____

d. Frequency

_____

e. Route of administration

_____

f. Dates of administration

_____

E. Adverse event narrative

34. Provide details about the serious adverse event, including dates. Type or print legibly.

a. Describe the serious adverse event and clinical significance; provide information or recovery or any sequelae:

b. Describe study treatment at the time of the event, changes to treatment, and impression of the relationship of the event to study treatment:

c. Explain any relevant medical history, including pre-existing conditions, or concomitant medications; discuss any other related serious adverse events reported in other Safety Reports (include dates of Safety Reports):

Signature: _____ Date: _____

F. Administrative information

35. Date form reviewed by study coordinator:

____ ____–____ ____ ____–____ ____
day month year

36. Study coordinator ID: ____ ____

37. Study coordinator signature:

_____

Study physician should review this form before signing below.

38. Date form reviewed by study physician:

____ ____–____ ____ ____–____ ____
day month year

39. Study physician ID: ____ ____

40. Study physician signature:

_____

G. Coordinating Center use

41. Date reviewed:

____ ____–____ ____ ____–____ ____
day month year

42. Safety Report number: ____ ____ ____