Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

Complete this form upon confirmation that a study participant is pregnant, regardless of assigned treatment group. No further study medication should be given.

Additional form(s) that need to be completed:
- Adverse Event Report Form (**CTL13**)
- Pregnancy Outcome Report Form (**CTL14R**)*

* When pregnancy has ended

A. REPORT INFORMATION

Pregnancy Identification Number: # # # #

1. Report Date: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

2. Last attended study visit prior to the confirmed pregnancy:

☐ 0	Baseline	☐ 8	Visit 8	☐ 16	Visit 16	☐ 24	Visit 24
☐ 1	Visit 1	☐ 9	Visit 9	☐ 17	Visit 17	☐ 25	Visit 25
☐ 2	Visit 2	☐ 10	Visit 10	☐ 18	Visit 18	☐ 26	Visit 26
☐ 3	Visit 3	☐ 11	Visit 11	☐ 19	Visit 19	☐ 27	Visit 27
☐ 4	Visit 4	☐ 12	Visit 12	☐ 20	Visit 20	☐ 28	Visit 28
☐ 5	Visit 5	☐ 13	Visit 13	☐ 21	Visit 21	☐ 29	Visit 29
☐ 6	Visit 6	☐ 14	Visit 14	☐ 22	Visit 22	☐ 30	Visit 30
☐ 7	Visit 7	☐ 15	Visit 15	☐ 23	Visit 23	☐ 31	Visit 31

B. PREGNANCY INFORMATION

1. Date of positive pregnancy test: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Date of last menstrual cycle: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
3. Estimated date of delivery: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
4. Is the participant planning on carrying the pregnancy to term? Y N
5. Is the participant willing to continue with future follow-up visits? Y N
6. Has the participant's obstetric care provider been informed of her participation in this study? Y N

C. PREGNANCY HISTORY

1. Record total number of <u>prior</u> pregnancies (not including this one): __ __
2. Has the participant ever had a pregnancy complication? Y N

   If YES,

   a. Has the participant ever had a miscarriage? Y N
   b. Has the participant ever had a pregnancy that resulted in a stillbirth? Y N
   c. Has the participant ever had a pregnancy result in neonatal death? Y N
   d. Has the participant ever had a pre-term delivery (< 37 gestational weeks)? Y N
   e. Has the participant ever had a post-term delivery (> 42 gestational weeks)? Y N

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*