October 10, 2017

Roisin Connolly M.D.
[via Email]

Re:  CIRB Approval of Amendment Review

Study ID, Study Title: E2112, A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer

Amendment: Update 3

Protocol Version Date 07/15/16 Update Date 10/04/17

Study Chair: Roisin Connolly M.D.

Dear Dr. Connolly:

On October 8, 2017, the NCI Adult CIRB - Late Phase Emphasis reviewed E2112 (Protocol Version Date 07/15/16 Update Date 10/04/17) and granted approval. The expedited review was conducted in accordance with the Federally-defined categories of expedited review stated in 45 CFR 46.110(b)(2) and 21 CFR 56.110(b)(2).

The following documents were reviewed:

1. Change Memo with tracked changes for study protocol with Protocol Version Date 07/15/16 Update Date 10/04/17
2. Study protocol with Protocol Version Date 07/15/16 Update Date 10/04/17
3. Consent form(s) with Protocol Version Date 07/15/16 Update Date 10/04/17

Update 3 involved changes to the protocol and the only change to the consent form(s) was the Update Date.

The Adult CIRB - Late Phase Emphasis agrees with the Study Chair’s determination that Update 3 does not include significant new findings that might relate to study participants’ willingness to continue participation. Therefore, study participants do not need to be notified of the changes included in this update.

The expiration date for CIRB approval remains January 18, 2018.

As the Study Chair, you are responsible for reporting all study-related activity and correspondence to the CIRB.


If you have any questions regarding this review, please contact the Adult CIRB - Late Phase Emphasis Coordinator at adultcirb@emmes.com.
Sincerely,

John Zapas, MD
Chair, NCI Adult CIRB—Late Phase Emphasis

cc: Pamela Cogliano
    Lauren DiFerdinando, CCRP
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