Alliance for Clinical Trials in Oncology

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October 20, 2020

Dear Alliance A221701 Investigator:

This letter is to provide you with new information regarding A221701, "Phase III placebo-controlled trial to evaluate dexamethasone use for everolimus-induced oral stomatitis: prevention versus early treatment approaches: MIST (My Individualized Stomatitis Treatment)."

Despite efforts to improve accrual, enrollment has remained insufficient. In addition, a recent drug distribution transition resulted in increased costs and institutional complexity and burden that likely would have continued to hamper accrual. Alliance has therefore decided to close A221701 to new patient accrual on November 1, 2020.

For patients enrolled until November 1, 2020, participating institutions must use existing supplies previously distributed by the Alliance. Prior to patient consent and enrollment, sites must verify that they have sufficient unexpired supplies for the duration of study treatment for each prospective patient. Patients registered on or before this date may continue to receive dexamethasone or placebo to allow for as many as 8 weeks of treatment necessary to achieve study endpoints and follow up.

The following actions are now required:

1) Upon receipt of this letter, physicians should discuss this decision with the patients who are currently receiving treatment on the study. To facilitate this discussion, a sample patient letter is available on the A221701 study page on the members' side of the Alliance and CTSU websites. Documentation of the discussion with the patient should be kept in the patient's medical record.

2) Please note that it is not necessary to obtain IRB approval before notifying patients. However, at this time, Investigators should notify their IRB of record and provide copies of this letter and the patient letter.

The Alliance is interested, if patients agree, to continue protocol treatment, required testing, follow-up, and data submission, for up to 8 weeks from the start of treatment for each patient. Sites will however need to use existing supplies as the Alliance will not be distributing additional study drug.

- Unblinding is not permitted prior to 8 weeks of study treatment, or if the patient chooses to be unblinded, additional study treatment will not be provided.
- Subjects and their treating physicians will have the option of being unblinded after 8 weeks of study treatment.
- Please ensure that all study activities (e.g. completing the HRQoL etc.) are completed prior to unblinding each subject.

cc: K.Ruddy, MD

Questions regarding this notice may be directed to Niveditha Subbiah, A221701 Protocol Coordinator, at nsubbiah@bsd.uchicago.edu or (773) 702 9934.

We greatly appreciate your support of this important clinical trial and the work of the Alliance for Clinical Trials in Oncology.

Sincerely,

Selina Chow, MD
Executive Officer
Alliance for Clinical Trials in Oncology