SWOG CANCER RESEARCH NETWORK

Distribution Date: March 15, 2019
E-mailed Dated: March 8, 2019

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS; CTSU

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: **S1612**, "A Randomized Phase II/III Study of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML), High-Risk Myelodysplastic Syndrome (MDS) or Chronic Myelomonocytic Leukemia (CMML), Age 60 or Older (LEAP: **LE**ss-Intense **A**ML **P**latform Trial)." Study Chairs: Drs. L. Michaelis and R. Walter.

MEMORANDUM

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IRB Review Requirements
(√) Expedited review allowed

MEMORANDUM

The purpose of this memorandum is to notify sites of an Action Letter received from Dr. Fernanda Arnaldez, CTEP, DCTD, NCI. The Action Letter is available on the SWOG and CTSU websites.

The Action Letter indicates the following changes to the risk profile for midostaurin:

- "Heart failure which may cause shortness of breath, swelling of ankles, and tiredness" has been identified as a new "rare" risk.
- "Change in the heart rhythm" and "Damage to the lungs which may cause shortness of breath" have increased in risk attribution from "also reported but with insufficient evidence for attribution" to "rare".

Patients currently receiving midostaurin must be notified of these changes as described on page 2 of the Action Letter.

SWOG has not yet prepared a protocol revision or consent revision in response to this Action Letter because the study is temporarily closed. A revision will be released at a later date, prior to reactivating the study.

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE
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