PATIENT INFORMATION LETTER
for

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutics" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older"

You chose to take part in a SWOG research study for AML (acute myeloid leukemia). When you made this choice, the doctors in charge of the study told you that you would be given any new details that might affect this choice. SWOG now wants to provide you with new information regarding the study.

In June of 2020, preliminary data from a clinical trial were presented showing that a combination of azacitidine plus venetoclax is more effective than azacitidine alone. The results from this trial change the current standard of care treatment for many older adults with AML. With this, we do not believe that S1612, which uses azacitidine alone as the control arm, will accrue sufficient patients to meet the study's endpoints. Therefore, the study is closing to new patients.

If you are currently getting the study treatment, you may continue to do so.

We are giving you this information whether or not you are still getting study treatment to keep you up to date with the study's progress. Patients such as you who take part in research studies have contributed enormously to doctors' ability to improve cancer treatment. Your well-being is the main focus of these studies. We will stay in touch with all the patients on this study.

You should discuss any questions you may have about this Patient Information Letter with your study doctor or the SWOG study team. We value the trust you have put in SWOG. The results from this trial will contribute to the knowledge of how best to treat patients with AML.

Sincerely,

Laura Michaelis, M.D.
S1612 Primary Study Chair