First Clinical Trial to Study Blood Cancer Patients with COVID-19

The trial will test the drug acalabrutinib in those with acute myeloid leukemia, acute lymphoblastic leukemia and myelodysplastic syndromes.

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With studies showing between 30-60% of blood cancer patients at risk of death if infected with the COVID-19 virus compared to patients who are cancer-free, The Leukemia & Lymphoma Society (LLS) announced today it is launching the first clinical trial dedicated solely to this most vulnerable population.

This trial (LLS Protocol Number: BAML-16-001-COV1) will test a drug called acalabrutinib in patients diagnosed with acute myeloid leukemia, acute lymphoblastic leukemia, myelodysplastic syndromes and aplastic anemia, all of whom are often excluded from COVID-19 clinical trials based upon very low blood counts. Other blood cancer patients, such as those with lymphoma and myeloma, will be eligible as well. All of the patients will also have tested positive for COVID-19.

LLS is leveraging rapidly the infrastructure of its innovative Beat AML Master Clinical Trial, a precision medicine study launched in 2016 to test multiple drugs at 16 cancer centers for patients with acute myeloid leukemia (AML), for this new “Beat COVID” trial. Beat AML was designed to be nimble and adaptable, thus allowing this quick pivot to treating patients with all types of blood cancers with an experimental treatment to address their life-threatening coronavirus symptoms.

Through a partnership with AstraZeneca, LLS will be leading the only dedicated clinical trial for blood cancer patients infected with COVID-19, a highly dangerous combination of diseases. Patients in the trial will receive acalabrutinib (CALQUENCE), a medicine already approved to treat two types of blood cancers, chronic lymphocytic leukemia and relapsed/refractory mantle cell lymphoma, but which shows promise in mitigating some life-threatening effects of COVID-19.

LLS’s pioneering Beat AML Master Clinical Trial launched in 2016 but in March the pandemic forced the Beat AML cancer centers to pause enrolling patients for that trial; under this arrangement they quickly will be able to treat patients with all types of blood cancers who are also diagnosed with COVID-19. The “Beat COVID” trial demonstrates the swift and significant adjustments many researchers and healthcare centers are making during the pandemic to address high-risk populations who contract COVID-19.

According to LLS President and CEO Louis J. DeGennaro, PhD, “We are extremely proud to be able to respond quickly during this pandemic to help blood cancer patients, using the groundbreaking clinical trial infrastructure we built for Beat AML. We are grateful for our partnership with AstraZeneca, and our collaboration with the U.S. Food & Drug Administration, to quickly adapt this “Beat COVID” trial to address the critical need for treatments for blood cancer patients severely sick with COVID-19. The Beat AML model has shown we can bring precision medicine to blood cancer patients, and we are hopeful this collaboration will bring vital relief and improve outcomes for these at-risk patients.”

Acalabrutinib is already being tested in multiple clinical trials worldwide for patients with COVID-19, both those who are diagnosed with cancer and those who are not. The “Beat COVID” trial, differs from these other trials in that it is dedicated only to blood cancer patients. Beat COVID will begin as a pilot treating approximately 60 patients at several of the Beat AML sites. AstraZeneca already had a connection to the Beat AML Master Clinical Trial as another one of its therapies is being tested in patients with acute myeloid leukemia in that study.

Acalabrutinib is a category of drug called BTK (Bruton’s tyrosine kinase) inhibitor. BTK is a protein that triggers the white blood cells of the immune system into action. One of the life-threatening symptoms of COVID-19 is an extreme immune response that causes inflammation frequently resulting in permanent, often fatal damage to lungs and other vital organs.

The Beat COVID trial will be led by LLS, with Michael Boyiadzis, MD, of the University of Pittsburgh, who serves as the Institutional principal investigator at this site for the Beat AML trial.

Investigators supported by The Leukemia & Lymphoma Society such as Jan Burger, MD, PhD, of MD Anderson, and John Byrd, MD, and Amy Johnson, MD, of The Ohio State University, made discoveries assessing the role of BTKi inhibition in B-cell malignancies that helped lead to the FDA approval of several BTK inhibitors for blood cancers.

“This drug was first approved thanks to blood cancer patients participating in clinical trials, so it stands to reason that these same patients should be the beneficiaries if it’s going to work to treat the symptoms of COVID-19, given the high rate of mortality for this population,” said Byrd, Chief Medical Officer of Beat AML.

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