Collaboration driven by the Leukemia & Lymphoma Society to expedite development of innovative therapies for Acute Myeloid Leukemia Patients

In 2016, the Leukemia & Lymphoma Society (LSS) in partnership with the FDA, leading leukemia MDs in North America, and several biopharmaceutical companies finalized plans for a groundbreaking platform “umbrella” trial—Beat AML—with an ambitious goal to speed development of targeted therapies for newly diagnosed patients with acute myeloid leukemia (AML). Within a single “Master Trial” built to initially support up to 10 different protocols, researchers aim to identify subsets of treatment-naïve AML patients based on NGS testing for known key mutational drivers, and target them with novel agents directed against those mutations. For patients with multiple mutations, advanced analytics including VAF (variant allele frequency) and a predetermined prioritization schema then steers each patient to the best sub-study.

The Oncology team at Syneos Health is delighted to be engaged with this Beat AML initiative, providing full-service clinical development support, and is thrilled to see the progress that will be reported at ASH 2018.

Pressure to be nimble and responsive is mirrored at each of the trial sites. Given the urgent needs of patients—and thanks to LLS’s hands-on partnering with the FDA—positive data can move the drug straight to registration. This means all the data must be clean from the get-go, and some traditional steps must be compressed. For example, Syneos Health and its partners are testing a novel clinical data "pipe" that can funnel information directly from patients' electronic records into the main database, skipping a traditional transcription step that's both time-consuming and vulnerable to errors. Accommodating and pioneering, the operational innovation during the conduct of this trial presents challenges and opportunities. Each partner or team has to bring a whole organization into the mission, which is getting drugs to the patient.

As of November 20, 2018, the Beat AML® Master Trial has screened more than 427 patients from 13 sites in 2 years.

Syneos Health is excited to note that the proofs of concept for this trial have worked. At this year’s American Society of Hematology (ASH) meeting in San Diego, Beat AML will provide multiple updates and presentations (oral and abstract) of data from the Master trial, as well as overviews via press and interviews.
Our team is delighted to convert that hard-won knowledge to support the Leukemia & Lymphoma Society with a groundbreaking targeted therapy trial in front line AML. This collaboration, which began over two years ago, started with the following objectives, and the successful achievement of these objectives has been the foundation of our collective success in managing this groundbreaking umbrella/Master Trial:

- One vision and mission shared across all stakeholders on the trial
- Maintain stable core teams across all partner organizations involved
- Produce a trial designed for the patient, not the patient for the trial
- Develop a targeted therapy model for AML
- Design a trial to facilitate FDA approval of new drugs
- Integrate NGS screening in the patient flow process to take no more than 7 days
- Implement an innovative approach to constantly look for ways to improve efficiencies and effectiveness to drive faster timelines while maintaining quality

For the clinical team at Syneos Health, this has been a wonderful opportunity to be directly involved in an important, new patient-centric novel design clinical trial. Umbrella trials present multiple operational and logistical challenges, and our team has been able to work with LLS and other providers to deliver practical and innovative solutions.

We encourage you to join the multiple opportunities at ASH to hear more about the Beat AML trial, and LLS’s patient-centric mission at the following times/venues.

**Beat AML at ASH:**

- **LLS ROUNDTABLE: “INNOVATIONS IN CANCER RESEARCH – BLOOD CANCERS AND BEYOND”**: Thursday, November 29, 2018, 5:00 p.m. – 7:30 p.m. PT Hilton San Diego Bayfront, Sapphire Ballroom
- **LLS ASH SATELLITE SYMPOSIUM: “INTEGRATION OF IMMUNOTHERAPY INTO TREATMENT FOR HEMATOLOGIC MALIGNANCIES”**: Friday, November 30, 2018, 7:00 a.m. – 11:00 a.m. PT San Diego Conference Center, Room 30
- **ASH PRESS BRIEFING: “MEDICINE OF THE FUTURE”**: Showcasing abstracts from LLS’s Beat AML Master Clinical Trial: Sunday, December 2, 2018, 8 a.m. - 9 a.m. PT San Diego Conference Center, Press Room 23
- **Beat AML presentations throughout ASH**
  - A next generation sequencing-based karyotyping algorithm reveals the genomic structure of acute myeloid leukemia: Abstract #2773
  - Development and Validation of a Dominant Clone Precision Medicine Classification for Treatment of Elderly Acute Myeloid Leukemia
  - Initial Report of the Beat AML Umbrella Study for Newly Diagnosed AML: Evidence of Feasibility and Early Success in Molecularly Driven Phase 1/2 Studies: Abstract #559
  - Enasidenib is Highly Active in Previously Untreated IDH2 mutant AML: Early Results from the Beat AML Master Trial: Abstract # 287
  - Phase 1b Dose Escalation Study of BI 836858 and Azacitidine in Previously Untreated AML: Results from Beat AML S2: Abstract #4053
  - A Precision Medicine Hierarchical Classification Developed Using Variant Allele Frequency (VAF) for Treatment of Older Patients (Pts) with Acute Myeloid Leukemia (AML): Alliance Clinical Trials in Oncology (Alliance) Historical Patient Control: Abstract #1489
- **“QUANTIFYING PATIENT AND CAREGIVER PREFERENCES FOR TREATMENT OUTCOMES IN AML”** LLS-supported and co-authored patient preference study presented in two oral sessions and one poster session: Abstracts #718, #717, #3573

**About Syneos Health**

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry leading companies – INC Research and inVentiv Health – we bring together more than 23,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers’ delivery of important therapies to patients. To learn more about how we are shortening the distance from lab to life® visit syneoshealth.com.

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