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EHA25Virtual: A Paradigm Shift for the Treatment of Newly Diagnosed Older Acute Myeloid Leukemia Patients

Acute myeloid leukemia (AML) is primarily a disease of older adults. Standard commonly utilized lower-intensity therapies, such as azacitidine or decitabine, provide only limited responses with expected median survival of 9-10 months and complete remission (CR) / CR with incomplete count recovery (CRi) rates <40%. We evaluated the efficacy of a combination regimen of azacitidine and venetoclax in treatment-naïve AML patients that were ineligible for intensive therapy.

In a Phase III randomized double-blinded multicenter trial called "VIALE-A", the efficacy of the combination regimen was compared to treatment with azacitidine plus a placebo. In 431 internationally enrolled patients in the VIALE-A trial, the combination of azacitidine and venetoclax led to improved overall survival (14.7 vs 9.6 months), and improved response rates CR/CRi (66% vs 28%), compared to azacitidine alone. In addition, the combination was associated with responses that occurred more quickly (median time to CR/CRi was only 1.3 months) and were more durable (lasting 1.5 years), and with increased incidence of transfusion independence (58% vs 34%).

In conclusion, this practice-changing multicenter randomized Phase III trial establishes venetoclax and azacitidine as a new standard of care for older patients with AML.

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Abstract: **#LB2601** VIALE-A: A Randomized, Double-blind, Placebo-Controlled Study of Venetoclax with Azacitidine vs Azacitidine in Treatment-naïve Patients with Acute Myeloid Leukemia Ineligible for Intensive Chemotherapy

About the EHA Annual Congress: Every year in June, EHA organizes its Annual Congress in a major European city. This year due to the COVID19 pandemic, EHA transformed its physical meeting into a Virtual Congress. The Congress is aimed at health professionals working in or interested in the field of hematology. The scientific program topics range from stem cell physiology and development to leukemia; lymphoma; diagnosis and treatment; red blood cells; white blood cells and platelet disorders; hemophilia and myeloma; thrombosis and bleeding disorders; as well as transfusion and



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stem cell transplantation. Embargo: Please note that our embargo policy applies to all selected abstracts in the Press Briefings. For more information, see our EHA Media and Embargo policy [here](#).

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