EMBARGOED UNTIL DEC. 11, 2023 @ 7 p.m. ET (4 p.m. PT)

918. **Patient-Reported Outcomes in Acute Myeloid Leukemia Patients with FLT3-ITD Mutation Receiving Quizartinib Vs. Standard Chemotherapy: Results from the Quantum-First Trial - Clinically Relevant Abstract**

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

Patients with a common form of acute myeloid leukemia report better quality of life when treatment includes new drug quizartinib

Sylvester-led international study shows the drug, which targets a specific change in a gene called FLT3, improved quality of life and had minimal side effects

MIAMI, FLORIDA **(EMBARGOED UNTIL MONDAY, DEC. 11, 2023 @ 7 P.M. ET)** – In a study led by researchers at **Sylvester Comprehensive Cancer Center** at the University of Miami Miller School of Medicine, patients recently diagnosed with a common and aggressive form of acute myeloid leukemia reported having improved quality of life when a newly approved drug was part of the treatment plan.

Study results will be released during an **oral presentation** at the 65th ASH Annual Meeting and Exposition, the American Society of Hematology's conference taking place in San Diego, California, Dec. 9-12. The report has been identified by ASH as a clinically relevant abstract.

Mutations in several genes have been implicated in the development of acute myeloid leukemia, or AML, a type of cancer that starts in the blood-forming cells of bone marrow. About 30% of all cases result from mutations in a gene called FLT3 – FMS-like tyrosine kinase 3 – and the majority of these involve "internal tandem duplication," or ITD. The new drug, quizartinib, specifically targets this FLT3-ITD mutation, which is found in about 25% of all AML cases and is associated with poor survival.

"In previous research, we showed that patients treated with quizartinib had improved survival compared with patients who didn't receive the drug. This study further demonstrated that patients treated with quizartinib had better quality of life over time and that the side effects from the drug did not negatively affect the improved quality of life," said **Dr. Mikkael A. Sekeres**, a Sylvester researcher, chief of the Division of Hematology, and senior author of the abstract presented at ASH. One focus of Sekeres' research is AML in older adults.

Quizartinib was recently approved by the U.S. Food and Drug Administration to be used in combination with chemotherapy for the first and second phases of treatment – called induction and consolidation phases – for adult patients with newly diagnosed FLT3-ITD-positive AML. It also can be used alone as maintenance therapy and has been approved for similar applications in the European Union and Japan.

The current study, looking specifically at patient-reported quality-of-life outcomes – is a continuation – an exploratory endpoint – of findings coming from QuANTUM-First, a global, Phase 3 clinical trial that evaluated the safety and effectiveness of the drug, marketed as VANFLYTA by Daiichi Sankyo Inc.

"Not only did we find that patients treated with quizartinib lived longer, and they lived better, but those who went on to have a bone marrow transplant had particularly improved quality of life," said Sekeres, who was a co-author of the **QuANTUM-First findings** reported earlier this year in The Lancet.

The current abstract's first author, Dr. Esther Natalie Oliva, will present the findings. Oliva is a hematologist and researcher at Grande Ospedale Metropolitano Bianchi Melacrino in Reggio Calabria, Italy.

The authors said QuANTUM-First is the first study to explore the impact of an FLT3-inhibitor as first-line therapy on patient-reported outcomes. Patients treated with quizartinib who achieve complete remission remain in remission longer, continue treatment longer, and have better quality of life than those who do not receive the drug.

Sekeres said the research team plans to conduct additional studies combining quizartinib with different chemotherapy regimens used to treat patients who have FLT3-positive AML to see if it provides similar improvements in quantity and quality of life.

Authors: In addition to senior author Sekeres and first author Oliva, authors included Sudhir Unni, Daiichi Sankyo Inc., Basking Ridge, New Jersey; Francesco Cottone, Ph.D., Daiichi Sankyo Italia, Rome, Italy; Rohan Vashi, Pharm.D., Daiichi Sankyo Inc., Basking Ridge, New Jersey;

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Conflicts and disclosures: Sekeres serves on advisory boards for Bristol Myers Squibb, Kurome Therapeutics, and Novartis.

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