

## Press Release

### **Daiichi Sankyo Receives Negative CHMP Opinion for FLT3 Inhibitor Quizartinib for Treatment of Patients with Relapsed/Refractory *FLT3*-ITD AML**

- Global clinical development program of quizartinib continues with focus on newly-diagnosed *FLT3*-ITD AML with enrollment completed into pivotal phase 3 QuANTUM-First study

**Tokyo and Munich – (October 18, 2019)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the Marketing Authorization Application (MAA) for quizartinib for the treatment of adults with relapsed/refractory *FLT3*-ITD acute myeloid leukemia (AML).

The CHMP opinion is based on the MAA submission of data from the global pivotal QuANTUM-R study of quizartinib. Results from QuANTUM-R were published in *The Lancet Oncology*.<sup>1</sup>

“While we are disappointed by this opinion, we will evaluate feedback received from the CHMP in order to determine next steps for quizartinib for the treatment of patients with relapsed/refractory *FLT3*-ITD AML in Europe,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “Despite this setback, we continue to believe in the potential benefit of quizartinib for patients with *FLT3*-ITD AML and we look forward to the results of the global, pivotal phase 3 QuANTUM-First study evaluating quizartinib in combination with chemotherapy for patients with newly-diagnosed *FLT3*-ITD AML. We remain committed to bringing quizartinib forward as a potential treatment option for this aggressive and difficult-to-treat subtype of AML in the U.S., Europe and other parts of the world.”

#### **About Quizartinib**

Quizartinib, an oral FLT3 inhibitor, is the lead product in the AML Franchise of Daiichi Sankyo. Quizartinib currently is approved for use in Japan under the brand name VANFLYTA® for the treatment of adult patients with relapsed/refractory *FLT3*-ITD AML, as detected by an approved test. It was launched in Japan on October 10, 2019.

Enrollment into QuANTUM-First, a global, pivotal phase 3 study evaluating quizartinib in combination with standard chemotherapy in newly diagnosed *FLT3*-ITD AML, was recently completed.

Other ongoing studies include phase 1/2 development for pediatric and young adult relapsed/refractory *FLT3*-ITD AML in North America and Europe; and phase 1 development in combination with milademetan, an investigational MDM2 inhibitor, for relapsed/refractory *FLT3*-ITD AML and newly-diagnosed *FLT3*-ITD AML unfit for intensive chemotherapy in the U.S. Milademetan is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established.

### **About *FLT3*-ITD AML**

AML is an aggressive blood and bone marrow cancer that causes uncontrolled growth and accumulation of malignant white blood cells that fail to function normally and interfere with the production of normal blood cells.<sup>2</sup> In the EU, there are approximately 18,000 new cases of AML each year,<sup>3</sup> and their five-year survival rate is less than 30 percent.<sup>4</sup>

*FLT3* gene mutations are one of the most common genetic abnormalities in AML.<sup>5</sup> *FLT3*-ITD is the most common *FLT3* mutation, affecting approximately one in four patients with AML.<sup>6</sup> *FLT3*-ITD is a driver mutation that presents with high leukemic burden, a poor prognosis and a significant impact on disease management for patients with AML.<sup>7</sup> Patients with *FLT3*-ITD AML have a worse overall prognosis, including an increased incidence of relapse, an increased risk of death following relapse and a higher likelihood of relapse following hematopoietic stem cell transplantation, as compared to those without this mutation.<sup>8,9</sup>

### **About Daiichi Sankyo Cancer Enterprise**

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by three pillars, including our investigational Antibody Drug Conjugate Franchise, Acute Myeloid Leukemia Franchise and Breakthrough Science, we aim to deliver seven distinct new molecular entities over eight years during 2018 to 2025. Our powerful research engines include two laboratories for biologic/immuno-oncology and small molecules in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. For more information, please visit:

[www.DSCancerEnterprise.com](http://www.DSCancerEnterprise.com).

### **About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a

strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com).

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## References:

<sup>1</sup> Cortes, et al. Lancet Oncol. Published online June 4, 2019, [http://dx.doi.org/10.1016/S1470-2045\(19\)30150-0](http://dx.doi.org/10.1016/S1470-2045(19)30150-0).

<sup>2</sup> Leukemia & Lymphoma Society. Facts 2017-2018. 2018.

<sup>3</sup> Visser O, et al. (RARECARE Working Group). Incidence, survival and prevalence of myeloid malignancies in Europe. Eur J Cancer. 2012;48:3257-3266.

<sup>4</sup> Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Hematology (HARMONY). Acute Myeloid Leukemia. Available at: <https://www.harmony-alliance.eu/en/hematologic-malignancies/acute-myeloid-leukemia>. Accessed : July 2019.

<sup>5</sup> Small D. Am Soc Hematol Educ Program. 2006;178-184.

<sup>6</sup> Schneider F, et al. Ann Hematol. 2012;91:9-18.

<sup>7</sup> Santos FPS, et al. Cancer. 2011;117(10):2145-2155.

<sup>8</sup> Wagner K, et al. Haematol. 2011;96(5):681-686.

<sup>9</sup> Brunet S, et al. J Clin Onc. 2012;30(7):735-741.