

Press Release

Daiichi Sankyo Data at ASH Showcases Scientific and Clinical Advancements Across AML/Blood Cancer Portfolio

- Three oral presentations to feature analyses from global pivotal phase 3 QuANTUM-R study of quizartinib
- Updated phase 1 study results for valemestostat in patients with relapsed/refractory non-Hodgkin lymphomas, including ATL/L
- Abstracts demonstrate advancements in science and progress in clinical development of novel targeted therapies for patients with AML and other blood cancers

Munich and Basking Ridge, NJ – (November 6, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it will present new data for several investigational therapies in its AML/blood cancer portfolio at the 61st Annual Meeting of the American Society of Hematology (ASH), December 7-10, 2019, in Orlando, Florida.

Highlights include three oral presentations featuring post-hoc analyses from the global, pivotal phase 3 QuANTUM-R study including post-transplant survival, genetic/biomarker-related responses and outcomes, and quality-adjusted time without symptoms or toxicity in patients with relapsed/refractory *FLT3*-ITD AML receiving quizartinib versus salvage chemotherapy.

“The additional findings from the phase 3 study will help inform clinical use as well as further development of quizartinib, which is currently being evaluated in newly-diagnosed *FLT3*-ITD AML in the QuANTUM-First trial,” said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. “Other ASH presentations reflect clinical development progress for several of our investigational therapies, including valemestostat, which is an important asset in our R&D program for patients with AML and other blood cancers.”

Updated phase 1 study results will be reported for valemestostat, a potential first-in-class EZH1/2 dual inhibitor, in relapsed/refractory non-Hodgkin lymphomas (NHLs), including a subgroup analysis in patients with adult T-cell leukemia/lymphoma (ATL/L). A pivotal phase 2 study in patients with ATL/L is planned in Japan.

Following is a full list of abstracts from the Daiichi Sankyo oncology portfolio accepted at ASH:

ASH Abstract Title	Presentation Details
<i>Quizartinib / QuANTUM-R</i>	
Clinical Outcomes and Characteristics of Patients with <i>FLT3</i> -ITD-Mutated Relapsed/Refractory (R/R) AML Undergoing Hematopoietic Stem Cell Transplantation (HSCT) after Quizartinib or Salvage Chemotherapy in the QuANTUM-R Trial	Abstract #736; Oral Presentation (<i>Ganguly S</i>) Monday, December 9, 2019 Session 613: 2:45 – 4:15 PM (3:30 PM) Tangerine 3, WF3-4
Effect of Co-Mutations and <i>FLT3</i> -ITD Variant Allele Frequency (VAF) on Response to Quizartinib or Salvage Chemotherapy (SC) in Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML)	Abstract #737; Oral Presentation (<i>Perl A</i>) Monday, December 9, 2019 Session 613: 2:45 – 4:15 PM (3:45 PM) Tangerine 3, WF3-4
Quality-Adjusted Time without Symptoms or Toxicity (Q-TWiST) Analysis of Quizartinib Vs. Salvage Chemotherapy in Patients with Relapsed/Refractory (R/R) <i>FLT3</i> -ITD AML	Abstract #382; Oral Presentation (<i>Cortes J</i>) Sunday, December 8, 2019 Session 903: 7:30 – 9:30 AM (8:15 AM). W307
Pooled Safety Analysis of Quizartinib Monotherapy in Patients with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML)	Abstract #1372; Poster Presentation (<i>Cortes J</i>) Saturday, December 7, 2019 Session 616: Poster I, 5:30 – 7:30 PM. Hall B
Characterization of Response and Transfusion Independence in Patients with <i>FLT3</i> -ITD-Mutated Relapsed/Refractory AML Treated with Quizartinib or Salvage Chemotherapy in the QuANTUM-R Trial	Abstract #2599; Poster Presentation (<i>Levis M</i>) Sunday, December 8, 2019 Session 613: Poster II, 6:00 – 8:00 PM. Hall B
Exposure-Response of Quizartinib Efficacy in Patients with Relapsed/Refractory AML	Abstract #1263; Poster Presentation (<i>Kang D</i>) Saturday, December 7, 2019 Session 604: Poster I, 5:30 – 7:30 PM. Hall B
A Phase 1/2 Study of Quizartinib (Q) in Combination with Re-Induction Chemotherapy and As Single-Agent Continuation Therapy in Pediatric and young Adult Patients with Relapsed/Refractory (R/R) <i>FLT3</i> -ITD AML	Abstract #3937; Poster Presentation (<i>Zwaan M</i>) Monday, December 9, 2019. Session 616: TiP Poster III, 6:00 – 8:00 PM. Hall B
An Evaluation of Major Comorbidities and Treatment Patterns of Newly Diagnosed Acute Myeloid Leukemia Patients: A Retrospective Analysis of Electronic Medical Records from US	Abstract #5106; Publication Only (<i>Tu N</i>)
<i>Valemetostat (DS-3201)</i>	
First-in-Human Study of the EZH1/2 Dual Inhibitor DS-3201b in Relapsed or Refractory Non-Hodgkin Lymphoma (NHL)— Interim Results Focusing on Adult T-Cell Leukemia-Lymphoma (ATL)	Abstract #4025; Poster Presentation (<i>Morishima S</i>) Monday, December 9, 2019 Session 624: Poster III, 6:00 – 8:00 PM. Hall B
Anti-tumor Effect of the EZH1/2 Inhibitor Valemetostat Against Diffuse Large B-Cell Lymphoma via Modulation of B-cell receptor Signaling and c-Myc Signaling Pathways (preclinical data)	Abstract #4642; Poster Presentation (<i>Hama Y</i>) Monday, December 9, 2019 Session 802: Poster III, 6:00 – 8:00 PM. Hall B
<i>Milademetan (DS-3032)</i>	
A Phase 1 Dose Escalation Study of Milademetan in Combination with 5-Azacitidine (AZA) in Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS)	Abstract #3932; Poster Presentation (<i>DiNardo C</i>) Monday, December 9, 2019 Session 616: Poster III, 6:00 – 8:00 PM. Hall B

A Phase I Study of Milademetan in Combination with Quizartinib in Patients with Newly Diagnosed (ND) or Relapsed/Refractory <i>FLT3</i> -ITD Acute Myeloid Leukemia (AML)	Abstract #1389; Poster Presentation (<i>Daver N</i>) Saturday, December 7, 2019 Session 616: Poster I, 5:30 – 7:30 PM. Hall B
Dual Inhibition of MDM2 and XPO1 Induces Synergistic Apoptosis in Acute Myeloid Leukemia with Wild-type TP53 through Nuclear Accumulation of p53 and Suppression of c-Myc (preclinical data)	Poster Presentation (<i>Nishida Y</i>) Sunday, December 8, 2019 Session 604: Poster II, 6 – 8:00 PM. Hall B
PLX2853	
Dose Escalation Study of BET inhibitor PLX2853 in Patients with Relapsed or Refractory Acute Myeloid Leukemia or High Risk Myelodysplastic Syndrome	Abstract #1391; Poster presentation (<i>N Pemmaraju</i>) Saturday, December 7, 2019 Session: 616: Poster I, 5:30 – 7:30 PM. Hall B
A Novel Combination Regimen of BET and <i>FLT3</i> Inhibition for <i>FLT3</i> -ITD Acute Myeloid Leukemia (preclinical)	Abstract #1373; Poster presentation (<i>Lee L</i>) Saturday, December 7, 2019 Session: 616: Poster I, 5:30 – 7:30 PM. Hall B
Bromodomain and Extraterminal (BET) Domain Inhibition with PLX51107 and PLX2853 Improves Survival and Decreases Acute GVHD Severity in Murine Models (preclinical)	Abstract #4429; Poster presentation (<i>H Choe</i>) Monday, December 9, 2019 Session: 701: Poster III, 6:00 – 8:00 PM. Hall B

About Quizartinib

Quizartinib, an oral *FLT3* inhibitor, is the lead product in the AML Franchise of Daiichi Sankyo.

Quizartinib currently is approved only 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. Quizartinib is also in 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.

About Valemetostat

Valemetostat (DS-3201) is an investigational and potential first-in-class EZH1/2 dual inhibitor in phase 1 clinical development for hematologic cancers including acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), and non-Hodgkin lymphomas (NHLs) including adult T-cell leukemia/lymphoma (ATL/L), peripheral T-cell lymphoma (PTCL) and B-cell lymphomas. Valemetostat has received SAKIGAKE Designation for the treatment of adult patients with relapsed/refractory peripheral T-cell lymphoma (PTCL) by the Ministry of Health, Labour and Welfare (MHLW) in Japan.

About Milademetan

Milademetan (DS-3032) is an oral selective MDM2 inhibitor currently in phase 1 development for solid and hematologic malignancies, including a combination study with quizartinib in patients with relapsed/refractory *FLT3*-ITD AML or newly-diagnosed *FLT3*-ITD AML unfit for intensive chemotherapy in the U.S., EU and Japan; a single agent and combination study with 5-azacitidine, an inhibitor of DNA methylation, in patients with newly-diagnosed AML unfit for intensive chemotherapy, relapsed/refractory AML or high-risk MDS in the U.S.; and two single agent studies in lymphomas and solid tumors in the U.S. and Japan.

About PLX2853

PLX2853 is an investigational oral small molecule BET inhibitor currently in phase 1 development for AML and high-risk myelodysplastic syndrome (MDS) and phase 1/2 development for advanced solid tumors in the U.S. PLX2853 was discovered by Plexxikon Inc.

Valemetostat, milademetan and PLX2853 are investigational agents that have not been approved for any indication in any country. Safety and efficacy have not been established.

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 pipeline, 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.

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.

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