

## Press Release

# **Daiichi Sankyo Announces ENLIVEN Phase 3 Study of Pexidartinib Met Primary Endpoint in Tenosynovial Giant Cell Tumor**

**Tokyo, Japan, Basking Ridge, NJ, and Munich, Germany – (October 31, 2017)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that the pivotal phase 3 placebo-controlled ENLIVEN (NCT02371369) study of pexidartinib met its primary endpoint of tumor response as measured by tumor size reduction in patients with symptomatic tenosynovial giant cell tumor (TGCT) where surgical resection is potentially associated with worsening functional limitation or severe morbidity. A comprehensive evaluation of the benefit/risk for TGCT based on the totality of the pexidartinib program is now underway and will guide next steps.

Pexidartinib is an investigational agent that has not been approved for any indication and safety and efficacy have not been established.

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

The vision of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order 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 our Antibody Drug Conjugate (ADC) and Acute Myeloid Leukemia (AML) Franchises, our cancer pipeline includes more than 20 small molecules, monoclonal antibodies and ADCs stemming from our powerful research engines: our 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. Compounds in development include: quizartinib, an oral FLT3 inhibitor, for newly-diagnosed and relapsed or refractory AML with FLT3-ITD mutations; DS-8201, an ADC for HER2-expressing breast and gastric cancer, and other HER2-expressing solid tumors; and pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), which is also being explored in a range of solid tumors in combination with the anti-PD1 immunotherapy pembrolizumab. 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 products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 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 hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com). Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: [www.dsi.com](http://www.dsi.com).

## **Contact**

Jennifer Brennan  
Daiichi Sankyo, Inc.  
[jbrennan2@dsi.com](mailto:jbrennan2@dsi.com)  
+1 908 992 6631 (office)  
+1 201 709 9309 (mobile)