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FDA approves Daiichi Sankyo's TURALIO

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TURALIO is the first and only approved therapy for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery



Daiichi Sankyo Company has announced that the U.S. Food and Drug Administration (FDA) approved TURALIO™ (pexidartinib) as the first and only treatment for adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery. TGCT is a rare, non-malignant tumor that affects small and large joints. The disease can cause debilitating symptoms and can be locally aggressive.

"The FDA approval of TURALIO represents a paradigm shift in the treatment of carefully selected TGCT patients who face significant disease morbidity and for whom surgery is not an option," said William D. Tap, MD, Chief of the Sarcoma Medical Oncology Service at Memorial Sloan Kettering Cancer Center, New York, and lead investigator for the pivotal phase 3 ENLIVEN study. "We now have a new oral treatment option that can have a meaningful clinical benefit in select patients, including a reduction in tumor size."

"We are proud to be a part of today's landmark approval and offer a much-needed treatment advancement for TGCT patients whose disease is not amenable to improvement with surgery, and who, until now, have had no approved systemic treatment options," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo, Inc. "With patients at the center of everything we do, Daiichi Sankyo believes patient safety and providing effective medicines are our most important responsibilities. As such, we are committed to educating patients and the healthcare providers who care for them about the benefits and risks associated with TURALIO to ensure appropriate prescribing and monitoring."

TURALIO is approved with a Boxed Warning for hepatotoxicity due to the risk of serious and potentially fatal liver injury. Hepatotoxicity with ductopenia and cholestasis has occurred in patients treated with TURALIO. Across 768 patients who received TURALIO in clinical trials, there were two irreversible cases of cholestatic liver injury.

Because of the risk of hepatotoxicity, TURALIO will be available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program. Under this program, only certified healthcare providers may prescribe TURALIO. Biologics by McKesson, an independent specialty pharmacy for oncology and other complex therapeutic areas, has been selected to be the exclusive specialty pharmacy provider for TURALIO.