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Tokyo: Daiichi Sankyo Inc and Plexxikon Inc, a member of the Daiichi Sankyo Group, has announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to its investigational oral CSF-1R inhibitor pexidartinib (formerly PLX3397) for the treatment of tenosynovial giant cell tumor (TGCT) where surgical removal of the tumor would be associated with potentially worsening functional limitation or severe morbidity.

Breakthrough Therapy Designation is designed to expedite the development and review of medicines that may demonstrate substantial benefit over currently available treatments in order to ensure that patients with serious diseases have access to new treatments as soon as possible. The company claims that currently there is no FDA-approved systemic therapy for the treatment of TGCT.

"Surgery is the primary treatment for TGCT, but for patients with a diffuse form of the condition, the tumor is more difficult to remove and has a high rate of recurrence, resulting in multiple complicated surgeries and even amputation in some patients," said Mahmoud Ghazzi, Executive Vice President and Global Head of Development for Daiichi Sankyo. "We are pleased that the FDA recognizes the unmet need for the treatment of TGCT and we look forward to working closely with the Agency on the expedited development of this potential non-surgical treatment for patients with TGCT."

The Breakthrough Therapy Designation was granted based on results from an extension cohort of a single-arm, multi-center phase 1 study that assessed the safety and efficacy of pexidartinib. Results of this study were published in the July 30, 2015 issue of The New England Journal of Medicine.