Daiichi Sankyo Notice to 340B Covered Entities Regarding Turalio™ (NDC 65597-402-20)

July, 2019

This notice provides information for eligible 3408 covered entities about how to acquire Turalio™ *(pexidartinib)* at the 340B price.

Turalio™ *(pexidartinib)* is the first and only approved treatment for adult patients with symptomatic tenosynovial giant cell tumor ("TGCT") associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

Due to the risk of hepatotoxicity, Turalio™ *(pexidartinib)* is subject to an FDA-approved Risk Evaluation and Mitigation Strategy ("REMS") program. As a condition of the REMS program, Daiichi Sankyo has developed a limited distribution network that applies to 340B covered entities and non-340B covered entities alike. Under the limited distribution network, the product is available only through one specialty pharmacy, which must meet stringent and onerous requirements and certifications to meet the REMS program requirements.

The REMS-certified network specialty pharmacy is:

Biologics, Inc.,
11800 Weston Parkway
Cary, NC 27513
Phone: 800-850-4306

340B covered entities with contract pharmacy relationships with the above REMS-certified network specialty pharmacy should contact it directly for ordering instructions.

The pharmacy will dispense and ship Turalio™ *(pexidartinib)* directly to patients consistent with the requirements of the REMS.

Daiichi Sankyo takes very seriously its commitment to patient safety and its obligations under the 340B Program and seeks to ensure that Turalio™ *(pexidartinib)* is available to 340B covered entities in the same manner in which the product is available to other entities.

If you have any questions regarding the REMS-restricted distribution of Turalio™ *(pexidartinib)*, please contact Tara Brodo at tbrodo@dsi.com.