

Gavreto® (pralsetinib) - Indication withdrawal

- On June 29, 2023, <u>Genentech and Blueprint Medicines announced</u> that they are voluntarily withdrawing the indication of <u>Gavreto (pralsetinib)</u> for treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *rearranged during transfection (RET)*-mutant medullary thyroid cancer (MTC) who require systemic therapy.
- Gavreto was granted approval for this indication under the accelerated approval pathway in December 2020. Full approval was contingent upon demonstration of clinical benefit in the confirmatory Phase 3 randomized AcceleRET MTC study.
 - Genentech and Blueprint Medicines made the decision to voluntarily withdraw the RET-mutant MTC indication following consultation with the FDA, as the confirmatory AcceleRET MTC study could not be activated to fulfill the postmarketing requirement.
- This decision is not based on the efficacy or safety of Gavreto and does not affect the other approved Gavreto indications for *RET* fusion-positive thyroid cancer and non-small cell lung cancer.
- Genentech with Blueprint Medicines will work with the FDA over the coming weeks to complete the withdrawal process and notify healthcare professionals about this withdrawal.
- Patients being treated with Gavreto for advanced or metastatic RET-mutant MTC who require systemic therapy should discuss their care options with their healthcare provider.



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