Gavreto® (pralsetinib) – Indication withdrawal

- On June 29, 2023, Genentech and Blueprint Medicines announced that they are voluntarily withdrawing the indication of Gavreto (pralsetinib) 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.