Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

June 2023

Subject: Gavreto™ (pralsetinib) indication in adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy is being voluntarily withdrawn in the United States (U.S.)

Dear Healthcare Provider:

This letter is to inform you about an important change to the Gavreto (pralsetinib) label in the U.S.

Indications

Genentech, a member of the Roche Group, announced the voluntarily withdrawal of the accelerated approval of the U.S. indication of Gavreto for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

Genentech made this decision following consultation with the U.S. Food and Drug Administration (FDA) based on the feasibility of the confirmatory study, and in accordance with the requirements of the Accelerated Approval Program. Genentech will work with the FDA over the coming weeks to complete the withdrawal process.

No new data on safety or efficacy of Gavreto informed this decision.

This change does NOT impact other approved Gavreto indications in the U.S, including for the treatment of RET fusion-positive thyroid cancer and non-small cell lung cancer.

Background

Gavreto was granted accelerated approval in 2020 for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy based on the positive overall response rate and duration of response results from the ARROW study.

The confirmatory Phase III trial, CO42865 (AcceleRET-MTC), was the designated postmarketing requirement (PMR) for the first-line RET-mutant MTC accelerated approval indication.

Prescriber Action

A Dear Patient Letter is enclosed. Please share this letter with your patients who are currently receiving Gavreto for the treatment of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy and discuss the impact of the withdrawal of this indication on their treatment plans.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events or side effects related to the use of these products to Genentech at 1-888-835-2555.

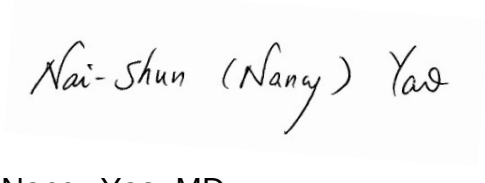
Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

You may also contact the Genentech Medical Communications department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of Gavreto.

This letter is not intended as a complete description of the benefits and risks related to the use of Gavreto. Please refer to the enclosed current full prescribing information and patient information. The revised Gavreto prescribing information is not yet available when this letter is released, and will be posted on gene.com and Gavreto.com as soon as possible.

Sincerely,



Nancy Yao, MD
Vice President
Chief Medical Partner, Oncology
U.S. Medical Affairs