FDA Approves Gavreto for RET Fusion Lung Cancer

The targeted therapy shrank tumors in more than half of people with previously treated non-small-cell lung cancer.

September 7, 2020 By Liz Highleyman

On September 4, the Food and Drug Administration (FDA) granted accelerated approval of Gavreto (pralsetinib) for people with metastatic non-small-cell lung cancer (NSCLC) with specific gene alterations.

In the ARROW study, Gavreto led to complete or partial remission in over half of people with previously treated lung cancer and 70% of those starting treatment for the first time.

Gavreto (formerly known as BLU-667), developed by Blueprint Medicine in collaboration with Genentech, inhibits a receptor tyrosine kinase known as RET. This enzyme plays a role in cell proliferation, and RET gene mutations or fusions can drive cancer growth. Around 1% to 2% of NSCLC patients are thought to have RET fusions.

“Targeted therapies have dramatically improved care for patients with non-small-cell lung cancer driven by oncogenes, including EGFR and ALK, and the approval of the selective RET inhibitor pralsetinib, or Gavreto, marks another milestone in a paradigm shift toward precision medicine,” study investigator Vivek Subbiah, MD, of the University of Texas MD Anderson Cancer Center said in a Blueprint press release. “This approval represents an important advance with the potential to change standards of care for patients with RET fusion-positive non-small-cell lung cancer, who have historically had limited treatment options.”

Gavreto is indicated for adults with metastatic RET fusion-positive NSCLC as determined by an FDA-approved test. It is the second approved RET inhibitor after Lilly’s Retevmo (selpercatinib), which got the nod for NSCLC and thyroid cancer in May. The FDA is also considering Gavreto for thyroid cancer. RET fusions and mutations occur rarely in other types of solid tumors as well.

The accelerated approval is supported by promising findings from the Phase I/II ARROW trial, which were presented at last year’s American Society of Clinical Oncology annual meeting.

The study included 87 patients with RET fusion-positive NSCLC who had previously used platinum-based chemotherapy and 27 people who were ineligible for this type of chemo and were starting

their first treatment regimen. In the first group, the overall response rate—meaning complete or partial tumor shrinkage—was 57%, including 6% with complete remission. In the previously untreated group, the overall response rate was 70%, including 11% with complete responses.

Treatment with Gavreto was generally safe and well tolerated. The most common adverse events include fatigue, constipation, muscle pain, high blood pressure, elevated ALT liver enzymes and other laboratory abnormalities. Gavreto can cause blood cell depletion, which can lead to infections and easy bleeding. The product label for Gavreto has warnings about potential serious side effects including lung inflammation, severe hypertension, liver toxicity, severe bleeding and slow wound healing.

Drugs that receive accelerated approval based on response rates in early studies are expected to undergo further testing in larger randomized trials to confirm their clinical benefits, and the FDA can rescind approval if they don't measure up. The Phase III AcceleRET Lung trial for previously untreated people with RET fusion-positive NSCLC is currently enrolling (ClinicalTrials.gov number NCT04222972).

Blueprint indicated that Gavreto should be available for prescription with a week of the approval. The recommended dose is four capsules taken once daily. Blueprint offers a patient support program for those who need financial assistance. Visit YourBlueprint.com or call 1-888-BLUPRNT.

The availability of drugs such as Gavreto and Retevmo highlights the importance of genetic testing to determine which patients could be eligible for these new targeted therapies. Next-generation sequencing of a tumor tissue biopsy sample or liquid biopsy using a blood sample can reveal actionable genetic alterations.

"We applaud therapeutic advancements like Gavreto that allow lung cancer treatment to be personalized based on the molecular drivers in a person's tumor," Andrea Ferris, president and chief executive officer of LUNGevity, said in the Blueprint press release. "There are now a number of tumor-specific gene alterations that can be targeted with FDA-approved therapies, reflecting an important inflection point supporting the widespread use of comprehensive biomarker testing. At LUNGevity, we want to empower patients and their families to discuss biomarker testing with clinicians prior to initiating treatment."

Click here for full prescribing information for Gavreto.

Click here to learn more about lung cancer.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.cancerhealth.com/article/fda-approves-gavreto-ret-fusion-lung-cancer