



December 2021

Subject: Alecensa® (alectinib), New Warning and Precaution: Hemolytic Anemia

Dear Health Care Provider:

The purpose of this letter is to inform you of updated safety information regarding hemolytic anemia for Alecensa (alectinib). Alecensa is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer as detected by an FDA-approved test.

Background on Risk of Hemolytic Anemia

Hemolytic anemia has been reported with Alecensa, including cases associated with negative direct antiglobulin test (DAT) result.

The benefit-risk profile of Alecensa in the approved indication continues to be favorable.

Prescriber Action

- If hemolytic anemia is suspected, withhold Alecensa and initiate appropriate laboratory testing.
- If hemolytic anemia is confirmed, consider resuming at a reduced dose upon resolution or permanently discontinue Alecensa. Refer to Section 2.3 “Dose Modifications for Adverse Reactions” of the [prescribing information](#).
- Counsel patients about the risks and benefits of Alecensa, including the risk of hemolytic anemia.
- Tell patients to contact their doctor right away if they experience signs or symptoms of hemolytic anemia, such as yellow skin (jaundice), weakness, dizziness, or shortness of breath.

Reporting Adverse Events

Health Care Providers should report any adverse events suspected to be associated with the use of Alecensa 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

Should you have any questions about the information in this letter or the safe and effective use of Alecensa, please feel free to contact us at: Genentech Medical Information Department at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of Alecensa. Please refer to the enclosed [full prescribing information](#) and [patient information](#).

Sincerely,

A handwritten signature in black ink that reads "Jamie Freedman". The signature is written in a cursive style with a long horizontal flourish at the end.

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs