FDA OKs 1st targeted drug for common lung cancer mutation

May 28 2021, by Linda A. Johnson

U.S. regulators have approved the first medicine for patients with the most common type of lung cancer whose tumors have a genetic mutation long considered untreatable with drugs.

The Food and Drug Administration on Friday said it has approved Amgen's drug Lumakras to treat non-small cell lung cancer with the mutation in patients who have worsened after initial treatment with at least one other drug. Each year, about 13,000 U.S. patients are diagnosed with this cancer and mutation.

This is the first targeted therapy for tumors with a so-called KRAS mutation, the FDA noted. This type of mutation occurs in genes that help regulate cell growth and division. The mutation is involved in many cancer types.

"Today's approval represents a significant step toward a future where more patients will have a personalized treatment approach," Dr. Richard Pazdur, director of the FDA's Oncology Center of Excellence, said in a statement.

Amgen said Lumakras, also known as sotorasib, will cost $17,900 per month, though most patients will pay less, depending on health insurance and other factors. Lung cancer is the most common cancer type and is the leading cause of cancer deaths in the U.S.

The agency also approved diagnostic tests from two companies that can

determine if patients have the specific mutation, known as KRAS G12C, targeted by the drug.

Amgen and other drugmakers are working to develop several medicines designed to attack tumors with KRAS mutations.

"KRAS has challenged cancer researchers for more than 40 years," Dr. David M. Reese, Amgen's head of research and development, said in a statement.

The FDA approved the drug on an accelerated schedule, based only on early study results, because of its potential and the lack of options for these patients. It is requiring further testing to confirm the drug's benefit.

In a study including 124 patients, 36% had their tumors shrink or disappear. Improvements lasted for six months or longer for nearly 60% of those who benefited.

Common side effects included diarrhea, joint and muscle pain, fatigue and liver damage. The FDA said the drug should be discontinued if patients develop liver damage or a type of lung disease.

© 2021 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed without permission.

Citation: FDA OKs 1st targeted drug for common lung cancer mutation (2021, May 28) retrieved 13 May 2024 from https://medicalxpress.com/news/2021-05-fda-oks-1st-drug-common.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.