First KRAS Drug Now Available

Lumakras (sotorasib) was granted accelerated approval for the treatment of advanced non-small-cell lung cancer.

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After three decades of frustration, the Food and Drug Administration has finally approved the first KRAS inhibitor. Lumakras (sotorasib) was granted accelerated approval for the treatment of advanced non-small-cell lung cancer (NSCLC), but the new targeted therapy shows promise for other cancers as well.

The KRAS gene makes proteins that regulate cell growth. Once considered “undruggable,” KRAS is the most commonly altered gene in people with cancer. Sotorasib targets a specific mutation, known as KRAS G12C, found in about 13% of NSCLC tumors.

The CodeBreaK 100 trial tested once-daily Lumakras pills in people with lung cancer and several other solid tumors. Among 124 previously treated people with locally advanced or metastatic NSCLC, 37% saw their tumors shrink, including four with complete remission; another 44% had stable disease without further progression. The median duration of response was 11.1 months, and the median overall survival was 12.5 months.

The approval highlights the importance of tumor genomic testing to determine who might benefit from Lumakras. “Biomarker testing for patients with non-small-cell lung cancer is critical because it informs a patient’s treatment path with a personalized and tailored approach,” says LUNGevity president and CEO Andrea Ferris.

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