FDA approves Genentech drug for advanced lung cancer

11 December 2015, byLinda A. Johnson

The Food and Drug Administration on Friday conditionally approved an experimental Genentech drug for patients with a certain type of lung cancer who have few other options.

Alecensa won accelerated approval for patients with advanced non-small cell lung cancer with a mutation in a gene called ALK who have relapsed after treatment with Pfizer Inc.'s Xalkori or who could not tolerate that drug. The mutation in ALK, or anaplastic lymphoma kinase, indirectly drives growth of tumors.

Accelerated approval is granted to medicines for serious or life-threatening conditions that show an effect likely to benefit patients. To maintain that conditional approval, the drugmaker must then do further testing to confirm that the medicine improves patients' condition. Genentech has already begun a larger, head-to-head study of how long Alecensa extends survival compared to New York-based Pfizer's Xalkori, in patients not previously treated with either pill.

In one of two midstage patient studies that led to Alecensa's approval, the twice-a-day pill shrank the lung tumors of 38 percent of the 87 participants, and that benefit lasted an average of 7 ½ months. In a second study, also funded by Genentech, tumors shrank in 44 percent of the 138 participants, and that benefit lasted an average of about 11 months. All those participants had previously taken Xalkori, but it had stopped working.

Both studies also tested the effects of Alecensa, known chemically as alectinib, on tumors that had spread to the brain, which often occurs in such patients. According to the FDA, 61 percent of patients in the two studies had their brain tumors shrink or disappear, with the effect lasting about nine months on average.

"In addition to the primary effect on tumors in the lung, Alecensa clinical trials provide evidence of an effect on tumors that had spread to the brain, which is an important effect," Dr. Richard Pazdur, director of the FDA's Office of Hematology and Oncology, said in a statement.

Alecensa is the only drug shown to do that, according to a Genentech spokesman.

Genentech, the biotech unit of Swiss drugmaker Roche Group, will have a list price of about $12,500 per month before discounts negotiated with insurers. The company is offering patients financial assistance, including copay cards that enable patients with commercial insurance to get the drug for a $25 monthly copayment.

Lung cancer is the top cause of cancer deaths in the U.S. The National Cancer Institute estimates it will kill about 158,000 people this year. About 85 percent of lung cancers are non-small cell lung cancer, which is usually diagnosed at an advanced stage, and about 5 percent of that group has the ALK mutation.

Alecensa can cause liver problems, life-threatening inflammation of the lungs, very slow heartbeats and severe muscle problems. More-common side effects include fatigue, constipation, muscle pain and swelling in the hands, feet, ankles and eyelids.

Besides giving Alecensa an expedited review and the accelerated approval, the FDA designated it as a breakthrough therapy.

The drug will be available to U.S. patients within two weeks, Genentech said.