First and only therapeutic drug for ALK-positive lung cancer approved

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In a major triumph for personalized medicine, the FDA approved the drug crizotinib for use with the lung cancer type known as ALK-positive.

"I know the names and I can see the faces of every ALK-positive patient I have treated with crizotinib. Most of them would not be alive today if not for this drug," says Ross Camidge, investigator at the University of Colorado Cancer Center and oncologist at the University of Colorado School of Medicine, who has been involved with the drug since its first trials in 2008.

Approximately 4% of the 220,000 Americans diagnosed with lung cancer each year have the ALK fusion gene, and 45,000 newly diagnosed lung cancer patients are ALK positive worldwide. The drug crizotinib targets this ALK fusion gene - which is expressed only in cancer cells and not their healthy neighbors - starving cancer cells of the energy they need to live and grow.

"By truly understanding the underlying genetic drivers of lung cancer, such as ALK, we can select patients who are more likely to respond to treatment. Crizotinib provides a model for how to approach future drug development and cancer care," says Paul Bunn, investigator at the University of Colorado Cancer Center and professor of medicine and the James Dudley chair in cancer research at the University of Colorado School of Medicine. "Crizotinib, the first new drug approved for lung cancer by the FDA in more than six years, represents a paradigm shift in lung cancer treatment, where we're moving away from a one-size-fits-all approach to biomarker-based treatment decisions."

The approval of this drug is also a major achievement for the University of Colorado Cancer Center, which has been involved in all phases of the drug's development and use, including creating the clinical test for ALK-positive lung cancers and enrolling the first patients in the phase I study of the drug, in 2008.

With the approval of crizotinib, today is the first day of FDA-approved, personalized treatment for lung cancer.

Provided by University of Colorado Denver