# Takeda's Alunbrig (Brigatinib) Receives FDA Accelerated Approval for Treatment of ALK+ Lung Cancer

MAY 5, 2017MAY 5, 2017

BY MAGDALENA KEGEL


**The U.S. Food and Drug Administration (FDA) has granted accelerated approval to Takeda's Alunbrig (brigatinib) to treat ALK-positive metastatic non-small cell lung cancer (NSCLC) in patients who either progressed or could not tolerate treatment with Xalkori (crizotinib).**

The approval, which Dr. Christophe Bianchi, president of Massachusetts-based Takeda Oncology, called "an important milestone" in a press release, was based on data from a Phase 2 trial (NCT02094573). Continued approval for this type of cancer may require Takeda to conduct more trials verifying the drug's benefits.

“In recent years, small molecule ALK [anaplastic lymphoma kinase] inhibitors have revolutionized the treatment options for those with advanced ALK+ non-small cell lung cancer,”said Dr. D. Ross Camidge, director of thoracic oncology at the University of Colorado. “Nevertheless, there is still a need for additional ALK inhibitors like brigatinib (Alunbrig), which have a manageable safety profile and may address mechanisms of clinical resistance to crizotinib, including progression in the central nervous system.”

Alunbrig is an oral treatment taken once daily. The Phase 2 trial, called ALTA, recruited 222 patients with either locally advanced or metastatic lung cancer. Participants were treated with one of two Alunbrig dose regimens. All patients started with a 90 mg dose, once daily. After seven days, about half the group continued on 180 mg, while the rest remained on the 90 mg dose. Patients were followed for a median of eight months.

An independent review committee deemed that patients in the higher-dose group had an overall response rate of 53 percent. Five patients in that group and four in the lower-dose group had a complete response. In both groups, the duration of response lasted for more than a year.

“For patients with ALK+ metastatic NSCLC who have progressed on or are intolerant to crizotinib, who are facing the uncertainty of disease progression and the potentially devastating impact of brain metastases, the approval of Alunbrig offers a new hope,” said Bonnie Addario, founder and chair of the Addario Lung Cancer Foundation.

The study also showed that 67 percent of patients with brain metastases achieved a confirmed intracranial overall response.

“The rapid development of Alunbrig is a tribute to the dedication of many research scientists and clinicians who carefully designed and developed this new medicine to address unmet medical needs in the ALK+ NSCLC patient population,” said Dr. Andy Plump, Takeda’s chief medical and scientific officer. “Most importantly, we would like to thank the patients and families who participated in the clinical trials.”

Takeda acquired the rights to Alunbrig when it took over Ariad Pharmaceuticals, which first discovered and developed the compound.