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Takeda gets positive CHMP opinion for ALUNBRIG

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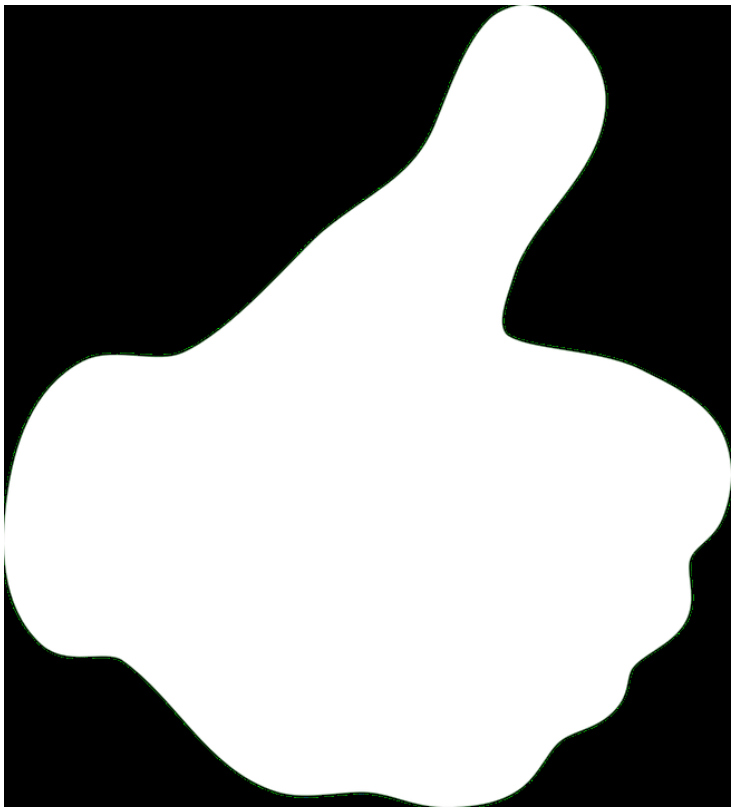
As part of this submission, the CHMP also reviewed data from the first interim analysis of the Phase 3 ALTA-1L trial, which met its primary endpoint, as supportive evidence. In ALTA-1L, treatment with ALUNBRIG resulted in a statistically and clinically significant improvement in PFS versus crizotinib as assessed by a blinded independent review committee. The safety profile associated with ALUNBRIG was generally consistent with prior studies and approved U.S. and Canadian labeling.



Takeda Pharmaceutical Company Limited has announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending the full approval of ALUNBRIG (brigatinib) as a monotherapy for the treatment of adult patients with anaplastic lymphoma kinase-positive (ALK+) advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. ALUNBRIG is a tyrosine kinase inhibitor (TKI) designed to target and inhibit the ALK mutation in NSCLC. Approximately three to five percent of NSCLC patients globally have the ALK mutation. If the CHMP opinion is affirmed, and the European Commission approves ALUNBRIG, it will become the only ALK inhibitor available in the European Union as a one tablet per day dose that can be taken with or without food.

The randomized, global Phase 2 ALTA trial was designed to investigate the efficacy and safety of ALUNBRIG in patients with locally advanced or metastatic ALK+ NSCLC who had progressed on crizotinib. Patients were randomized to receive one of two regimens of ALUNBRIG: 90 mg of ALUNBRIG once daily (n=112) or 180 mg once daily with seven-day lead-in at 90

mg once daily (n=110).

“ALK+ NSCLC is a serious and life-threatening disease that affects approximately 40,000 people worldwide every year, and many patients will progress on or stop responding to first-line treatment,” said Stefania Vallone, President, Lung Cancer Europe. “For European people with ALK+ NSCLC, there remains a significant unmet need for new and effective treatment options.”

“While ALK inhibitors have demonstrated tremendous growth in this treatment space over the past decade, having an additional targeted therapy option available for the treatment of ALK+ NSCLC has been eagerly anticipated,” said Enriqueta Felip, M.D., PhD, Head of the Thoracic Oncology Unit, Oncology Department at Vall d’Hebron University Hospital in Barcelona. “With a median progression-free survival of 16.7 months and overall survival of 34.1 months, ALUNBRIG has shown impressive results, representing new progress for ALK+ NSCLC treatment in this setting.”

“The ALTA trial has established ALUNBRIG as a potential second-line treatment option for ALK+ NSCLC, by demonstrating significant efficacy with a manageable safety profile,” said Jesús Gómez-Navarro, M.D., Vice President, Head of Oncology Clinical Research and Development, Takeda. “With 16.7 months median progression-free survival, the longest of any ALK inhibitor to be reported in this setting, ALUNBRIG offers great potential for patients who progressed on crizotinib. Today’s positive opinion brings us closer toward the ultimate goal of advancing the treatment paradigm for the considerable number of crizotinib-treated ALK+ NSCLC patients living in Europe. We look forward to the European Commission’s review of the CHMP positive opinion and introducing ALUNBRIG to patients and healthcare professionals in the European Union if approved.”

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The CHMP positive opinion for ALUNBRIG will now be reviewed by the European Commission, which has the authority to approve medicines for use in the 28 member states of the European Union, as well as Norway, Liechtenstein and Iceland.