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EC Approves Takeda's ALUNBRIG for ALK+ Non-Small Cell Lung Cancer

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"The European Commission's decision to approve ALUNBRIG for patients with ALK+ NSCLC is a significant advancement for European patients impacted by this life-threatening disease"

Takeda Pharmaceutical Company Limited announced that the European Commission (EC) granted marketing authorization for 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. The decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) on September 20, 2018.

"The introduction of targeted therapies has greatly improved the treatment of ALK+ NSCLC, yet for the approximately 70 percent of patients who progress on crizotinib with brain metastases, additional therapeutic options are needed," said Enriqueta Felip, M.D., PhD., Head of the Thoracic Oncology Unit, Oncology Department at Vall d'Hebron University Hospital in Barcelona.

"Data from the ALTA trial investigating ALUNBRIG showed sustained systemic and intracranial efficacy results and a manageable safety profile, leading to the longest progression-free survival and overall survival reported in this setting. This approval gives physicians in the European Union another choice in addressing ALK+ NSCLC patients previously treated with crizotinib."

"The European Commission's decision to approve ALUNBRIG for patients with ALK+ NSCLC is a significant advancement for European patients impacted by this life-threatening disease," said Jesús Gómez-Navarro, M.D., Vice President, Head of Oncology Clinical Research and Development, Takeda.

“This is the first time a median progression-free survival of over 16 months as assessed by an independent review committee and median overall survival of 34 months have been reported in the post-crizotinib setting, which highlights the strength of the ALTA trial data. The authorization of ALUNBRIG in the EU speaks to our ongoing commitment to developing innovative solutions to improve the lives of the approximately 40,000 patients diagnosed with this disease worldwide each year.”

This decision by the European Commission means that ALUNBRIG is now approved for marketing of this indication in the 28 member states of the European Union, and applicable in Norway, Liechtenstein and Iceland.