U.S. FDA APPROVES TAKEDA’S LUNG CANCER THERAPY

Reuters - 16/09/2021 - Japanese pharma company Takeda Pharmaceutical Co said on Wednesday the U.S. Food and Drug Administration approved its drug, Exkivity, to treat a type of lung cancer.

Takeda said the approval was based on an early-to-mid-stage trial testing 114 patients with non-small cell lung cancer, with results showing clinically meaningful responses with a median duration of about 18 months.

Exkivity was approved for patients with a specific gene mutation called EGFR Exon20 insertions in non-small cell lung cancer, whose disease has progressed on or after chemotherapy.

The company said the approval for the indication was contingent upon verification and description of clinical benefit in a confirmatory trial.

Non-small cell lung cancer is the most common form of lung cancer, accounting for about 85% of the estimated 2.2 million new cases of lung cancer diagnosed each year worldwide, according to the World Health Organization.

The drug comes with a boxed warning flagging risks of potential heart toxicity, lung disease and heart rhythm disturbances.

By Reuters Staff

