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Roche has announced that the US Food and Drug Administration (US FDA) has approved Esbriet (pirfenidone) as a treatment for idiopathic pulmonary fibrosis (IPF), a chronic lung disease.

"This is a historic day for the people and their families in the United States who live with this deadly, incurable disease," said Ms Sandra Horning, chief medical officer and head of global product development. She added, "With today's approval of Esbriet in the United States, people with IPF finally have an FDA-approved medicine that may slow the worsening of the disease."

The approval of Esbriet is based on data from a large, placebo-controlled Phase III study known as ASCEND and is supported by two other large Phase III trials known as CAPACITY 1 and 2. In the ASCEND study, more patients who received Esbriet had a delay in the decline of lung function compared to those who received placebo as defined by the primary endpoint of percent change in Forced Vital Capacity (FVC), a measure of how well the lungs work based on the amount of air one can exhale with force after inhaling as deeply as possible.

Esbriet was developed by InterMune, a California-based biotechnology company which Roche acquired this year.

"Until today, the 100,000 people with IPF living in the United States did not have an FDA-approved treatment," said Mr Jonathan Leff, executive vice president R&D, InterMune."Today's approval would not have been possible without the courage of patients, their families and the medical community that participated in the clinical studies of Esbriet," he added.