Study reveals long-term safety, efficacy of Ofev in patients with idiopathic pulmonary fibrosis

Results from INPULSIS®-ON, published today in *Lancet Respiratory Medicine*, provide insights into the long-term safety, efficacy and tolerability of Ofev® (nintedanib) in patients with idiopathic pulmonary fibrosis (IPF). These data suggest that the effect of nintedanib on slowing disease progression of IPF persists beyond four years.[1] Results also indicate that the long-term efficacy of nintedanib in reducing disease progression may be sustained in patients who require dose adjustments.

The exploratory findings of the open-label extension trial are consistent with results from the Phase III INPULSIS® trials and show that continued treatment with nintedanib, for up to 68 months, has a manageable safety and tolerability profile, with no new safety signals identified. The INPULSIS®-ON trial featured a large cohort of patients with IPF who have received nintedanib, and these data add to the growing body of evidence suggesting that nintedanib provides long-term benefits to patients with IPF.

IPF is a rare, debilitating and fatal lung disease that affects approximately 3 million people worldwide. It causes progressive scarring of the lungs, resulting in continuous and irreversible deterioration in lung function and breathing difficulties. As IPF progresses, lung function gradually and irreversibly deteriorates.

In the INPULSIS®-ON trial, involving 734 patients:

- Descriptive efficacy assessments of lung function showed the annual rate of decline in forced vital capacity (FVC) over 192 weeks was -135.1 mL/year. This was consistent with the annual rate of FVC decline in patients treated with nintedanib in the INPULSIS® trials (-113.6 mL/year in patients treated with nintedanib). Data from clinical trials suggest that FVC decline in placebo-treated patients with IPF and mild or moderate lung function impairment at baseline is approximately 200 mL over 1 year.
- The annual rate of decline in FVC was consistent irrespective of age, race and FVC % predicted at the start of INPULSIS®-ON.
- The incidence rate of acute exacerbations in INPULSIS®-ON was similar to that in patients treated with nintedanib in the INPULSIS® trials, further supporting the effect of nintedanib on reducing the risk of acute exacerbation.
- An acute exacerbation is a sudden deterioration in respiratory function, in many cases with unknown cause, which negatively impacts the disease course and often leads to death within a few months.

The most common adverse event during INPULSIS®-ON was diarrhoea, as in the

INPULSIS® and TOMORROW trials, and led to treatment discontinuation in 4.7% and 10.2% of patients who continued and initiated nintedanib during INPULSIS®-ON, respectively. Cardiovascular (major adverse cardiac and vascular events, e.g heart attack or stroke) and bleeding exposure-adjusted event rates collected in patients who continued or initiated nintedanib in INPULSIS®-ON were similar to those observed in placebo-treated patients in the INPULSIS® trials.[1,2] These findings are also consistent with post-marketing surveillance data collected in the US during the first year following the launch of nintedanib as a treatment for IPF.[15]

“The results of INPULSIS®-ON add to a growing body of evidence showing that nintedanib provides long-term benefits to patients with IPF,” said Professor Bruno Crestani, lead investigator of INPULSIS®-ON, Professor of Pneumology at the Paris Diderot University School of Medicine, France and Head of the Pneumology and Rare Lung Disease Department at Bichat Hospital, France. “IPF is a chronic disease that requires long-term treatment; therefore, long-term safety and efficacy data beyond four years of treatment is important. With these positive data from INPULSIS®-ON, physicians can feel confident that their patients can benefit from nintedanib over the long term.”

Dr Susanne Stowasser, Associate Head of Medicine Respiratory at Boehringer Ingelheim said: “The INPULSIS®-ON results provide valuable insights about the long-term safety and efficacy of OFEV® in IPF and supply further evidence of its positive impact on the lives of people living with this disease.” Dr Stowasser added: “Progressive fibrosing lung diseases like IPF continue to have a devastating impact on people’s lives and our focus remains on researching and bringing to market treatments that improve the lives of these patients at need.”

Source:

https://www.boehringer-ingelheim.com/press-release/inpulsis-shows-ofev-slows-progression-ipf