Ofev® (nintedanib) – Expanded indication

- On March 9, 2020, the FDA announced the approval of Boehringer Ingelheim's Ofev (nintedanib), for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

- Ofev is also approved for the treatment of idiopathic pulmonary fibrosis and to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated ILD.

- Chronic fibrosing ILD with a progressive phenotype encompasses a group of fibrotic lung diseases caused by different underlying diseases or conditions, including autoimmune ILD, hypersensitivity pneumonitis and idiopathic nonspecific interstitial pneumonia.

    — Progressive lung scarring leads to breathlessness and respiratory failure. Lung function declines over time among these patients and can be debilitating and life-threatening.

- The approval of Ofev for the new indication was based on a randomized, double-blind, placebo-controlled study in 663 patients with chronic fibrosing ILDs with a progressive phenotype. Patients received either Ofev or placebo for at least 52 weeks. The primary endpoint was the annual rate of decline in Forced Vital Capacity (FVC) (in mL) over 52 weeks. Other endpoints included time to first acute ILD exacerbation and time to death.

    — The adjusted annual rate of decline in FVC over 52 weeks was -81 mL and -188 mL for Ofev and placebo, respectively (difference of 107; 95% CI: 65, 148).
    — The risk of first acute ILD exacerbation did not show a statistically significant difference between the Ofev group vs. placebo (52 week treatment period: hazard ratio [HR] 0.72; 95% CI: 0.38, 1.37; whole trial: HR 0.63; 95% CI: 0.37, 1.07).
    — All-cause mortality did not show a statistically significant difference (52 week treatment period: HR 0.94; 95% CI: 0.47, 1.86; whole trial: HR 0.78; 95% CI: 0.50, 1.21).

- The recommended dosage of Ofev for all of its indications is 150 mg orally twice daily administered approximately 12 hours apart.

    — Liver function tests should be conducted in all patients and a pregnancy test in females of reproductive potential prior to initiating treatment with Ofev.