Immediate Release:
First Treatment of Rare Lung Disease

On September 6, 2019, the U.S. Food and Drug Administration (FDA) approved a new indication for Boehringer Ingelheim's Ofev® (nintedanib). Ofev is the first treatment to slow the rate of pulmonary function decline in adults with interstitial lung disease associated with systemic sclerosis or scleroderma, known as SSc-ILD.

Systemic sclerosis (SSc) is a rare autoimmune disease that causes tissues in the body, including the lungs, to thicken and scar. SSc affects approximately 100,000 individuals in the U.S. and 2.5 million worldwide. Interstitial lung disease (ILD) is one of the most common disease manifestations of SSc, causing a loss of lung function due to the lungs not supplying enough oxygen to the heart. SSc-ILD is a progressive lung disease that can be debilitating and life-threatening as lung function declines over time. SSc-ILD is diagnosed in approximately half of the patients with SSc and is the leading cause of death.

The Ofev prescribing information contains warnings for patients with moderate or severe liver impairment, elevated liver enzymes, drug-induced liver injury and gastrointestinal (GI) disorders. In addition, Ofev contains warnings for the ability to cause fetal harm, blood clots, bleeding and tearing of the stomach or intestinal wall. Common side effects of Ofev include diarrhea, nausea, abdominal pain, vomiting, liver enzyme elevation, decreased appetite, headache, weight loss and high blood pressure.

Ofev provides the first treatment for patients with SSc-ILD and it received a Priority Review and Orphan Drug designation from the FDA. It was previously approved in 2014 for adult patients with idiopathic pulmonary fibrosis. Ofev is supplied as 100 mg or 150 mg capsules and is only available through a limited pharmacy distribution network.

For additional details, view the manufacturer's press release or FDA's news release.

References

1. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205832s012lbl.pdf. Accessed September 17, 2019.
2. FDA approves first treatment for patients with rare type of lung disease. FDA News Release. https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-rare-type-lung-disease. Updated September 6, 2019. Accessed September 17, 2019.
3. FDA approves Ofev® as the first and only therapy to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated ILD. Boehringer Ingelheim Press Release. https://www.boehringer-ingelheim.us/press-release/fda-approves-ofev-first-and-only-therapy-slow-rate-decline-pulmonary-function. Updated September 6, 2019. Accessed September 17, 2019.