FDA Approves Nerandomilast for Progressive Pulmonary Fibrosis

Key Takeaways

- Nerandomilast is now FDA-approved for progressive pulmonary fibrosis, following its prior approval for idiopathic pulmonary fibrosis.
- Progressive pulmonary fibrosis leads to lung scarring, causing breathing difficulties and reduced oxygenation, with millions affected globally.
- The FIBRONEER-ILD Phase 3 trial showed nerandomilast significantly reduced lung function decline compared to placebo.
- While nerandomilast did not significantly impact acute exacerbations or hospitalizations, it provides a new treatment option for PPF patients.

The approval offers hope for improved lung function and new treatment options for patients.

The FDA has approved nerandomilast (Jascayd; Boehringer Ingelheim) tablets for the treatment of progressive pulmonary fibrosis (PPF) in adults, offering a new treatment option for this patient population. This approval marks nerandomilast's second FDA-approved indication, following its recent authorization for the treatment of idiopathic pulmonary fibrosis (IPF) in adults.[1]

"[Individuals] living with progressive pulmonary fibrosis often carry a heavy burden that others don't always see," Scott Staszak, president and CEO of the Pulmonary Fibrosis Foundation, said in a news release. "A progressive disease condition process like PPF can worsen lung function quickly, and patients have been eagerly awaiting additional treatment options. The FDA approval of [nerandomilast] for PPF is a welcomed milestone for the community."[1]

What is PPF?

Nearly 5.6 million individuals globally and 100,000 US individuals are affected with PPF, which can be caused by environmental exposure to asbestos, silica or other toxins, or result from an unknown cause. PPF is a condition in which lung tissue becomes scarred, making it harder to breathe and get enough oxygen into the bloodstream. The condition worsens over time, but its progression varies depending on the individual.[1,2]

"Progressive pulmonary fibrosis is linked to underlying clinical ILD diagnoses, including autoimmune ILDs—which can be caused by disorders like rheumatoid arthritis or systemic sclerosis—as well as hypersensitivity pneumonitis, among other conditions," Shervin Assassi, MD, professor and director of rheumatology at McGovern Medical School, UTHealth Houston, said in the news release.[1]

PPF commonly causes shortness of breath, particularly during or after physical activity, along with rapid, shallow breathing. Individuals could also experience a persistent dry cough, ongoing fatigue, and unexplained weight loss. In more advanced cases, changes such as clubbed fingers and bluish, gray, or white discoloration around the lips, eyes, or nails can occur due to low oxygen levels.[2]

"These underlying conditions often lead to the lungs being overlooked, yet lung scarring may lead to debilitating and irreversible impact on lung function. This can have a detrimental effect on patients' lives

and highlights the need for new treatment options that can help reduce the decline in lung function, as has been observed with [nerandomilast]," Assassi continued.[1]

Pivotal Phase 3 FIBRONEER-ILD Trial Data Supporting FDA Approval

Nerandomilast's approval is based on data from the pivotal phase 3 FIBRONEER-ILD clinical trial (NCT05321082), which compared nerandomilast treatment with placebo.[1,3]

In the phase 3 trial, the primary end point was the absolute change from baseline in forced vital capacity (FVC), a key measure of lung function, at week 52. The results demonstrated that nerandomilast significantly reduced the decline in FVC compared with placebo, with adjusted mean declines of -86 mL and -69 mL in patients that received 18 mg and 9 mg, respectively, compared to -152 mL in the placebo group.[1]

The key secondary end point assessed time to the first occurrence of acute ILD exacerbation, respiratory-related hospitalization, or death during the blinded trial period. Overall, nerandomilast did not demonstrate a statistically significant difference compared with placebo for this end point, with hazard ratios of 0.77 for the 18 mg dose and 0.88 for the 9 mg dose.[1]

The most common adverse events in patients with PPF were generally consistent with those seen in patients with IDF, with diarrhea as the most reported reaction and cause of treatment discontinuation.[1]

"Progressive pulmonary fibrosis is a life-threatening condition with a high unmet medical need. The US approval of [nerandomilast] is an important step forward to help slow lung function decline for people living with PPF, providing a new, well-tolerated treatment option," Shashank Deshpande, chairman of the board of managing directors and head of human pharma at Boehringer Ingelheim, said in the news release. "My gratitude goes to patients; investigators and our teams whose dedication made this milestone possible. We will now work closely with stakeholders to enable access and work tirelessly to ensure patients around the world can benefit from [nerandomilast] as quickly as possible."[1]

REFERENCES

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