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Boehringer Ingelheim receives DCGI approval for SSc-ILD drug

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Approval is based on the SENSCIS® study which showed Nintedanib slows the loss of pulmonary function inpeople living with systemic sclerosis-associated ILD (SSc-ILD)

Boehringer Ingelheim (India) announced that the DCGI has approved Nintedanib for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD) in adults. The approval comes after the Subject Expert Committee (CDSCO) had adopted a positive opinion for Nintedanib in treatment of SSc-ILD on 3rd March 2020.

Systemic sclerosis (SSc), also known as scleroderma, is a disfiguring, disabling and potentially fatal rare autoimmune disease. It causes scarring (fibrosis) of various organs, including the lungs, heart, digestive tract and kidneys and can lead to life-threatening complications. When the lungs are affected, it can cause interstitial lung disease (ILD), known as SSc-ILD. ILD is a leading cause of mortality, accounting for almost 35% of SSc-related deaths.

“Systemic sclerosis is a life- altering condition and Nintedanib is the first and only approved treatment for SSc-ILD, serving a high unmet need making a real positive difference. For the treatment of people living with SSc-ILD, this is a quantum leap” said Sharad Tyagi, MD, Boehringer Ingelheim India. “The DCGI approval is a milestone in Boehringer Ingelheim’s dedication towards providing the best possible treatment for people living with SSc-ILD in India.” he added.

DCGI’s approval is based on the results of the SENSCIS® trial, a Phase III, double-blind, placebo-controlled trial conducted to investigate the efficacy and safety of Nintedanib in patients with SSc-ILD. The primary endpoint was the annual rate of decline in Forced Vital Capacity (FVC) assessed over a 52-week period. Results showed Nintedanib slowed the loss of pulmonary function by 44% (41mL/year) relative to placebo, as measured in FVC over 52 weeks.1 Furthermore, results showed that Nintedanib had a safety and tolerability profile similar to that observed in patients with idiopathic pulmonary fibrosis (IPF).

Regulatory approvals for the treatment of patients living with SSc-ILD have also been granted in several countries including EU, Canada, Japan and Brazil. Nintedanib is approved in over 75 countries for the treatment of IPF, and it is the first

approved treatment for SSc-ILD.