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BI drug gets 'breakthrough therapy designation'

23 July 2014 | News | By BioSpectrum Bureau

Singapore: Boehringer Ingelheim has recieved 'breakthrough therapy' designation from US Food & Drug Administration (FDA) for Nintedanib, an investigational therapy currently under FDA and European Medicines Agency (EMA review) for idiopathic pulmonary fibrosis (IPF), a devastating and fatal lung disease.

"We're excited nintedanib has been granted breakthrough therapy designation in the US, which we hope will make the treatment available to IPF patients as quickly as possible. Currently there are no FDA-approved treatments available for IPF. We are committed to working with all regulatory bodies to make nintedanib available to people living with this serious and life-threatening lung disease." said Professor Klaus Dugi, chief medical officer, Boehringer Ingelheim.

The Breakthrough Therapy designation process was established by the FDA in 2012. It is intended to facilitate and expedite the development and review of treatments for serious or life-threatening conditions if preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

IPF is a debilitating and fatal lung disease that causes permanent scarring of the lungs, difficulty breathing and decreases the amount of oxygen the lungs can supply to the major organs of the body. IPF affects as many as 14-43 people per 100,000 worldwide.

Nintedanib is the first targeted treatment for IPF that has consistently demonstrated to slow disease progression in IPF by significantly reducing the annual decline in lung function by approximately 50 percent.