# Saudi Food & Drug Authority (SFDA)

# SAFETY COMMUNICATION

**27/02/2018**

## Increased risk of drug-induced liver injuries associated with the use of nintedanib (OFEV)

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals (HCPs) that nintedanib (OFEV) use might increase the risk of drug-induced liver injuries (DILIs), which can be serious or life threatening. Patients with low body weight (< 65 kg), female patients, or older age population might be at greater risk for DILIs.

OFEV is used to treat idiopathic pulmonary fibrosis (IPF). IPF is a type of lung disease in which the lungs become scarred and breathing becomes difficult, for an unknown reason. There have been several internationally reported cases of DILIs, including one death, in patients treated with OFEV. In most of these cases, patients have recovered when the dose was reduced or treatment was stopped.

Based on the current information SFDA requested the marketing authorization holder to update OFEV's summary of product characteristics (SPC) and patient information leaflet (PIL) to include the necessary warnings and precautions concerning DILIs. In addition, a direct healthcare professional communication (DHPC) has been distributed by the marketing authorization holder in agreement with SFDA to inform the HCPs about the risk of DILIs with OFEV use.

The SFDA emphasizes that HCPs should perform liver functions tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and bilirubin) before starting

OFEV therapy, then monthly during the first three months of treatment. Liver functions should be assessed as clinically indicated thereafter. Patients should be advised to seek medical help if they experience symptoms of liver injury such as yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, or loss of appetite.

Discontinue OFEV therapy if:

- AST or ALT levels are 3 times higher than the upper limit of normal (ULN) and the patient have signs or symptoms of hepatic injury
- AST or ALT levels are 5 times higher than ULN

Reduce or interrupt OFEV therapy if:

- AST or ALT levels are 3 times ULN but less than 5 without signs of hepatic injury

**Report Adverse Drug Reactions (ADRs) to the SFDA**

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Reporting hotline: 19999
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa

Webpage: www.sfda.gov.sa/npc