This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Nintedanib ethanesulfonate

March 15, 2022

Non-proprietary name

Nintedanib ethanesulfonate

Brand name (Marketing authorization holder)

Ofev Capsules 100 mg, 150 mg (Boehringer Ingelheim Japan, Inc.)

Indications

Idiopathic pulmonary fibrosis

Systemic sclerosis-associated interstitial lung disease

Progressive fibrosing interstitial lung disease

Summary of revisions

1. A cautionary statement for nephrotic syndrome should be added to the IMPORTANT PRECAUTION section.
2. “Nephrotic syndrome” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of nephrotic syndrome have been reported in patients treated with nintedanib ethanesulfonate in Japan and overseas. MHLW/PMDA, in consultation with expert advisors, concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Cases involving nephrotic syndrome

A total of 6 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for all the cases.)
No patient mortalities have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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