HCP AUTHORIZATION FORM

OFEV® (nintedanib) capsules 150mg

Dear Healthcare Provider:

Boehringer Ingelheim is providing education classes for patients whose physicians or other healthcare providers have prescribed OFEV® (nintedanib) therapy. These classes will be conducted by Clinical Educators, employees of Boehringer Ingelheim, who may either meet with the patient in person or speak with the patient over the phone. These classes may be individualized (one on one) or conducted in a group setting. The group setting could include others with idiopathic pulmonary fibrosis (IPF), caregivers, family members, healthcare professionals, or individuals with an interest in IPF. In person classes may take place in a clinic, hospital, or community setting. All classes are free of charge and are available as soon as the OFEV capsules prescription is written. The following topics will be discussed:

- Idiopathic Pulmonary Fibrosis (IPF) Education Class will include general information about the disease and some of the tests that are used for diagnosis and follow-up
- OFEV Education Class will include information about treatment with OFEV capsules, including potential side effects, Important Safety Information, and the benefits of taking and adhering to the dosing regimen as you have prescribed it
- Specialty Pharmacy (SP) Process Training will explain how to fulfill a prescription for OFEV through our network of specialty pharmacies. This class also covers important information for patients in need of payment assistance

If you are interested in informing your patients about these classes, please complete this form and return it to Boehringer Ingelheim. This will enable the Clinical Educator to arrange for an initial touch point with the patient, to schedule a Patient Education Class, as well as have follow-up touch points.

This information is intended to provide general information only and is not intended to provide healthcare advice or medical care to any patient. It will not replace the healthcare provided by you or any members of your practice or staff, and it will not replace any obligation you have to inform patients of the risks associated with treatment and healthcare recommendations. Participating patients will be instructed to contact your office staff about any individual questions and concerns raised at the class about their particular health or treatment, including your decision to prescribe OFEV.

The Clinical Educator will not perform duties outside the scope of the program as described above and will not assist with medical office activities. Your office will receive no form of compensation for this education program, and the availability of these classes is not intended to influence your prescribing decisions.

If the class will be conducted in your institution, you acknowledge that you will be responsible for securing any necessary permission from the institution. In addition, you agree that you will inform patients, in advance of their participation in a class, that it will be conducted by a Boehringer Ingelheim employee and that Boehringer Ingelheim is not an entity that is bound by HIPAA and may not be bound by other federal or state patient privacy laws. You will be provided a blank copy of the patient consent form to provide to and review with patients in advance of the OFEV Patient Education Class.

PLEASE PRINT:

HCP Name: _____

Address: _____

Phone Number: _____

Signature: _____ Date: _____

Office Contact: _____ Phone Number: _____

IMPORTANT SAFETY INFORMATION AND INDICATION

WARNINGS AND PRECAUTIONS

Hepatic Impairment

- OFEV is not recommended in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dosage (100 mg twice daily). Consider treatment interruption or discontinuation for management of adverse reactions.

Elevated Liver Enzymes and Drug-Induced Liver Injury

- Cases of drug-induced liver injury (DILI) have been observed with OFEV treatment. In the post-marketing period, non-serious and serious cases of DILI, including severe liver injury with fatal outcome, have been reported. The majority of hepatic events occur within the first three months of treatment. OFEV was associated with elevations of liver enzymes (ALT, AST, ALKP, and GGT) and bilirubin. Liver enzyme and bilirubin increases were reversible with dose modification or interruption in the majority of cases. The majority (94%) of patients with ALT and/or AST elevations had elevations less than 5 times ULN. The majority (95%) of patients with bilirubin elevations had elevations less than 2 times ULN.

Please see additional Important Safety Information on the back of this form and accompanying full Prescribing Information, including Patient Information.

IMPORTANT SAFETY INFORMATION AND INDICATION

WARNINGS AND PRECAUTIONS (cont'd)

Elevated Liver Enzymes and Drug-Induced Liver Injury (cont'd)

- Patients with a low body weight (less than 65 kg), Asian, and female patients may have a higher risk of elevations in liver enzymes. Nintedanib exposure increased with patient age, which may result in increased liver enzymes.
- Conduct liver function tests prior to initiation of treatment, at regular intervals during the first three months of treatment, and periodically thereafter or as clinically indicated. Measure liver function tests promptly in patients who report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice. Dosage modifications, interruption, or discontinuation may be necessary for liver enzyme elevations.

Gastrointestinal Disorders

Diarrhea

- Diarrhea was the most frequent gastrointestinal event reported in 62% versus 18% of patients treated with OFEV and placebo, respectively. Events were primarily mild to moderate intensity and occurred within the first 3 months. Diarrhea led to permanent dose reduction in 11% and discontinuation in 5% of OFEV patients versus 0 and less than 1% in placebo patients, respectively.
- Dosage modifications or treatment interruptions may be necessary in patients with diarrhea. Treat diarrhea at first signs with adequate hydration and antidiarrheal medication (e.g., loperamide), and consider treatment interruption if diarrhea continues. OFEV treatment may be resumed at the full dosage (150 mg twice daily), or at the reduced dosage (100 mg twice daily), which subsequently may be increased to the full dosage. If severe diarrhea persists, discontinue treatment.

Nausea and Vomiting

- Nausea was reported in 24% versus 7% and vomiting was reported in 12% versus 3% of patients treated with OFEV and placebo, respectively. Events were primarily of mild to moderate intensity. Nausea and vomiting led to discontinuation of OFEV in 2% and 1% of patients, respectively.
- If nausea or vomiting persists despite appropriate supportive care including anti-emetic therapy, consider dose reduction or treatment interruption. OFEV treatment may be resumed at full dosage or at reduced dosage, which subsequently may be increased to full dosage. If severe nausea or vomiting does not resolve, discontinue treatment.

Embryofetal Toxicity: OFEV can cause fetal harm when administered to a pregnant woman and patients should be advised of the potential risk to a fetus. Women should be advised to avoid becoming pregnant while receiving OFEV and to use effective contraception during treatment and at least 3 months after the last dose of OFEV. Verify pregnancy status prior to starting OFEV.

Arterial Thromboembolic Events: Arterial thromboembolic events were reported in 2.5% of OFEV and 0.8% of placebo patients, respectively. Myocardial infarction was the most common arterial thromboembolic event, occurring in 1.5% of OFEV and 0.4% of placebo patients. Use caution when treating patients at higher cardiovascular risk including known coronary artery disease. Consider treatment interruption in patients who develop signs or symptoms of acute myocardial ischemia.

Risk of Bleeding: OFEV may increase the risk of bleeding. Bleeding events were reported in 10% of OFEV versus 7% of placebo patients. Use OFEV in patients with known risk of bleeding only if the anticipated benefit outweighs the potential risk. In the post-marketing period, non-serious and serious bleeding events, some of which were fatal, have been observed.

Gastrointestinal Perforation: OFEV may increase the risk of gastrointestinal perforation. Gastrointestinal perforation was reported in 0.3% of OFEV versus in 0% placebo patients. In the postmarketing period, cases of gastrointestinal perforations have been reported, some of which were fatal. Use caution when treating patients who have had recent abdominal surgery, previous history of diverticular disease or receiving concomitant corticosteroids or NSAIDs. Discontinue therapy with OFEV in patients who develop gastrointestinal perforation. Only use OFEV in patients with known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

ADVERSE REACTIONS

- Adverse reactions reported in greater than or equal to 5% of OFEV patients included diarrhea, nausea, abdominal pain, liver enzyme elevation, vomiting, decreased appetite, weight decreased, headache, and hypertension.
- The most frequent serious adverse reactions reported in OFEV patients were bronchitis and myocardial infarction. The most common adverse events leading to death in OFEV patients versus placebo were pneumonia (0.7% vs. 0.6%), lung neoplasm malignant (0.3% vs. 0%), and myocardial infarction (0.3% vs. 0.2%). In the predefined category of major adverse cardiovascular events (MACE) including MI, fatal events were reported in 0.6% of OFEV versus 1.8% in placebo patients.

DRUG INTERACTIONS

- **P-glycoprotein (P-gp) and CYP3A4 Inhibitors and Inducers:** Coadministration with oral doses of a P-gp and CYP3A4 inhibitor, ketoconazole, increased exposure to nintedanib by 60%. Concomitant use of potent P-gp and CYP3A4 inhibitors (e.g., erythromycin) with OFEV may increase exposure to nintedanib. In such cases, patients should be monitored closely for tolerability of OFEV. Management of adverse reactions may require interruption, dose reduction, or discontinuation of therapy with OFEV. Coadministration with oral doses of a P-gp and CYP3A4 inducer, rifampicin, decreased exposure to nintedanib by 50%. Concomitant use of P-gp and CYP3A4 inducers (e.g., carbamazepine, phenytoin, and St. John's wort) with OFEV should be avoided as these drugs may decrease exposure to nintedanib.
- **Anticoagulants:** Nintedanib may increase the risk of bleeding. Monitor patients on full anticoagulation therapy closely for bleeding and adjust anticoagulation treatment as necessary.

USE IN SPECIFIC POPULATIONS

- **Nursing Mothers:** Because of the potential for serious adverse reactions in nursing infants from OFEV, advise women that breastfeeding is not recommended during treatment.
- **Reproductive Potential:** OFEV may reduce fertility in females of reproductive potential.
- **Smokers:** Smoking was associated with decreased exposure to OFEV, which may affect the efficacy of OFEV. Encourage patients to stop smoking prior to and during treatment.

INDICATION

OFEV (nintedanib) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

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Please see accompanying full Prescribing Information, including Patient Information.

Boehringer Ingelheim

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