# A PARTNERSHIP PLAN
## FOR IDIOPATHIC PULMONARY FIBROSIS

### A STRATEGY FOR DEVELOPING AN IPF MANAGEMENT PLAN BASED ON REALISTIC PATIENT GOALS

## Indication

Esbriet® (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

## Select Important Safety Information

**Elevated liver enzymes:** Increases in ALT and AST >3× ULN have been reported in patients treated with Esbriet. In some cases these have been associated with concomitant elevations in bilirubin. Patients treated with Esbriet had a higher incidence of elevations in ALT or AST than placebo patients (3.7% vs 0.8%, respectively). No cases of liver transplant or death due to liver failure that were related to Esbriet have been reported. However, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that could lead to death or the need for liver transplants in some patients. Conduct liver function tests (ALT, AST, and bilirubin) prior to initiating Esbriet, then monthly for the first 6 months and every 3 months thereafter. Dosage modifications or interruption may be necessary.

**Photosensitivity reaction or rash:** Patients treated with Esbriet had a higher incidence of photosensitivity reactions (9%) compared with patients treated with placebo (1%). Patients should avoid or minimize exposure to sunlight (including sunlamps), use a sunblock (SPF 50 or higher), and wear clothing that protects against sun exposure. Patients should avoid concomitant medications that cause photosensitivity. Dosage reduction or discontinuation may be necessary.

**Please see additional Select Important Safety Information throughout and the accompanying full Prescribing Information.**

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# EXPAND THE PARTNERSHIP WITH YOUR PATIENTS

## STEP 1 Set expectations about the reality of IPF—while providing inspiration

Receiving an IPF diagnosis can be devastating for your patients.[1,2] Experts within the medical community recommend balancing the irreversible and progressive reality of IPF with a positive discussion of management options to inspire your patients to fight IPF.[3–5]

**Let your patients know that while you cannot stop or reverse the progression of IPF, there are things you can do to manage the disease[3,4]**

## STEP 2 Find out what motivates your patients to fight IPF

Experts within the medical community believe that an individualized management plan is one approach that may help your patients stay motivated while living with IPF.[6,7] They recommend anchoring an IPF management plan to the things that are most important to your patients.[7,8]

To find out what motivates your patients, ask open-ended questions such as[7,9]:

***"What's important to you?"*** or ***"What motivates you?"***

***"Is there a family event you are looking forward to?"***

## Select Important Safety Information *(continued)*

**Gastrointestinal disorders:** Gastrointestinal events of nausea, diarrhea, dyspepsia, vomiting, gastroesophageal reflux disease, and abdominal pain were more frequently reported in patients treated with Esbriet. Dosage reduction or interruption for gastrointestinal events was required in 18.5% of patients in the 2403 mg/day group, as compared to 5.8% of patients in the placebo group; 2.2% of patients in the Esbriet 2403 mg/day group discontinued treatment due to a gastrointestinal event, as compared to 1.0% in the placebo group. The most common (>2%) gastrointestinal events that led to dosage reduction or interruption were nausea, diarrhea, vomiting, and dyspepsia. Dosage modifications may be necessary in some cases.

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# CREATE AN INDIVIDUALIZED MANAGEMENT PLAN

## STEP 3 Identify realistic goals as part of a plan to manage IPF

Work with your patients to translate their motivations into realistic personal goals that you deem achievable within an appropriate time period.

> A **realistic personal goal** can be something your patients take part in regularly or an upcoming special occasion they are looking forward to, such as a book club, family dinner, or a grandchild's birthday party.

**Partner with your patients to develop an IPF management plan that aligns with their motivations, realistic goals, and preferences[6]**

## STEP 4 Recommend an IPF management plan

Explain the components of the management plan, including pharmacologic and nonpharmacologic options. Set expectations if pharmacologic treatment is appropriate.[6] Make it clear that while IPF-specific therapies may help slow disease progression, they do not address the symptoms of IPF, so your patients may not feel better. It is unknown whether the management plan will have any impact on your patients' day-to-day activities.[10]

### Management plans may include:

| Nonpharmacologic treatment | Pharmacologic treatment |
|---|---|
| • Supplemental oxygen[3,6]<br>• Evaluation for lung transplant[3,6]<br>• Pulmonary rehabilitation[3,6]<br>• Disease education[3,6]<br>• Psychosocial support[2,3,6]<br>• Palliative care[3,6] | • IPF-specific therapy (including a discussion of benefits and risks, dosing, and management of side effects)[3]<br>• Clinical trials enrollment[3,6]<br>• Management of comorbidities[3,6]<br>• Symptom management[6] |

Use clinical markers along with the goals you set together as benchmarks for future visits.[6]

**Explain your patients' role in this plan and ask them to share their progress on their personal goals as part of an ongoing conversation[6]**

## Select Important Safety Information *(continued)*

**Adverse reactions:** The most common adverse reactions (≥10%) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastroesophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia.

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# PARTNER WITH YOUR PATIENTS TO MANAGE THEIR IPF

- **Ask** open-ended questions to find out what motivates your patients[7,9]
- **Identify** realistic personal goals and use them to build an individualized IPF management plan[6]
- **Recommend** an individualized management plan to your patients, including pharmacologic and nonpharmacologic options[6]
- **Encourage your patients** to share their progress on their personal goals
- **Adjust the management plan** over time, if necessary[6]

**Connect with what motivates your patients with IPF—and take the first step in creating a management plan in which you both have confidence[6–8,11]**

## Select Important Safety Information *(continued)*

**Drug interactions:** Concomitant administration with strong inhibitors of CYP1A2 (eg, fluvoxamine) significantly increases systemic exposure of Esbriet and is not recommended. Discontinue prior to administration of Esbriet. If strong CYP1A2 inhibitors cannot be avoided, dosage reductions of Esbriet are recommended. Monitor for adverse reactions and consider discontinuation of Esbriet as needed.

Concomitant administration of Esbriet and ciprofloxacin (a moderate inhibitor of CYP1A2) moderately increases exposure to Esbriet. If ciprofloxacin at the dosage of 750 mg twice daily cannot be avoided, dosage reductions are recommended. Monitor patients closely when ciprofloxacin is used.
*(Continued on next page.)*

**Learn more about Esbriet and how to access medication at EsbrietHCP.com**

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## Select Important Safety Information *(continued)*

**Drug interactions *(continued)*:** Agents that are moderate or strong inhibitors of both CYP1A2 and CYP isoenzymes involved in the metabolism of Esbriet should be avoided during treatment.

The concomitant use of a CYP1A2 inducer may decrease the exposure of Esbriet, and may lead to loss of efficacy. Concomitant use of strong CYP1A2 inducers should be avoided.

**Specific populations:** Esbriet should be used with caution in patients with mild to moderate (Child Pugh Class A and B) hepatic impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with severe hepatic impairment. Esbriet is not recommended for use in patients with severe (Child Pugh Class C) hepatic impairment.

Esbriet should be used with caution in patients with mild ($CL_{cr}$ 50–80 mL/min), moderate ($CL_{cr}$ 30–50 mL/min), or severe ($CL_{cr}$ less than 30 mL/min) renal impairment. Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. The safety, efficacy, and pharmacokinetics of Esbriet have not been studied in patients with end-stage renal disease requiring dialysis. Use of Esbriet in patients with end-stage renal diseases requiring dialysis is not recommended.

Smoking causes decreased exposure to Esbriet, which may alter the efficacy profile of Esbriet. Instruct patients to stop smoking prior to treatment with Esbriet and to avoid smoking when using Esbriet.

**You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.**

**Please see additional Select Important Safety Information throughout and the accompanying full Prescribing Information.**

**References: 1.** Duck A, Spencer LG, Bailey S, Leonard C, Ormes J, Caress AL. Perceptions, experiences and needs of patients with idiopathic pulmonary fibrosis. *J Adv Nurs.* 2015;71(5):1055–1065. **2.** Russell AM, Ripamonti E, Vancheri C. Qualitative European survey of patients with idiopathic pulmonary fibrosis: patients' perspectives of the disease and treatment. *BMC Pulm Med.* 2016;16:10. http://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-016-0171-y. Accessed March 6, 2017. **3.** Raghu G, Collard HR, Egan JJ, et al; ATS/ERS/JRS/ALAT Committee on Idiopathic Pulmonary Fibrosis. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med.* 2011;183(6):788–824. **4.** Raghu G, Rochwerg B, Zhang Y, et al; ATS, ERS, JRS, and ALAT. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. An update of the 2011 clinical practice guideline [published correction appears in *Am J Respir Crit Care Med*. 2015;192(5):644]. *Am J Respir Crit Care Med*. 2015;192(2):e3–e19. **5.** Belkin A, Swigris JJ. Patient expectations and experiences in idiopathic pulmonary fibrosis: implications of patient surveys for improved care. *Expert Rev Respir Med*. 2014;8(2):173–178. http://www.tandfonline.com/doi/full/10.1586/17476348.2014.880056. Accessed November 4, 2016. **6.** Lee JS, McLaughlin S, Collard HR. Comprehensive care of the patient with idiopathic pulmonary fibrosis. *Curr Opin Pulm Med.* 2011;17(5):348–354. **7.** Smith RC. *Patient-Centered Interviewing: An Evidence-Based Method.* 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2002. **8.** Wuyts WA, Peccatori FA, Russell AM. Patient-centred management in idiopathic pulmonary fibrosis: similar themes in three communication models. *Eur Respir Rev.* 2014;23(132):231–238. **9.** Marcus JD, Mott FE. Difficult conversations: from diagnosis to death. *Ochsner J.* 2014;14(4):712–717. **10.** Padilla M. Idiopathic pulmonary fibrosis: the role of pathobiology in making a definitive diagnosis. *Am J Manag Care*. 2015;21(suppl 14):s276–s283. **11.** Scobbie L, McLean D, Dixon D, Duncan E, Wyke S. Implementing a framework for goal setting in community based stroke rehabilitation: a process evaluation. *BMC Health Serv Res.* 2013;13(190):1–13.

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