“Promising long-term safety of Esbriet (pirfenidone)”

Several presentations at ERS 2014 focused on the long-term safety profile of pirfenidone. The two studies presented here, from a long-term, open-label study and a patient registry, together included over 1100 patients on pirfenidone.

RECAP: a long-term extension study

RECAP examined long-term safety of pirfenidone in an open-label extension study in 603 IPF patients who had completed the CAPACITY trial. An interim analysis, from Sept 2008 to August 2013, was presented by Dr. Ulrich Costabel from Essen University Hospital in Germany. The median pirfenidone exposure in RECAP was just over 3 years; the maximum exposure was 4.9 years. The type and frequency of adverse events were consistent with the 72-week CAPACITY and 52-week ASCEND phase III pirfenidone trials, suggesting that long-term treatment with pirfenidone, up to 4.9 years, is safe and generally well tolerated.

PASSPORT: a registry evaluating safety in a real-world setting

Safety data was also evaluated in the PASSPORT registry, a post-authorization registry examining pirfenidone in the European clinical setting. Patient registries are extensive collections of data from patients who have been prescribed a drug, and they play an important role in post-authorization surveillance, the monitoring of drug safety after it has been released on the market. Dr. Dirk Koschel, of Fachkrankenhaus Coswig in Germany, presented data from the first 530 enrolled patients from 68 sites in 7 countries. Adverse events reported in PASSPORT were comparable to those in the clinical trials of pirfenidone in IPF. Therefore, in the real-world setting, which includes a more varied group of patients, there were no new safety issues in patients on pirfenidone treatment.

Dr. Joseph Lockyear, a respirologist from Newfoundland, said of the long-term data, “With more patients, it just makes us [as respirologists] feel more comfortable [with the safety profile of pirfenidone].”