BACKGROUND

- To characterize the use of concomitant anti-thrombotic agents and to examine the incidence of treatment-emergent bleeding events (TE bleeding) in the pooled populations of patients with IPF enrolled in the Phase II-III trials.

METHODS

- **Data Source**
  - All patients randomized to treatment with pirfenidone 2403 mg/day or placebo in the Phase II-III ASCEND (Study 101); NCT03520302 and CAPACITY (Studies 100 and 103; NCT03071710 and NCT03072730) clinical trials were included in this analysis.

- **In the 2 CAPACITY Trials**, patients were treated for a minimum of 72 weeks and followed up until study discontinuation or the last on-treatment visit (n = 2275) weeks.

- **In ASCEND**, patients were treated and followed up for 52 weeks.

- **Patients with a history of undiagnosed or deteriorating cardiac disease within the 6 months before enrollment** were excluded from all trials.

- **Analyses**
  - A post hoc, blinded review of TE bleeding adverse events (AEs) was conducted. ATE bleeding events, defined as bleeding events occurring between the first dose and 28 days after the last dose of study drug, were assessed in the pooled pirfenidone and placebo groups.
  - The use of anti-thrombotic and anti-platelet agents, including any concomitant medication use by patients with AEs (collinear), was described for the pooled pirfenidone and placebo groups (p-value 0.3). The Coxon-Marine-Beaudet test, stratified by study, was used to compare treatment groups with respect to concomitant anti-thrombotic use.

OBJECTIVES

- **To characterize the use of concomitant anti-thrombotic agents and to examine the incidence of treatment-emergent bleeding events (TE bleeding) in the pooled populations of patients with IPF enrolled in the Phase II-III trials.**

RESULTS

**Cardiovascular Risk Profile**

- The CV-related risk profiles at baseline were generally similar between the pirfenidone and placebo groups (Table 1).

**Treatment-Emergent Bleeding Events During the Pirfenidone Phase III Clinical Trials**

- Of the 601 patients (42.7%) in the pirfenidone and placebo groups, respectively, did not receive any anti-thrombotic agents.

**Table 4. Summary of TE Bleeding Incidence by Concomitant Anti-Thrombotic Agent Use**

**CONCLUSIONS AND IMPLICATIONS**

- **Anti-thrombotic use** is a common and low-risk practice in those who have IPF. The beneficial effects of bleeding events were low, with a similar incidence between patients receiving pirfenidone or placebo.

- **No apparent relationship** was observed between anti-thrombotic agent use and occurrence of bleeding events.

- **These results suggest** that the overall incidence of TE bleeding events in patients with IPF is low, with a similar incidence between patients receiving pirfenidone or placebo.

- **TE bleeding event rates do not appear to differ based on treatment with pirfenidone, either alone or with concomitant anti-thrombotic agents**.

REFERENCES