Background
The frequency of concomitant medication use that may affect CV and bleeding risks– The proportion of patients with a history of myocardial infarction was 5.1% in the pirfenidone group and 5.3% in the placebo group – The proportion of patients experiencing myocardial infarction or stroke was also similar between the 2 groups – Concomitant anti-coagulation agents were administered to 10.6% of patients in the pirfenidone group and 13.8% of patients in the placebo group – Concomitant anti-platelet agents were used by 47.2% of patients in the pirfenidone group and 50.6% of patients in the placebo group

Methods
- The frequency of concomitant medication use that may affect CV and bleeding risks was similar between the pirfenidone and placebo groups (Table 3). - Concomitant anti-platelet agents (including aspirin) were administered to 47.2% of patients in the pirfenidone group and 50.6% of patients in the placebo group. - Concomitant anti-coagulation agents were administered to 10.6% of patients in the pirfenidone group and 13.8% of patients in the placebo group. - Concomitant anti-platelet agents were used by 47.2% of patients in the pirfenidone group and 50.6% of patients in the placebo group.

Results
Cardiovascular and Bleeding Events in Phase III Trials of Pirfenidone in Idiopathic Pulmonary Fibrosis

CONCLUSION AND IMPLICATIONS
- Patients with IPF may be at an increased risk of complications due to CV medications and use of concomitant CV medications – The incidence of MACE and bleeding events were similar between the pirfenidone and placebo groups in both the ASCEND (PIPF-004/-006) and ASCEND (PIPF-016) studies.

This post hoc analysis suggests that pirfenidone did not increase the risk of CV and bleeding events in patients with IPF and patients in the placebo group.

Table 1. Baseline Demographics and Clinical Characteristics

Table 2. Medical History that May Affect Cardiovascular and Bleeding Risks

Table 3. Most Common Concomitant Medications That May Affect Cardiovascular and Bleeding Risks

Table 4. Treatment-Emergent Major Adverse Cardiovascular Events

Table 5. Treatment-Emergent Bleeding Events

Cardiovascular Risk Profile
The risk of adverse medical outcomes or deaths were generally similar between the pirfenidone and placebo groups (Table 3). The proportion of patients with a history of coronary artery disease was 15.6% in the pirfenidone group and 17.1% in the placebo group. The proportion of patients with a history of myocardial infarction was 5.1% in pirfenidone group and 5.3% in the placebo group. The proportion of patients experiencing myocardial infarction or stroke was also similar between the 2 groups.

Cardiovascular and Bleeding Events
The mean duration of exposure to pirfenidone and placebo was 14.2 and 14.4 months, respectively.

Figure 1. Treatment-Emergent Major Adverse Cardiovascular Events

Figure 2. Treatment-Emergent Bleeding Events

REFERENCES
- No author listed

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