

Safety, tolerability and appropriate use of nintedanib in idiopathic pulmonary fibrosis

Additional files

Additional file 2

Cardiac disorders and ischemic heart disease in the INPULSIS® trials

Table

| N (%) | Nintedanib (n = 638) | Placebo (n = 423) |
|---|-------------------------|----------------------|
| Cardiac disorder adverse events | 64 (10.0) | 45 (10.6) |
| Serious cardiac disorder adverse events | 32 (5.0) | 23 (5.4) |
| Fatal cardiac disorders | 3 (0.5) | 6 (1.4) |
| Ischemic heart disease | 27 (4.2) | 17 (4.0) |
| Myocardial infarction | 17 (2.7) | 5 (1.2) |
| Myocardial infarction | 7 (1.1) | 2 (0.5) |
| Acute myocardial infarction | 3 (0.5) | 0 (0.0) |
| Blood creatine phosphokinase increase | 5 (0.8) | 3 (0.7) |
| ECG Q-wave abnormal | 1 (0.2) | 0 (0.0) |
| Coronary artery occlusion | 1 (0.2) | 0 (0.0) |
| Other ischemic heart disease | 11 (1.7) | 13 (3.1) |
| Coronary artery disease | 5 (0.8) | 3 (0.7) |
| Angina pectoris | 2 (0.3) | 5 (1.2) |
| Coronary angioplasty | 1 (0.2) | 0 (0.0) |
| Coronary artery stenosis | 2 (0.3) | 3 (0.7) |
| Myocardial ischemia | 0 (0.0) | 3 (0.7) |
| Coronary artery stent insertion | 1 (0.2) | 0 (0.0) |
| ECG ST segment depression | 1 (0.2) | 0 (0.0) |

“Ischemic heart disease” is a standardized MedDRA query (SMQ), comprising the subordinate SMQs “myocardial infarction” and “other ischemic heart disease”.