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Cardiovascular safety of nintedanib in subgroups by cardiovascular risk at baseline in the TOMORROW and INPULSIS trials

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In pooled data from the randomised TOMORROW and INPULSIS trials in patients with IPF, the incidence rates of major adverse cardiovascular events were similar in the nintedanib and placebo groups both in patients with higher and lower cardiovascular risk http://bit.ly/2KUY8IP

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ABSTRACT Nintedanib is a tyrosine kinase inhibitor used to treat idiopathic pulmonary fibrosis (IPF). We investigated the cardiovascular safety of nintedanib using pooled data from the TOMORROW and INPULSIS trials.

Cardiovascular events were assessed *post hoc* in patients with a history of atherosclerotic cardiovascular disease (CVD) and/or one or more cardiovascular risk factors at baseline ("higher cardiovascular risk") and patients with no history of atherosclerotic CVD and no cardiovascular risk factors at baseline ("lower cardiovascular risk").

Incidence rates were calculated for 1231 patients (n=723 nintedanib and n=508 placebo), of whom 89.9% had higher cardiovascular risk. Incidence rates of major adverse cardiovascular events were similar in the nintedanib and placebo groups in patients with higher cardiovascular risk (3.88 (95% CI 2.58–5.84) and 3.49 (95% CI 2.10–5.79) per 100 patient-years, respectively) and lower cardiovascular risk (4.78 (95% CI 1.54–14.82) and 5.37 (95% CI 1.73–16.65) per 100 patient-years, respectively). Incidence rates of myocardial infarction in the nintedanib and placebo groups, respectively, were 3.03 (95% CI 1.91–4.81) and 1.16 (95% CI 0.48–2.79) per 100 patient-years in patients with higher cardiovascular risk and 1.59 (95% CI 0.22–11.29) and 1.78 (95% CI 0.25–12.64) per 100 patient-years in patients with lower cardiovascular risk. Incidence rates of other ischaemic heart disease in the nintedanib and placebo groups, respectively, were 1.85 (95% CI 1.02–3.34) and 3.28 (95% CI 1.94–5.54) per 100 patient-years in patients with higher cardiovascular risk and 0 and 1.80 (95% CI 0.25–12.78) per 100 patient-years in patients with lower cardiovascular risk.

These data help to establish the cardiovascular safety profile of nintedanib in IPF.