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Patient characteristics and treatment patterns in the multicentre, retrospective chart review of first-time Opsumit (macitentan) users in the United States (OrPHeUS)

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Introduction: The OPsumit® Historical USers cohort (OrPHeUS) is a multicentre, US, retrospective medical chart review conducted to supplement the OPsumit® USers (OPUS) Registry to fulfil the FDA request to characterise the safety of macitentan in clinical practice.

Purpose: To describe patient characteristics, treatment patterns, hepatic safety and survival in patients with pulmonary hypertension (PH) newly treated with macitentan.

Methods: OrPHeUS (NCT03197688) aimed to include 2200 new users of macitentan, between October 2013 and March 2017, who were not enrolled in OPUS. Here we present patients with follow-up data, including characteristics and treatment patterns at macitentan initiation, hepatic adverse events (HAEs) identified using preferred terms in chart entries and pharmacovigilance reporting, hospitalisations and survival.

Results: OrPHeUS included 2982 patients newly treated with macitentan and with follow-up data; the reason for macitentan prescription was pulmonary arterial hypertension (PAH) in 2362 (79.3%) patients, other PH aetiologies in 612 (20.6%) patients and 8 patients with other/unknown reasons. At macitentan initiation, the median (Q1, Q3) age of the patients was 62 (51, 72) years and 73.9% were female. WHO functional class (FC) was documented in 654 (21.9%) patients, 35.6% of patients were in FC I/II and 64.4% in FC III/IV; median (Q1, Q3) 6-minute walk distance, documented in 411 (13.8%) patients, was 293 (200, 383) metres. At macitentan initiation, 41.5% (n=1239) of patients were not receiving PAH therapy, 46.3% (n=1382) were already receiving one PAH therapy and 11.9% (n=356) were already receiving two PAH therapies. The median (Q1, Q3) exposure to macitentan was 14.9 (5.6, 27.1) months; 57% and 43% of patients had exposures of >12 and >18 months. During the exposure period, 933 (31.3%) patients discontinued treatment, including 474 (15.9%) patients who discontinued due to an adverse event (AE), 6 (0.2%) due to a HAE, 449 (15.1%) for reasons other than an AE/HAE, and 4 (0.1%) for unknown reasons. There were 275 (9.2%) patients who experienced =1 HAE (incidence rate [IR]: 0.07 [95% CI, 0.06, 0.08] per 1 person-year); alanine aminotransferase (ALT) or aspartate aminotransferase (AST) =3x upper limit of normal (ULN) were experienced by 113 (3.8%) patients (IR: 0.028 [95% CI, 0.023, 0.033] per 1 person-year); ALT/AST =x3 ULN and bilirubin =2x ULN was experienced by 33 (1.1%) patients (IR: 0.008 [95% CI, 0.006, 0.011] per 1 person-year). There were 1148 (38.5%) patients who experienced at least one hospitalisation (IR: 0.36 [95% CI, 0.34, 0.39] per 1 person-year). The 12-month Kaplan-Meier survival estimate was 92% (95% CI, 91, 93).
Conclusion: OrPHeUS provides additional real-world evidence in patients newly treated with macitentan, confirming the hepatic safety profile of macitentan.