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Session L. Gastrointestinal (noncolorectal) cancer

L17 Safety and efficacy of sorafenib in stella study, a Multicenter, Observational, Phase IV Study In Italian Centers

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Background: Sorafenib, a multikinase inhibitor, is the only systemic treatment approved for hepatocellular carcinoma (HCC). Data collected on sorafenib in routine clinical practice provides valuable information on patient characteristics, etiology, pattern of disease and treatment modalities in a specific geographical area. This helps to better understand the use of sorafenib in order to maximize its safety and efficacy.

Materials and methods: STELLA (Sorafenib Treatment modalities for HEpatoceLLular Carcinoma patients in ltAly) is a phase IV, prospective, non-interventional, Italian, multicenter study, aiming to evaluate the efficacy and safety of sorafenib (400 mg/bid) in terms of overall survival (OS) rate at 12 months (primary endpoint) in patients (pts) with HCC under daily-life treatment conditions. Additional objectives were safety and OS. Pts with HCC in whom a decision to treat with sorafenib has been made, were enrolled. The observation period for each patient is the time from the start of sorafenib to withdrawal of consent, death, or the last visit.

Results: A total of 234 pts were enrolled. Of these 224 received sorafenib and were valid for the intention-to-treat (ITT) analysis and 214 pts for safety. Male 79%, median age 70 years, hepatitis C virus infection in 115(51%)pts, followed by alcohol abuse in 58 (26%)pts and hepatitis B virus infection in 42(19%)pts; ECOG performance status 0/1/2 in 143(64%), 69(31%) and 11(5%) respectively; Child-Pugh class A/B/C in 179(80%), 34(15%) and 2(1%) respectively. The distribution per BCLC stage A/B/C: 10(4.5%), 67 (30%) and 146(65%) respectively. The OS rate at 12 months was 54% [90% CI: 48-60%]. Adverse events (all grades) in 176(82%)pts whereas drug-related adverse events (all grades) in 151(71%), most of which were grade 1 or 2 (11% and 29% respectively). The most frequent drug-related AEs were gastrointestinal (33%), dermatologic (30%), fatigue (27%) and anorexia (13%). Drug-related AEs resulting in permanent study drug discontinuation in 31% of pts.

Conclusion: The STELLA study provides additional insight on the use of sorafenib in Italian clinical practice. The OS rate at 12 months compares favourably with that observed in the phase III SHARP study. This may be explained by a lower percentage of BCLC C pts than in SHARP (65% and 82% respectively). The safety profile was comparable in nature and frequency to that seen in other studies under real-life conditions, with no new safety signals observed.

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