gastrointestinal tumours,
non-colorectal

AN INTERNATIONAL OBSERVATIONAL STUDY TO ASSESS THE USE OF SORAFENIB AFTER TRANSARTERIAL CHEMOEMBOLIZATION (TACE) IN PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC): OPTIMIS

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Background: TACE is currently recommended for the treatment of patients with intermediate-stage HCC (Barcelona Clinic Liver Cancer [BCLC] stage B). However, it remains unclear which patients are most likely to benefit from TACE, or when TACE should be stopped and alternative treatments considered. The multikinase inhibitor sorafenib is the only systemic therapy currently approved for the treatment of advanced HCC. The aim of this observational study is to prospectively collect data from patients with HCC who either receive or do not receive sorafenib subsequent to TACE.

Trial design: Patients aged ≥18 years, with histologically/cytologically documented or radiographically diagnosed HCC classified as BCLC stage B or higher, with a life expectancy of ≥8 weeks, and for whom a decision to treat with TACE has been made at the time of study enrollment (one prior TACE treatment is allowed if performed at the same center and all required data about the procedure are available), are eligible. Treatment decisions made before a patient is enrolled, and during the observation period, must be according to investigators’ regular practice. Exclusion criteria include any systemic anti-cancer therapy prior to the first TACE, or participation in an interventional study of locoregional or systemic therapy. The primary objective is evaluation of overall survival in patients who received sorafenib subsequent to TACE non-eligibility (early sorafenib) compared with those who did not (non-early sorafenib). The non-early sorafenib group includes patients who did not receive sorafenib or who received it at a later point. Secondary objectives include progression-free survival, time to progression, tumor response, and safety. Planned enrollment is approximately 1600 patients from about 30 countries across Europe, Latin America, and Asia-Pacific, and from Canada. One interim analysis is planned once 500 patients have been observed for at least 6 months. Final analysis will be performed once the last enrolled patient has been followed for 18 months, has been lost to follow-up, or has died. The study began in October 2013 and 69 patients have been enrolled as of January 2014. This abstract was accepted and previously presented at the 2014 ASCO Annual Meeting Chicago, June 2014 (TPS4155).

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