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Basic Programme:
MOLECULAR PATHOGENESIS & TRANSLATIONAL RESEARCH IN LIVER CANCER
FEBRUARY **13-14, 2014**

Clinical Programme:
LIVER CANCER MANAGEMENT
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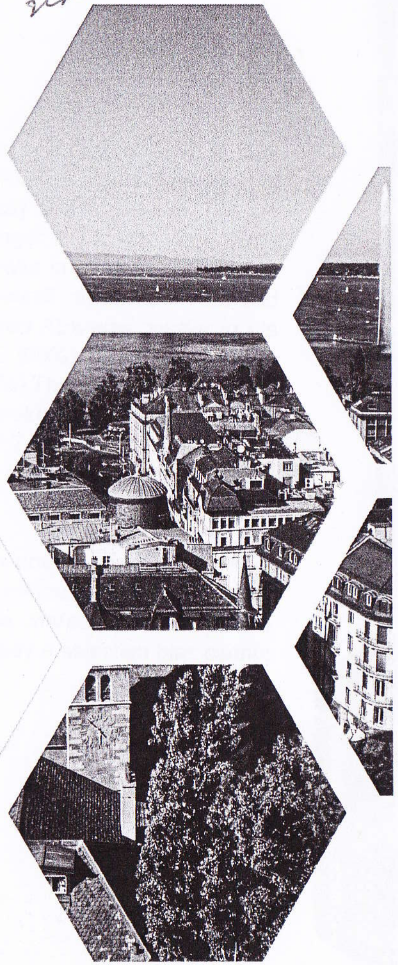
GENEVA. SWITZERLAND



PROGRAMME AND ABSTRACTS

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HCC MANAGEMENT WITH SORAFENIB AND TACE: ITALIAN EXPERIENCE FROM GIDEON (GLOBAL INVESTIGATIONAL OF THERAPEUTIC DECISIONS IN HCC AND OF ITS TREATMENT WITH SORAFENIB)

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Introduction: The global, prospective, non-interventional GIDEON study (NCT00812175) enrolled 3371 patients (pts) with HCC treated with sorafenib (SOR) in real-life practice conditions. We report the outcomes of HCC pts treated with SOR in Italy according to prior or concomitant (ct) use of transarterial chemoembolization (TACE).

Aims: The primary aim of the study was evaluate the safety of sorafenib in HCC patients in clinical practice.

Methodology: Patients with unresectable HCC for whom a decision to treat with SOR was taken were eligible for inclusion. Disease and pts characteristics were assessed at baseline. SOR dose, adverse events (AEs) and outcomes were recorded at follow-up.

Results: Of the 278 pts enrolled in Italy, 274 received at least one dose of SOR. In total 36.5 % (n=100) pts received prior TACE and 4 % (n=11) ctTACE. A higher proportion of ECOG PS 0 pts received prior TACE or ctTACE. Median daily SOR dose was 776 mg (n=241) across all subgroups. Duration of treatment was longer in pts with prior TACE or ctTACE (19.3 weeks [wks], 15.7 wks, 38.9 wks and 15.9 wks in pts with prior TACE, no prior TACE, ctTACE and no ctTACE, respectively). The overall incidence of AEs and serious AEs was similar across these subgroups. Drug-related AEs was greater in pts with prior TACE (79%) than those who received no prior TACE (60%) and in pts with prior ctTACE (91%) than those who received no prior ctTACE (66%).The most frequent drug-related AEs were diarrhea (24%), fatigue (23%) and hand foot skin reaction (24%). There were no new unexpected AEs. Median OS was 97.5 wks, 47.7 wks and 51.7 wks in pts with prior TACE, no prior TACE and no ctTACE respectively (not assessable in ctTACE group).

Conclusions: The safety profile of SOR in pts treated with prior or concurrent TACE is consistent with those observed in previous clinical trials without new safety signals in a real-life setting in Italian centers. Diifferences in baseline characteristics may have played a role in OS. Given the observational nature of the study a selection bias cannot be excluded.

CLINICAL POSTER ABSTRACTS