

Pioneering. Powerful. Proven.

6 years of delivering unsurpassed survival in your unresectable hepatocellular carcinoma (HCC) patients not eligible for LRT*

Nexavar® is the first proven systemic therapy to consistently demonstrate an overall survival (OS) benefit vs placebo in unresectable HCC patients among approximately 100 trials in over 30 years¹

-44% to 47% improvement in OS vs placebo in 2 phase III trials of Western and Asian patients^{1,2}

Nexavar® is the recommended standard for advanced HCC and in patients not eligible/refractory to earlier treatments³

With Nexavar® you can optimize outcomes for your patients with HCC

*LRT=locoregional therapies

Essential Information

C: sorafenib tosylate. It: treatment of patients with hepatocellular carcinoma and treatment of advanced renal cell cancer after nephrectomy and palliative or adjuvant prior therapy with cytokines (IL-2, IFN γ). P/A: 400 mg (= 2 tablets of 200 mg) twice a day until progression or unacceptable toxicity. CI: hypersensitivity reaction to active or to any of the excipients, long QT interval, severe rash, hypertension, hemorrhage, warfarine or neomycin co-administration, unstable coronary heart disease, long QT interval, severe hepatic impairment, impairment of fertility. UE: Very common: lymphopenia, hypophosphatemia, hemorrhage, hypertension, diarrhea, nausea, vomiting, hand-foot syndrome, rash, erythema, pruritus, alopecia, fatigue, pain, increased lipase, increased amylase. Common: leucopenia, anemia, neutropenia, thrombocytopenia, weight loss, anorexia, hypocalcemia, hypokalaemia, depression, peripheral sensory neuropathy, tinnitus, congestive heart failure, myocardial ischaemia, myocardial infarction, flushing, hoarseness, dyspnea, cough, dyspepsia, dysphagia, constipation, pain and disorders of the mouth, renal insufficiency, proteinuria, dry skin, acne, dermatitis exfoliative, desquamation, myalgia, arthralgia, erectile dysfunction, influenza like illness, asthenia, fever, edema of the lower leg, increase in transaminases. I: with substrates UGT 1A1 and UGT 1A9 (i.e. barbitalurates, iminotetran, paditaxel, estradiol, propofol), inducers of CYP3A4 (rifampicin, St. John's wort, phenytoin, carbamazepine, phenobarbital, dexamethasone), coumarin preparations, docetaxel, neomycin. D: Bayer (Schweiz) AG, 8045 Zurich, List A. Reimbursed (L). Status January 2013. For further information please consult the professional information on www.swissmedinfo.ch.

References: 1. Llover JM, Ricci S, Mazzaferro V, et al: for the SHARP Investigators Study Group. Sorafenib in advanced hepatocellular carcinoma. *N Engl J Med*. 2008;359:378-390. 2. Cheng A-L, Kang Y-K, Chen Z, et al: Efficacy and safety of sorafenib in patients in the Asia-Pacific region with advanced hepatocellular carcinoma: a phase III randomised, double-blind, placebo-controlled trial. *Lancet Oncol*. 2009;10(11):25-34. 3. Bruix J, Sherman M: American Association for the Study of Liver Diseases. Management of hepatocellular carcinoma: an update. *Hepatology*. 2011;53(3):1020-1022.

Bayer (Schweiz) AG
Grubenstrasse 6
CH-8045 Zurich
www.bayer.ch

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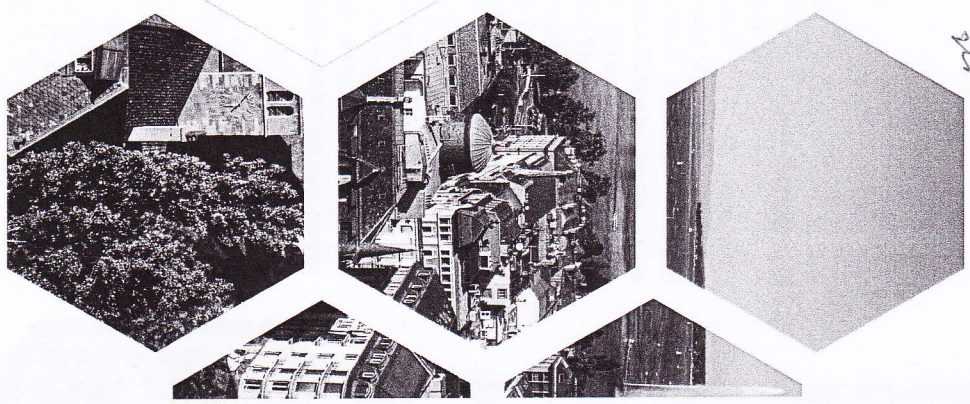
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Poster Board Number C40

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

Vito Lorusso¹, Domenico Germano², Maria T. Zolfino³, Domenico Sansommo⁴, Giuseppe Montalto⁵, Antonio Benedetti⁶, Vincenzo Montesarchio⁷, Adolfo F. Attili⁸, Sergio Frustaci⁹, Antonio Gasparri¹⁰, Umberto Cillo¹¹, Daniela Carpani¹², Antonino Picciotto¹³, Salvatore D'Angelo¹⁴

¹UOC Oncologia Medica, IRCCS Ospedale di Bari, Bari, ²UO Oncologia Medica, AO G. Rummo, Benevento, ³SC Gastroenterologia, AO G. Brotzu, Cagliari, ⁴Scienze Biomediche e Oncologia Umara. Sez Medicina Interna e Oncologia Clinica, Università degli Studi di Bari A.Moro, Bari, ⁵DIBIMIS, UOC Medicina Interna ed Epatologia, AOUP Paolo Giaccone, Palermo, ⁶Clinica di Gastroenterologia, AOU Ospedali Riuniti, Torrette di Ancona, ⁷UOC di Oncologia, AORN dei Colli - Ospedali Monaldi-Cotugno-CTO, Napoli, ⁸UOC di Gastroenterologia, Policlinico Umberto I, Roma, ⁹SOC Oncologia Medica B, Centro di Riferimento Oncologico CRO, Aviano, ¹⁰Gastroenterologia, Ospedale Universitario Gemelli-Università Cattolica, Roma, ¹¹Unità di Chirurgia Epatobiliare e Trapianto Epatico, AOU di Padova, Padova, ¹²Medical Department, Bayer Spa, Milano, ¹³U.O. Diagnosi e terapia delle epatiti e ambulatorio trapianto di fegato, IRCCS A.U.O. San Martino-IST, Genova, ¹⁴Unità Fegato, AORN San G. Moscati, Avellino, Italy

Corresponding author's e-mail: daniela.carpani@bayer.com

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. Differences in baseline characteristics may have played a role in OS. Given the observational nature of the study a selection bias cannot be excluded.