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posters

P – 110 Hepatocellular carcinoma in elderly patients: Final results of the Italian cohort of GIDEON study

T. Zolfino[1], V. Lorusso[2], S. D'Angelo[3], D. Sansonno[4], L. Giannitrapani[5], A. Benedetti[6], V. Montesarchio[7], A. Attili[8], A. Buonadonna[9], S. Barni[10], A. Gasbarrini[11], M. Pirisi[12], U. Cillo[13], A. Picciotto[14], E. Villa[15], P. Giovanis[16], G. Pinotti[17], G. Raimondo[18], C. Erminero[19], M. De Giorgio[20], B. Daniele[21]
[1]*AO G. Brotzu, Cagliari, Italy*
[2]*Oncologic Institute Vito Fazzi Hospital, Lecce, Italy*
[3]*AO San Giuseppe Moscati, Avellino, Italy*
[4]*AOU Policlinico Consorziale di Bari G. Bacelli, Bari, Italy*
[5]*AOUP Paolo Giaccone, Palermo, Italy*
[6]*AOU Ospedali Riuniti - PO Umberto I, Ancona, Italy*
[7]*AORN AO dei Colli Monaldi-Cotugno CTO, Napoli, Italy*
[8]*Azienda Policlinico Umberto I, Roma, Italy*
[9]*Dipartimento di Oncologia Medica, Istituto Nazionale Tumori, Aviano, Italy*
[10]*AO Ospedale Treviglio-Caravaggio, Treviglio, Italy*
[11]*Policlinico Universitario A. Gemelli - UCSC, Roma, Italy*
[12]*AOU Maggiore della Carità, Novara, Italy*
[13]*AOU di Padova, Padova, Italy*
[14]*IRCCS AUO S.Martino IST, Genova, Italy*
[15]*AOU Policlinico, Modena, Italy*
[16]*Azienda U.L.S.S. n. 9 di Treviso, Treviso, Italy*
[17]*Ospedale di Circolo e Fondazione Macchi, Varese, Italy*
[18]*AOU Policlinico G. Martino, Messina, Italy*
[19]*Bayer, Milano, Italy*
[20]*AO Papa Giovanni XXIII, Bergamo, Italy*
[21]*Dipartimento di Oncologia - Ospedale Rummo, Benevento, Italy*

Introduction: GIDEON (Global Investigational of therapeutic DEcisions in HCC and Of its treatment with sorafeNib) is a global, prospective, non-interventional study in unresectable HCC (uHCC) patients (pts) receiving sorafenib. Over 3200 pts were enrolled worldwide. The aim was to evaluate safety and efficacy of sorafenib in real life clinical practice. Elderly pts are often underrepresented in clinical trials and thus related data are limited. The aim of this analysis was to evaluate the tolerability and efficacy of sorafenib in pts 70 years of age or older in the Italian cohort of the GIDEON study.

Methods: Patients with uHCC candidates for systemic therapy in whom a decision to treat with sorafenib was taken, were eligible for enrollment. Patient and tumor characteristics, safety and efficacy were analyzed by age. A cut-off of ≥70 years of age was chosen to define the elderly patient subgroup. As an observational study, all results are descriptive in nature.

Results: In Italy, 278 pts were enrolled overall, of which 271 were valid for safety and 274 valid for efficacy analysis. Median age was 70 (44-90) years. Of the total of 278 pts, 141 were ≥ 70 years. Performance status (ECOG PS 0,1,2) was 65/26/9% respectively for the younger age subgroup and 58/35/6% respectively for the elderly subgroup. Stage of disease (BCLC A,B,C,D) was 11/24/62/2% for the younger subgroup and 14/39/42/1% for elderly. Macroscopic vascular invasion and extrahepatic spread was 33 and 29% respectively in the younger age group and 19% each in the elderly. Child-Pugh class A was present in 73% in the younger subgroup and 83% in the elderly subgroup. Median OS was 10 (8-18) months in the younger age subgroup and 20 (12-23) months in the elderly pts. The median TTP was also longer in the elderly group than in the younger subgroup 7.6 and 5 months respectively. The median duration of treatment was similar in both subgroup: 4.2 and 3.5 months respectively. The standard starting dose (400 mg bid) was administered in 89% of the younger pts and 85% of the elderly pts. The type and incidence of adverse events (AE) (serious and non-serious) were similar in the younger and the elderly subgroups and in line with the known sorafenib safety profile. The most frequent AEs were gastrointestinal (diarrhea), dermatologic (hand-foot skin reaction/rash) and fatigue.

Conclusion: In the Italian cohort of the GIDEON study sorafenib proved to be a safe and effective treatment option in both younger pts as well as in elderly pts. Elderly pts had longer OS than younger pts possibly because of more advanced disease in the younger subgroup. However due to the limitation and potential bias of an observational non-randomized study it is not possible to attribute this difference to a different treatment effect.

Table: P-110

Table: Safety results according to age

Adverse Events (AE) (all grades), n (%)	**< 70 years** n=131	**≥ 70 years** n=140	**Overall** n=271
AEs	111 (84.7)	108 (77.1)	219 (80.8)
Drug-related AEs	88 (67.2)	93 (66.4)	181 (66.8)
Serious AEs	48 (36.6)	35 (25.0)	83 (30.6)
Drug-related serious AEs	11 (8.4)	11 (7.9)	22 (8.1)
AE leading to permanent sorafenib discontinuation	45 (34.4)	44 (31.4)	89 (32.8)