Interview with Elizabeth Smith about 3rd line Trifluridine/Tipiracil (TAS-102); Choice of Posters with TAS-102

801P

Alsina et al. Efficacy and safety of trifluridine/tipiracil (FTD/TPI) in European patients with heavily pretreated metastatic gastric cancer (mGC): an analysis of the TAGS study

Conclusions: FTD/TPI was effective and well tolerated in European patients, consistent with the overall population of TAGS. (**also of interest:** *Efficacy and Safety of Trifluridine/Tipiracil Treatment in Patients With Metastatic Gastric Cancer Who Had Undergone Gastrectomy* Subgroup Analyses of a Randomized Clinical Trial

See also:

- *David H. Ilson et al.* Efficacy and safety of trifluridine/tipiracil (FTD/TPI) in patients (pts) with metastatic gastric cancer (mGC) with or without prior gastrectomy: Results from a phase III study (TAGS). Abstract
- *Wasat Mansoor et al.* Trifluridine/tipiracil (FTD/TPI) in patients (pts) with metastatic gastroesophageal junction cancer (mGEJC): Subgroup analysis from TAGS. Abstract **4038**
- *H-T Arkenau et al.* LBA25 TAGS: A phase III, randomised, double-blind study of trifluridine/tipiracil (TAS-102) versus placebo in patients with refractory metastatic gastric cancer. *Annals of Oncology*, Volume 29, Issue suppl_8, October 2018, mdy424.027
- *J Tabernero et al.* LBA-002 Overall survival results from a phase III trial of trifluridine/tipiracil versus placebo in patients with metastatic gastric cancer refractory to standard therapies (TAGS). *Annals of Oncology*, Volume 29, Issue suppl_5, June 2018, mdy208.001

691P

Macarulla et al. Integrated population pharmacokinetic modelling of liposomal irinotecan in patients with various tumour types, including untreated metastatic pancreatic cancer (mPC)

Conclusions: The PK of nal-IRI and SN-38 in patients with mPC is well described by the population model. The results suggest that UGT status has no impact on the PK of nal-IRI.

See also:

- *Adiwijaya BS et al.* Population Pharmacokinetics of Liposomal Irinotecan in Patients With Cancer. Clin Pharmacol Ther. 2017 Dec;102(6):997-1005. PDF
- Single Technology Appraisal Pegylated liposomal irinotecan hydrochloride trihydrate for treating pancreatic cancer after gemcitabine
- *Teresa Mercade Macarulla et al.* Subgroup analysis by baseline pain intensity (BPI) and analgesic use (BAU) in NAPOLI-1: A phase III study of liposomal irinotecan (nal IRI)±5-fluorouracil/ leucovorin (5-FU/LV) in patients (pts) with metastatic pancreatic ductal adenocarcinoma (mPDAC) previously treated with gemcitabine-based therapy. Abstract 379
- Lei F et al. Combination Therapies and Drug Delivery Platforms in Combating Pancreatic Cancer. J Pharmacol Exp Ther. 2019 Sep;370(3):682-694. PDF

697P

Merz et al. Plasmatic CXCL8 is a marker for TGFß- activated kinase 1 (TAK1) activation which may predict resistance to nanoliposomal irinotecan (nal-IRI) in gemcitabine- refractory pancreatic cancer (PC) patients

Conclusions: We identified CXCL8 as the most significant circulating marker of TAK1 activation. Our study candidates CXCL8 as a potential predictive biomarker of resistance to nal-IRI in gemcitabine-refractory PC patients.

See also:

- Glassman DC et al. Nanoliposomal irinotecan with fluorouracil for the treatment of advanced pancreatic cancer, a single institution experience. BMC Cancer.2018 Jun 27;18(1):693. PDF
- Woo W et al. Spotlight on liposomal irinotecan for metastatic pancreatic cancer: patient selection and perspectives. Onco Targets Ther. 2019 Feb 21;12:1455-1463 PDF

829TiP

Yoo et al. Multicenter randomized phase II trial of 5-Fluorouracil/leucovorin (5FU/LV) with or without liposomal irinotecan (nal-IRI) in metastatic biliary tract cancer (BTC) as second-line therapy after progression on gemcitabine plus cisplatin (GemCis): NIFTY trial

Trial design: NIFTY trial is a multicenter, open-label, randomized, phase II trial and 5 referral cancer centers in Korea participated in this study. Histologically documented biliary tract cancer (intrahepatic and extrahepatic cholangiocarcinoma, and gallbladder cancer), documented progression on 1st line Gem/Cis, and at least one measurable lesion are key inclusion criteria. Eligible patients are randomized with 1:1 ratio

to experimental arm (80 mg/m2 irinotecan hydrochloride trihydrate salt equivalent to 70 mg/m2 irinotecan free base over 90 minutes, followed by 400 mg/m2 LV over 30 min, and then 2400 mg/m2 5-FU over 46 h, every 2 weeks) and control arm (400 mg/m2 LV over 30 min, and then 2400 mg/m2 5-FU over 46 h, every 2 week). Response evaluation is graded by RECIST v1.1 and conducted every 6 weeks. Primary endpoint is progression-free survival and secondary endpoints are overall survival, response rates, quality of life assessed by EORTC QLQ-C30 and safety profile. We hypothesized that the addition of nal-IRI to 5-FU/LV would enhance the PFS to median 3.3 months (P1) from median 2.0 (P0) with 5-FU/LV alone. With alpha of 0.05, power of 80%, and drop-out rates of 10%, a total of 174 patients (87 patients per each arm) are needed based on this hypothesis. As of March 2019, a total of 89 patients (51% of the target number) are enrolled.

See also:

- *Thomas Jens Ettrich et al.* Liposomal irinotecan (nal-IRI) plus 5-fluorouracil (5-FU) and leucovorin (LV) or gemcitabine plus cisplatin in advanced cholangiocarcinoma: The AIO-NIFE-trial, an open label, randomized, multicenter phase II trial. Abstract **TPS4145**