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FIGHT-202 trial

Pemigatinib could be a new treatment option for previously treated patients with cholangiocarcinoma with *FGFR2* gene rearrangements or fusions, according to results from the phase 2, open-label FIGHT-202 trial, presented by Arndt Vogel (Hannover Medical School, Hannover, Germany). 145 patients were recruited and assigned to cohorts A (*FGFR2* gene rearrangements or fusions; n=107), B (other *FGF*/*FGFR* gene alterations; n=20), or C (no *FGF*/*FGFR* gene alterations; n=18). Patients received oral pemigatinib 13·5 mg once daily (21-day cycle; 2 weeks on, 1 week off). The primary endpoint, centrally confirmed objective responses in cohort A, was achieved by 38 (35·5%; 95% CI 26·5–45·4) of 107 patients, including three complete responses. The most common adverse events were hyperphosphataemia (60%), alopecia (49%), and diarrhoea (47%).

M6620 for ovarian cancer

Panagiotis Konstantinopoulos (Dana-Farber Cancer Institute, Boston, MA, USA) presented results from a randomised, phase 2 study of the ATR inhibitor M6620. 70 patients with platinum-resistant high-grade serous ovarian cancer were randomly assigned to gemcitabine alone (1000 mg/m^2 intravenously on days 1 and 8; n=36) or to gemcitabine and M6620 (210 mg/m^2 intravenously on days 2 and 9 of a 21-day cycle; n=34). Median progression-free survival—the primary endpoint—was 14·7 weeks in the gemcitabine group and 22·8 weeks in the gemcitabine plus M6620 group (hazard ratio [HR] 0·57 [90% CI 0·33–0·99]; p=0·049). 69% of patients in the gemcitabine alone group and 65% in the gemcitabine plus M6620 had treatment-related grade 3 or worse adverse events.

TROPHY-U-01 trial

Interim results from an open-label, phase 2 study, presented by Scott Tagawa (Weill Cornell Medicine, New York, NY, USA), suggest that sacituzumab govitecan is well tolerated and has antitumour activity in patients with metastatic urothelial cancer. 35 patients who had progressed after platinum-based and anti-PD-1 or anti-PD-L1-based therapies received 10 mg/kg sacituzumab govitecan on days 1 and 8 of 21-day cycles. The primary endpoint in this pre-planned interim analysis was investigator-assessed objective response as per RECIST 1.1. At a median follow-up of 4·1 months, ten (29%) of 35 patients had achieved an objective response; two (6%) had confirmed complete responses, six (17%) confirmed partial responses, and two (6%) unconfirmed partial responses. Common grade 3 or worse treatment-related adverse events included neutropenia (23%), anaemia (17%), febrile neutropenia (11%), and diarrhoea (11%).

MONALEESA-3 trial update

Dennis Slamon (University of California Los Angeles, Santa Monica, CA, USA), presented overall survival results from the phase 3 MONALEESA-3 trial of ribociclib plus fulvestrant versus placebo plus fulvestrant in postmenopausal patients with hormone receptor-positive, HER2-negative, advanced breast cancer. The primary endpoint of progression-free survival had previously been shown to be improved in the ribociclib group. In this prespecified overall survival analysis, at a median follow-up of 39·4 months, median overall survival was not reached in the ribociclib group versus 40·0 months in the placebo group (HR 0·724 [95% CI 0·568–0·924]; p=0·00455). The adverse event profile was similar to that in previously published reports from the trial.

Endometrial cancer treatment

Final results show promising antitumour activity of lenvatinib and pembrolizumab in a cohort of patients with metastatic endometrial cancer, according to findings presented by Vicky Makker (Memorial Sloan Kettering Cancer Center, New York, NY, USA). In an ongoing, phase 1b–2 study, a cohort of 108 patients with previously treated, metastatic endometrial cancer were enrolled and followed-up for a median of 18·7 months. The primary endpoint of the phase 2 part was objective response at 24 weeks. 41 (38·0%; 95% CI 28·8–47·8) of 108 patients achieved an objective response. In exploratory analyses, activity was reported irrespective of microsatellite instability or mismatch-repair deficient status. The most frequent grade 3 or worse treatment-related adverse events were hypertension (35 [32%] of 108 patients), fatigue (nine [8%]), and diarrhoea (seven [7%]).

Targeting mutant IDH1 in advanced cholangiocarcinoma

Patients receiving ivosidenib—an oral inhibitor of the mutant IDH1 protein—had significantly longer progression-free survival than those given placebo, according to results from the ClarIDHy trial, presented by Ghassan Abou-Alfa (Memorial Sloan Kettering Cancer Center, New York, NY, USA). In the randomised, phase 3 trial, patients were randomly assigned (2:1) to either ivosidenib (500 mg once daily; n=124) or matching placebo (n=61) and assessed for the primary endpoint of progression-free survival by central review. Median progression-free survival was 2·7 months in the ivosidenib group and 1·4 months in the placebo group (HR 0·37 [95% CI 0·25–0·54]; p<0·001). Grade 3 or worse adverse events were reported in 46% of patients in the ivosidenib group and 36% of patients in the placebo group.

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