D842V-mutant GIST who received less than the 300 mg RP2D (n=17), an ORR of 82% was achieved, with 2 (12%) CR and 12 (71%) PR. The most common adverse events (AEs, any grade) in ≥10% of pts with PDGFRA D842V-mutant GIST treated at 300/400 mg were nausea (74%), anemia (68%), diarrhea (66%), fatigue (58%), memory impairment (47%), periorbital edema (45%), decreased appetite (39%), increased lacrimation (34%), and vomiting, abdominal pain, hypokalemia, increased blood bilirubin and peripheral edema (all 32%). A total of 21% of pts discontinued treatment due to drug-related AEs. There were no treatment-related deaths.

Conclusions: In pts with U/M PDGFRA D842V-mutant GIST, avapritinib has clinical activity with durable responses and a tolerable safety profile, with no additional safety signals to those found in the NAVIGATOR study overall GIST population.

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116MO Efficacy, safety, and quality of life (QoL) with futibatinib in patients (pts) with intrahepatic cholangiocarcinoma (iCCA) harboring FGFR2 fusions/rearrangements: FOENIX-CCA2

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Background: iCCA has a poor prognosis and its incidence is higher in Asian vs Western countries. Futibatinib is an oral, highly selective, irreversible FGFR1–4 inhibitor that demonstrated safety and preliminary efficacy in pts with iCCA harboring FGFR2 aberrations. This study evaluated safety, efficacy, and QoL with futibatinib treatment in pts with iCCA and FGFR2 fusions/rearrangements.

Methods: FOENIX-CCA2 (NCT02052778), a global phase II study, enrolled pts with unresectable/metastatic iCCA harboring an FGFR2 fusion/rearrangement and disease progression after ≥1 line of systemic therapy (including gemcitabine–cisplatin) but no prior FGFR inhibitors. Pts received futibatinib 20 mg once daily until disease progression/intolerability. The primary endpoint was objective response rate (ORR) per independent central radiology review and RECIST v1.1; secondary endpoints were disease control rate (DCR), duration of response (DOR), progression-free survival (PFS), safety, and patient-reported outcomes (PROs). ORRs of subgroups by baseline demographic, fusion partner, and other molecular alteration (eg, TP53) were also determined.

Results: Of 103 enrolled pts, planned interim data are reported for 67 pts (54% white, 24% Asian) with ≥6 mo of follow-up; 55% of pts received ≥2 prior therapy lines, and 82% had tumors harboring an FGFR2 fusion (BICC1, n=15). ORR was 37.3%, DCR was 82.1%, and median DOR was 8.3 mo. Objective responses occurred regardless of baseline characteristic (subgroup: ≥65 y, ORR: 57.1%), FGFR2 fusion partner (BICC1, 33.3%), or other genetic mutation (TP53, 16.7%). Median PFS was 7.2 mo. The most common treatment-related adverse events (TRAEs; any grade/grade 3) were hyperphosphatemia (81%/27%), diarrhea (37%/0%), and dry mouth (33%/0%); no grade 4–5 TRAEs occurred. TRAEs were managed with dose interruption/reduction (55%/51%); only 1 pt discontinued due to a TRAE. PROs were stable through 273 days (13 cycles) of treatment.

Conclusions: Futibatinib resulted in durable objective responses in pts with iCCA and FGFR2 fusions/rearrangements, including within pt subgroups. Adverse events were manageable, and QoL was maintained.

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117MO Comparison of survival and patterns of recurrence in gastric neuroendocrine carcinoma, mixed adenoneuroendocrine carcinoma and adenocarcinoma: A multicenter study from China

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Background: Gastric neuroendocrine carcinoma (G-NEC) and mixed adenoneuroendocrine carcinoma (G-MANEC) are rare pathological types of gastric cancer, and there is a lack of multicenter studies comparing the prognosis and recurrence patterns of G-NEC, G-MANEC and gastric adenocarcinoma (G-AC).

Methods: Patients with resectable G-NEC and G-MANEC at 23 hospitals in China from January 2006 to December 2016 were identified. In addition, 2,785 patients with G-AC were selected as controls. Propensity score-matched analysis was used to match stage among the different pathological types, and disease-free survival (DFS), post-recurrence survival (PRS) and patterns of recurrence were examined.

Results: We reviewed 3,689 patients: 503 of with G-NEC, 401 with G-MANEC and 2,785 with G-AC. After propensity score matching, the DFS and PRS of G-NEC and G-MANEC were significantly worse than those of G-AC (all $P<0.05$). Multivariable analyses revealed that G-NEC and G-MANEC (vs. G-AC) were independent risk factors for DFS and PRS (all $P<0.05$). Compared with G-AC patients, G-NEC and G-MANEC patients were more likely to have distant recurrence ($P<0.05$). On multivariate analysis, G-NEC and G-MANEC were independent predictors for distant recurrence (both $P<0.001$). Additionally, T3-T4 stage and lymph node metastasis were independent risk factors for distant recurrence of G-NEC and G-MANEC (both $P<0.05$).

Conclusions: G-NEC and G-MANEC have worse prognoses and are more prone to distant recurrence than G-AC. Thus, different follow-up and treatment strategies should be developed for G-NEC and G-MANEC, especially patients with tumors penetrating into the subserosa or deeper layers and with lymph node metastasis.

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118MO Circulating tumour DNA methylation are markers for early detection of pancreatic ductal adenocarcinoma (PDAC)

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Background: PDAC is a cancer of high mortality and low survival. Its early detection is critical due to symptoms often occur only at advanced stages. However, there is no reliable screening tool to identify high-risk patients. ctDNA methylation has recently emerged as a promising new target to differentiate PDAC plasma from normal plasma for its early detection.

Methods: Reduced representation bisulfite sequencing libraries were made in 46 PDAC tissues, 30 para-PDAC tissues and 20 PDAC plasmas to screen PDAC-specific markers, which was done by quantifying and comparing methylation levels of genomic regions and individual CpG sites between those groups. Markers were validated in plasma samples from 84 PDAC patients and 64 normal controls to propose a blood classifier. The best-performing markers were developed into a targeted sequencing panel, which was tested on a larger collection of plasma samples from patients of a variety of pancreatic diseases to build and validate a PDAC-predicting model.

Results: We profiled genome-wide methylation patterns of tissues samples to identify 171 PDAC-specific markers. We reiterated training and cross-validating PDAC classification models using SVM method and achieved an average sensitivity of 86% and specificity of 88%. To prove the feasibility of a non-invasive detection in plasma, a targeted methylation assay using those markers was tested on PDAC and normal plasmas and yielded an average sensitivity of 68.4% and a specificity of 85.8%. We refined the panel by selecting the most discriminatory markers and built a smaller panel for a more efficient target capture, which is validated in an independent cohort of 200 plasma samples that included PDAC, chronic pancreatitis (CP) and normals from multiple centers. The smaller panel achieved an AUC above 0.90 when classifying PDAC from normals, and an AUC of 0.88 when separating PDAC from CPs.

Conclusions: We have developed an NGS based target assay covering PDAC-specific DNA methylation targets by screening and validation on PDAC tissues and plasmas. It has shown encouraging results to classify PDAC plasma from non-malignant diseases, demonstrating its potential to be optimized into non-invasive diagnostics for blood-based early PDAC screening.

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119MO Application of an artificial neural network for predicting the chemotherapy benefit of patients with gastric cancer after radical surgery

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Background: Artificial neural network (ANN) models have a strong self-learning ability and can deal with complex biological information, but there is no ANN model for predicting the benefits of adjuvant chemotherapy in patients with gastric cancer (GC).

Methods: The clinicopathological data of patients who underwent radical resection of GC from January 2010 to September 2014 were analyzed retrospectively. Patients who underwent surgery combined with adjuvant chemotherapy were randomly divided into a training cohort (70%) and a validation cohort (30%). An ANN model (CT-benefit-ANN) was established, and its ability to predict the benefit of chemotherapy was evaluated by the C-index. The prognostic prediction and stratification ability of CT-benefit-ANN and the 8th AJCC staging system were compared by ROC curves and Kaplan-Meier curves.

Results: In the training and validation cohort, CT-benefit-ANN both shows good prediction accuracy for adjuvant chemotherapy benefit. The ROC curve showed that the prediction accuracy of CT-benefit-ANN was better than that of the 8th AJCC staging system in all groups. The calibration plots showed that the predicted prognosis of CT-benefit-ANN was highly consistent with the actual value. The survival curves showed that CT-benefit-ANN could stratify prognosis well for all groups and performed significantly better than the 8th AJCC staging system.

Conclusions: The CT-benefit-ANN model developed in this study can accurately predict the benefits of adjuvant chemotherapy in patients with stage II/III GC. The benefit