

# GI ONCOLOGY

# CLINICAL TRIALS AT UCDAVIS

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Please contact us with any questions or any potential clinical trial patients

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# PANCREAS

setting	phase trial	study name	study drug	study status	target population	Clinical research coordinator
borderline	pilot	<b>CCHO-023</b> - Pilot Study of Kernel-Based Dynamic 18F-Fludeoxyglucose Positron Emission Tomography (KBD FDG-PET) for Detection of Residual Disease in Patients with Borderline Resectable Pancreatic Adenocarcinoma Treated with Chemotherapy	n/a	open to enrollment	borderline resectable	Edward Kim 916-816-4059
	II	<b>A021501</b> - Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas	SBRT	temp closed for interim analysis	borderline resectable - FOLFIRINOX candidates	Christina Devisser 916-734-1787
metastatic (1st line)	III	<b>CanStem111P</b> - A Phase III Study of BBI-608 plus nab-Paclitaxel with Gemcitabine in Adult Patients with Metastatic Pancreatic Adenocarcinoma.	Napabucasin (BBI-608) - STAT3 inhibitor	open to enrollment	untreated metastatic - gem/nab-paclitaxel candidate	Christina Devisser 916-734-1787
advanced (2nd line only)	III	<b>TRYbeCA-1</b> - A Randomized, Phase 3 Study of Eryaspase in Combination with Chemotherapy Verses Chemotherapy Alone as Second-Line Treatment in Patients with Pancreatic Adenocarcinoma	Eryaspase (erythrocyte encapsulated L-asparaginase)	opening soon	LA or metastatic, 2nd line only.	TBD
	II	<b>SGNTV-001</b> : Open Label Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors	Tisotumab Vedotin (Tissue Factor Antibody Drug Conjugate)	opening soon	LA or metastatic, 2nd line only.	TBD
advanced (2nd line and beyond)	II	<b>PhII-157</b> - A Phase II Study of Selumetinib (AZD6244) for the Treatment of Advanced Pancreas Cancer harboring KRAS G12R Mutations	Selumetinib - MEK inhibitor	open to enrollment	metastatic pancreatic with KRAS <b>G12R</b> mutation - at least 6 months of prior therapy	Christina Devisser 916-734-1787
	I	<b>SM08502-ONC-01</b> : A Phase 1, Open-Label, Dose-Escalation, Dose-Finding Study Evaluating the Safety and Pharmacokinetics of Orally Administered SM08502 in Subjects with Advanced Solid Tumors	SMO8502 - wnt pathway inhibitor	open to enrollment	any solid tumor	Corinne Turrell 916-734-3089
	I	<b>PAYLOAD RRx001-16-01</b> - A Phase I, Open-Label, Multiple Ascending Dose Study to Assess the Safety and Tolerability of RRx-001 in Combination with Irinotecan in Metastatic or Advanced Cancer patients Without Life Prolonging Therapies of Demonstrated Clinical Benefit	RRx-001 - epigenetic modulator	open to enrollment	any tumor type - irinotecan candidate - allows prior irinotecan b/c RRx001 can resensitize tumors to irinotecan - UGT1A1 6/6 only	Corinne Turrell 916-734-3089
	I	<b>PHI-87</b> : Phase I Clinical Trial of VX-970 in Combination With the Topoisomerase I Inhibitor Irinotecan in Patients With Advanced Solid Tumors	VX-970 - ATR kinase inhibitor	open to enrollment	any tumor type - irinotecan candidate - UGT1A1 6/6 only	Corinne Turrell 916-734-3089
	II	<b>DART</b> - Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	nivolumab/ipilumumab	Temp closed	rare pancreatic tumor histologies - NOT adenocarcinoma	Diem Le 916-734-4942
any stage	pilot	<b>CCHO-022 - PanDORA</b> :Pancreatic ADenocarcinoma Organoids as a model system for correlative science ReseArch	none	open to enrollment	any patient undergoing biopsy or surgery	Edward Kim 916-816-4059

# COLORECTAL

setting	phase trial	study name	study drug	study status	target population	Clinical research coordinator
Adjuvant (Anal)	II	<b>EA 2165</b> -Nivolumab After Combined Modality Therapy in Treating Patients With High Risk Stage II-IIIB Anal Cancer	nivolumab	open to enrollment	High risk Anal cancer	Andrew Buck 916-734-1787
Adjuvant	III	<b>A021502</b> - Randomized std adj chemo alone or combined with Atezo in stage III MSI high colon cancer	Atezolizumab (PDL1)	open to enrollment	stage III colon cancer with <b>MSI High</b>	Christina Devisser 916-734-1787
metastatic (1st line)	III	<b>NRG-GI004</b> - A Phase III study of mFOLFOX6/Bev with or without Atezolizumab or Atezolizumab monotherapy in 1st line treatment of patients with dMMR metastatic colorectal cancer	Atezolizumab (PDL1)	open to enrollment	stage IV colon cancer with <b>MSI High</b>	Christina Devisser 916-734-1787
	I	<b>MedImmune D419NC00001</b> -A Study of Durvalumab (MEDI4736) and IPH2201 in Solid Tumors	Durvalumab (PDL1) + IPH2201 (NK cell activator)	opening soon	stage IV CRC, <b>MSS</b> 1st line	TBD
metastatic (2nd line and beyond)	I	<b>ADU-CL-12</b> : A Phase 1 Trial of Personalized LADD Vaccine (pLADD) in Recurrent Microsatellite Stable Metastatic Colorectal Cancer	personalized vaccine+/- pembrolizumab	open to enrollment	stage IV <b>MSS</b> colorectal cancer	Corinne Turrell 916-734-3089
	II	<b>SGNTV-001</b> : Open Label Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors	Tisotumab Vedotin (Tissue Factor Antibody Drug Conjugate)	opening soon	stage IV colon cancer $\leq 3$ prior lines but must have received 5FU,oxali,irin, bev	TBD
	II	<b>SWOG S1613</b> - A randomized phase II study of pertuzumab and Trastuzumab(TP) compared to Cetuximab and irinotecan (CETIRI) in metastatic colorectal cancer with HER2 amplification	Pertuzumab and Trastuzumab	open to enrollment	stage IV colorectal cancer with HER2 amplification before anti EGFR therapy	Christina Devisser 916-734-1787
	I	<b>SM08502-ONC-01</b> : A Phase 1, Open-Label, Dose-Escalation, Dose-Finding Study Evaluating the Safety and Pharmacokinetics of Orally Administered SM08502 in Subjects with Advanced Solid Tumors	SM08502 - wnt pathway inhibitor	open to enrollment	<i>any solid tumor</i>	Corinne Turrell 916-734-3089
	I	<b>PAYLOAD RRx001-16-01</b> - A Phase I, Open-Label, Multiple Ascending Dose Study to Assess the Safety and Tolerability of RRx-001 in Combination with Irinotecan in Metastatic or Advanced Cancer patients Without Life-Prolonging Therapies of Demonstrated Clinical Benefit	RRX-001 - epigenetic modulator	open to enrollment	any tumor type - irinotecan candidate - allows prior irinotecan b/c RRX001 can resensitize tumors to irinotecan	Corinne Turrell 916-734-3089
	I	<b>PHI-87</b> - Phase I Clinical Trial of VX-970 in Combination With the Topoisomerase I Inhibitor Irinotecan in Patients With Advanced Solid Tumors	VX-970 - ATR kinase inhibitor	open to enrollment	any tumor type - irinotecan candidate - UGT1A1 6/6 only	Corinne Turrell 916-734-3089

# HCC and Biliary

setting	phase trial	study name	study drug	study status	target population	Clinical research coordinator
1st line advanced HCC	I/II	<b>UCDCC-276</b> - Phase I/II Trial of BMS-986205 and Nivolumab as First Line Therapy in Hepatocellular Carcinoma	MBS-986205 (IDO inhibitor)	open ing soon	untreated advanced HCC Child-Pugh A	TBD
Unresectable or metastatic cholangio or GB - <b>1st line</b>	Ib	<b>HALO-110-101</b> - A Phase 1b, Randomized, Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination With Cisplatin Plus Gemcitabine and PEGPH20 in Combination With Atezolizumab and Cisplatin Plus Gemcitabine Compared With Cisplatin Plus Gemcitabine in Hyaluronan-High (HA-high) Subjects with Previously Untreated, Unresectable, Locally Advanced, or Metastatic Intrahepatic and Extrahepatic Cholangiocarcinoma and Gallbladder Adenocarcinoma	atezolizumab (PDL-1) and PEGPH20 (hyaluronidase)	open to enrollment	untreated locally advanced unresectable or metastatic intra-, extra-heptic, and gallbladder. Gem cis candidate.	Christina Devisser 916-734-1787
unresectable cholangiocarcinoma - 2nd or 3rd line	II	<b>PHI-165</b> - A Randomized Phase 2 Study of Atezolizumab in Combination with Cobimetinib versus Atezolizumab Monotherapy in Participants with Unresectable Cholangiocarcinoma	atezolizumab (PDL1 inhibitor) and Cobimetinib (MEK inhibitor)	open to enrollment	2nd/3rd line cholangiocarcinoma	Christina Devisser 916-734-1787
advanced cholangio or GB - 2nd line and beyond	I	<b>SMO8502-ONC-01</b> : A Phase 1, Open-Label, Dose-Escalation, Dose-Finding Study Evaluating the Safety and Pharmacokinetics of Orally Administered SMO8502 in Subjects with Advanced Solid Tumors	SMO8502 - wnt pathway inhibitor	open to enrollment	any solid tumor	Corinne Turrell 916-734-3089
	I	<b>PAYLOAD RRx001-16-01</b> - A Phase I, Open-Label, Multiple Ascending Dose Study to Assess the Safety and Tolerability of RRx-001 in Combination with Irinotecan in Metastatic or Advanced Cancer patients Without Life-Prolonging Therapies of Demonstrated Clinical Benefit	RRX-001 - epigenetic modulator	open to enrollment	any tumor type - irinotecan candidate - allows prior irinotecan b/c RRX001 can resensitize tumors to irinotecan - UGT1A1 6/6 only	Corinne Turrell 916-734-3089
	I	<b>PHI-87</b> : Phase I Clinical Trial of VX-970 in Combination With the Topoisomerase I Inhibitor Irinotecan in Patients With Advanced Solid Tumors	VX-970 - ATR kinase inhibitor	open to enrollment	any tumor type - irinotecan candidate - UGT1A1 6/6 only	Corinne Turrell 916-734-3089
any HCC	registry	A 5-Year Observational Study of the Natural History and Management of Patients with Hepatocellular Carcinoma	n/a	open to enrollment	HCC patients	Chung Heng (Peter) Liu 916-734-8985
unresectable advanced HCC	I	<b>Phi-97</b> : A Phase 1 Trial of ABT-263 (Navitoclax), a Bcl-2 inhibitor, and Sorafenib (Nexavar) in Patients with Relapsed or Refractory Solid Organ Tumors	Navitoclax (Bcl-2i)	open to enrollment	HCC patients Child-Pugh A/B7	Corinne Turrell 916-734-3089

# Esophageal and Gastric

setting	phase trial	study name	study drug	study status	target population	Clinical research coordinator
First Line		<b>CL-0301:</b> A Phase 3, Global, Multi-Center, Double-Blind, Randomized, Efficacy Study of IMAB362 Plus mFOLFOX6 Compared with Placebo Plus mFOLFOX6 as First-line Treatment of Subjects with Claudin (CLDN)18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma	IMAB362 (mAb Claudin-18)	opening soon	Her2-, Claudin-18+ advanced Gastric/(GEJ) Adenocarcinoma	TBD
advanced GEJ/Gastric (2nd line and beyond)	I/II	<b>PHI-162:</b> A Phase 1 / 2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction	Olaparib (PARPi) and Ramucirumab	open to enrollment	gastric and GEJ, beyond 1st line progression prior to ramucirumab	Christina Devisser 916-734-1787
	I	<b>SM08502-ONC-01:</b> A Phase 1, Open-Label, Dose-Escalation, Dose-Finding Study Evaluating the Safety and Pharmacokinetics of Orally Administered SM08502 in Subjects with Advanced Solid Tumors	SM08502 - wnt pathway inhibitor	open to enrollment	any solid tumor	Corinne Turrell 916-734-3089
	I	<b>PAYLOAD RRx001-16-01-</b> A Phase I, Open-Label, Multiple Ascending Dose Study to Assess the Safety and Tolerability of RRx-001 in Combination with Irinotecan in Metastatic or Advanced Cancer patients Without Life-Prolonging Therapies of Demonstrated Clinical Benefit	RRx-001 - epigenetic modulator	open to enrollment	any tumor type - irinotecan candidate - allows prior irinotecan b/c RRx001 can resensitize tumors to irinotecan	Corinne Turrell 916-734-3089
	I	<b>PHI-87:</b> Phase I Clinical Trial of VX-970 in Combination With the Topoisomerase I Inhibitor Irinotecan in Patients With Advanced Solid Tumors	VX-970 - ATR kinase inhibitor	open to enrollment	any tumor type - irinotecan candidate - UGT1A1 6/6 only	Corinne Turrell 916-734-3089
	II	<b>DART -</b> Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	nivolumab and ipilimumab	open to enrollment	undifferentiated adenocarcinoma of GI track	Diem Le 916-734-4942