CHNw Oncology Research Protocols (OPEN and PENDING)

4/11/2025

Multiple Disea	ase Sites	NCT #	Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study (Bedano)	<u>NCT02693535</u>	Various	Various	Various	Indy
Tempus TP-CA-005	Polaris - Umbrella Study for Analysis of Data Related to Patients with Cancer (O'Neil)	NCT06018753	N/A - data collection only	Subjects diagnosed with cancer	N/A	Indy
AbbVie M24-311	A Phase 2, Randomized Study to Evaluate Safety, Efficacy, and Optimal Dose of ABBV-400 in Combination with Fluorouracil, Folinic Acid, and Bevacizumab in Previously Treated Subjects with Unresectable Metastatic Colorectal Cancer (O'Neil)	<u>NCT06107413</u>	c-Met targeting antibody conjugated to a potent inhibitor of Top1 payload	CRC	c-Met	Indy
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab (N. Reddy)	<u>NCT05005403</u>	ABBV-514 is a T-regs cell depleter	Stage 1 complete	NA	Indy
LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS C12C- Mutant Advanced Solid Tumors (N. Reddy)	<u>NCT04956640</u>	KRAS G12C Inhibitor	enrollment paused 8/9/24	KRAS G12C	Indy

Amgen 20220127	A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 inCombination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05975073</u>	Methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor	Part 1: MTAP-null or lost MTAP expression solid tumors	MTAP-null	Indy
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05094336</u>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1c: NSCLC, 1e: BTC, 1f: HNSCC, 1g: PDAC, 1h: Basket (can include: NSCLC, BTC, HNSCC, PDAC)	MTAP-null	North and East
Artios ART0380C001	A Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the ATR Kinase Inhibitor ART0380 Administered Orally as Monotherapy and in Combination to Patients with Advanced or Metastatic Solid Tumors (O'Neil)	<u>NCT04657068</u>	ART0380	Advanced or metastatic solid tumors w/ATM alterations	ATM	North
Relay Therapeutics RLY-2608-101	A First-in-Human Study of Mutant-selective PI3Kα Inhibitor, RLY-2608, as a Single Agent in Advanced Solid Tumor Patients and in Combination With Fulvestrant in Patients With Advanced Breast Cancer (O'Neil)	<u>NCT05216432</u>	RLY-2608	RLY-2608 single agent: unresectable or metastatic solid tumors	PIK3CA	North and South
GV20 Therapeutics GV20-0251-100	GV20-0251-100, An Open-Label Study of GV20-0251 in Patients with Advanced and/or Refractory Solid Tumor Malignancies (O'Neil)	<u>NCT05669430</u>	IGSF8 antibody	Cohort C1: endometrial carcinoma, head and neck squamous, cell carcinoma (HNSCC), cutaneous melanoma, and non-small cell lung cancer	IGSF8 and others	North and South

C4 Therapeutics CFT1946-1101	A Phase 1/2 Open-Label Multicenter Trial to Characterize the Safety, Tolerability, and Preliminary Efficacy of CFT1946 as Monotherapy and Combination therapy in Subjects with BRAF- V600 Mutant Solid Tumors (Shukla)	<u>NCT05668585</u>	CFT1946	BRAF-V600 Mutant Solid non- CNS Tumors	BRAF-V600	Indy
Lilly J5J-OX-JZZA	Phase 1a/1b Study of LY3962673 in Patients with KRAS G12D- Mutant Solid Tumor (N. Reddy)	NCT06586515	LY3962673	KRAS G12D-Mutant Solid Tumors	KRAS G12D	Indy
KaliVir STEALTH-001	A Phase 1/1b Study of VET3-TGI Administered Alone and in Combination with Pembrolizumab in Patients with Advanced Solid Tumors (O'Neil)	NCT06444815	VET3-TGI	Advanced Solid Tumors IV Cohort Only	Various	Indy
Servier CL1-95035-001	A Phase 1, open-label, multicenter clinical trial of S095035 (MAT2A inhibitor) in adult participants with advanced or metastatic solid tumors with homozygousdeletion of MTAP (N. Reddy)	<u>NCT06188702</u>	MAT2A inhibitor	Advanced or metastatic solid Tumors	МТАР	North (South & East Pending)
Breast			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
CCTG MA.39	A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (Weed)	<u>NCT03488693</u>	RT	Low-risk breast cancer (Oncotype DX ≤25) or T3N0 disease	ER+	Indy
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab (N. Reddy)	<u>NCT05005403</u>	ABBV-514 is a T-regs cell depleter	ТИВС	NA	Indy

Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer (O'Neil)	NCT05902988	Oral KIF18A Inhibitor	Expansion - TNBC	KIF18A	North and South
A011801 - Compass HER2 RD	A Double-Blinded, Phase III, Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib (Walling)	NCT04457596	MOA – ADC – linking Trastuzumab to emtansine (DM1)	HER2+ RD after preoperative chemo & HER2 directed therapy (Substudy H01 is closed)	HER2+	Indy
Relay Therapeutics RLY-2608-101	A First-in-Human Study of Mutant-selective PI3Kα Inhibitor, RLY-2608, as a Single Agent in Advanced Solid Tumor Patients and in Combination With Fulvestrant in Patients With Advanced Breast Cancer (O'Neil)		RLY-2608	HR+, HER2– locally advanced or metastatic breast cancer	PIK3CA HR+, HER2–	North and South
BioNTech BNT327-02	A Phase II, multi-site, randomized, open-label clinical trial to evaluate the safety, efficacy, and pharmacokinetics of BNT327 at two dose levels in combination withchemotherapeutic agents as first- and second-line treatment in triple-negative breast cancer (Shukla)	NCT06449222	BNT327	TNBC	PD-L1, HR (ER and PR), and HER2	Indy
Lung			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
SignalChem SLC-391-102	A Single-Arm, Open-Label, Phase 1b/2 Study of SLC-391, an AXL Inhibitor, in Combination with Pembrolizumab in Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) (SKYLITE) (N. Reddy)	<u>NCT05860296</u>	Selective AXL Inhibitor	NSCLC Enrolling in Cohort 1 (ICI Naïve) & Cohort 2 (ICI Resistant)	AXL/TYRO3/MER	North and South

LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS C12C- Mutant Advanced Solid Tumors (N. Reddy)	<u>NCT04956640</u>	KRAS G12C Inhibitor	NSCLC 1st line, NSCLC w Brain mets Combo therapy - NSCLC 1st line (pembro)	KRAS G12C	Indy
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab (N. Reddy)	<u>NCT05005403</u>	ABBV-514 is a T-regs cell depleter	NSCLC	NA	Indy
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05094336</u>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1c: NSCLC	MTAP-null	North and East
Amgen 20220127	A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 inCombination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05975073</u>	Methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor	Part 2: MTAP-null or lost MTAP expression NSCLC	MTAP-null	Indy
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer (O'Neil)	<u>NCT05902988</u>	Oral KIF18A Inhibitor	Expansion - sq-NSCLC	KIF18A	North and South

Hematology			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
Seagen SGNB6A-001	A Phase 1 Study of SGN-B6A in Advanced Solid Tumors (Shukla)	<u>NCT04389632</u>	ADC targeting integrin beta-6	Dose expansion NSCLC	Integrin beta-6	Indy
Lilly J5J-OX-JZZA	Phase 1a/1b Study of LY3962673 in Patients with KRAS G12D- Mutant Solid Tumor (N. Reddy)	<u>NCT06586515</u>	LY3962673	KRAS G12D-Mutant Solid Tumors NSCLC	KRAS G12D	Indy
C4 Therapeutics CFT1946-1101	A Phase 1/2 Open-Label Multicenter Trial to Characterize the Safety, Tolerability, and Preliminary Efficacy of CFT1946 as Monotherapy and Combination therapy in Subjects with BRAF- V600 Mutant Solid Tumors (Shukla)	<u>NCT05668585</u>	CFT1946	BRAF-V600 Mutant NSCLC	BRAF-V600	Indy
GV20 Therapeutics GV20-0251-100	GV20-0251-100, An Open-Label Study of GV20-0251 in Patients with Advanced and/or Refractory Solid Tumor Malignancies (O'Neil)	<u>NCT05669430</u>	IGSF8 antibody	Non-small cell lung cancer	IGSF8 and others	North and South
Lilly SUNRAY-01	SUNRAY-01, A Global Pivotal Study in Participants with KRAS G12C- Mutant, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Comparing First-Line Treatment of LY3537982 and Pembrolizumab vs Placebo and Pembrolizumab in those with PD-L1 expression ≥50% or LY3537982 and Pembrolizumab, Pemetrexed, Platinum vs Placebo and Pembrolizumab, Pemetrexed, Platinum regardless of PD-L1 Expression (N. Reddy)	<u>NCT06119581</u>	LY3537982 in combination with Pembrolizumab Pemetrexed and Platinum	KRAS G12C-Mutant, Locally Advanced or Metastatic NSCLC	KRAS G12C-Mutant	North and South

TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study (Bedano)	NCT02693535	Various	Mulitiple Myeloma, B cell NHL	Various	Indy
Pfizer C1071032	MAGNETISMM-32: A Phase 3, Open-Label Study of Elranatamab Monotherapy Versus Elotuzumab, Pomalidomide, Dexamethasone (EPd) or Pomalidomide, Bortezomib, Dexamethasone (PVd) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed/Refractory Multiple Myeloma Who Received Prior Anti- CD38 Directed Therapy (Bedano)	NCT06152575	BsABS against BCMA and CD3	Relapsed/Refractory Multiple Myeloma	Various	North for C1D1 & C1D4 (if C1D1 is not tolerated well); open @ South for all other cycles
Head and Nec	K		Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab (N. Reddy)	<u>NCT05005403</u>	ABBV-514 is a T-regs cell depleter	HNSCC	NA	Indy
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05094336</u>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1f: HNSCC	MTAP-null	North and East
GV20 Therapeutics GV20-0251-100	GV20-0251-100, An Open-Label Study of GV20-0251 in Patients with Advanced and/or Refractory Solid Tumor Malignancies (O'Neil)	<u>NCT05669430</u>	IGSF8 antibody	Squamous head and neck	IGSF8 and others	North and South
Amgen 20220127	A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 inCombination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors (O'Neil)	<u>NCT05975073</u>	Methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor	GMB	MTAP-null	Indy

C4 Therapeutics CFT1946-1101	A Phase 1/2 Open-Label Multicenter Trial to Characterize the Safety, Tolerability, and Preliminary Efficacy of CFT1946 as Monotherapy and Combination therapy in Subjects with BRAF- V600 Mutant Solid Tumors (Shukla)	<u>NCT05668585</u>	CFT1946	BRAF-V600 Mutant Anaplastic thyroid carcinoma	BRAF-V600	Indy
Seagen SGNB6A-001	A Phase 1 Study of SGN-B6A in Advanced Solid Tumors (Shukla)	NCT04389632	ADC targeting integrin beta-6	Dose expansion HNSCC	Integrin beta-6	Indy
MDA 3-D Stent 2020-1153	A randomized study of head and neck radiotherapy with or without customized 3D printed oral stents (Turchan)	<u>NCT04870762</u>	Head and Neck Radiotherapy	Head and Neck Cancers	NA	Indy (Pts must start at North for scan)
Gyn			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
Zentalis ZN-c3-005 GOG-3066	A Phase 2 Open-Label, Multicenter, Study to Evaluate Efficacy and Safety of ZN-c3 in Subjects with High-Grade Serous Ovarian, Fallopian Tube or Primary Peritoneal Cancer (DENALI) (N. Reddy)	<u>NCT05128825</u>	WEE-1 Inhibitor	Part 1b: high cyclin E1 protein expression (regardless of CCNE1 gene amp status); Part 2: <i>Cohort 2A</i> CCNE1 gene amplified, <i>Cohort 2B</i> CCNE1 non-amplified/cyclin E1 IHC- Positive, <i>Cohort 2C</i> CCNE1 non- amplified/cyclin E1 IHC- Low/Negative	CCNE1 amplification, cyclin E1 protein expression	Indy

Artios ART0380C001	A Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the ATR Kinase Inhibitor ART0380 Administered Orally as Monotherapy and in Combination to Patients with Advanced or Metastatic Solid Tumors (O'Neil)	<u>NCT04657068</u>	ART0380	Advanced or metastatic solid tumors w/ATM alterations Endometrial	ATM	North
GV20 Therapeutics GV20-0251-100	GV20-0251-100, An Open-Label Study of GV20-0251 in Patients with Advanced and/or Refractory Solid Tumor Malignancies (O'Neil)	<u>NCT05669430</u>	IGSF8 antibody	Endometrial carcinoma	IGSF8 and others	North and South
Kelun SKB264-II-06	A Multicenter, Open-label, Phase 2, Basket Study to Evaluate the Efficacy and Safety of SKB264 in Combination with Pembrolizumab in Subjects with Selected Solid Tumors (N. Reddy)	<u>NCT05642780</u>	TROP2 monoclonal antibody (mAb) of immunoglobulin (Ig)G1 class & toxin molecule KL610023	Cohort A - 2L or 3L recurrent or metastatic cervical cancer	TROP2	North
Genitourinary			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
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Gastrointestin	al		Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
Gastrointestin AbbVie M21-410	al NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab (N. Reddy)	<u>NCT05005403</u>	Study Drug MOA ABBV-514 is a T-regs cell depleter	Indication/Population Panc, Gastric/GEJ	Biomarker Target	Sites Open Indy

CG Pharma CG-745-2-08	A Phase 1b/2, Dose-escalation, Randomized, Multicenter study of Maintenance Ivaltinostat plus Capecitabine or Capecitabine Monotherapy in Patients with Metastatic Pancreatic Adenocarcinoma Whose Disease Has Not Progressed on First Line FOLFIRINOX Chemotherapy (O'Neil)	<u>NCT05249101</u>	pan-HDAC inhibitor	Metastatic Pancreatic enrolling in Phase 2 (Ivaltinostat 250 mg/m2)	NA	Indy
LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS C12C- Mutant Advanced Solid Tumors (N. Reddy)	<u>NCT04956640</u>	KRAS G12C Inhibitor	Pancreatic, CRC	KRAS G12C	Indy
TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study (Bedano)	<u>NCT02693535</u>	Various	CRC - Nivo and Ipi cohort (BRCA1 and BRCA2 mutation)	Various	Indy
AbbVie M24-311	A Phase 2, Randomized Study to Evaluate Safety, Efficacy, and Optimal Dose of ABBV-400 in Combination with Fluorouracil, Folinic Acid, and Bevacizumab in Previously Treated Subjects with Unresectable Metastatic Colorectal Cancer (O'Neil)	<u>NCT06107413</u>	c-Met targeting antibody conjugated to a potent inhibitor of Top1 payload	CRC	c-Met	North & South (East Pending)
Artios ART0380C001	A Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the ATR Kinase Inhibitor ART0380 Administered Orally as Monotherapy and in Combination to Patients with Advanced or Metastatic Solid Tumors (O'Neil)	<u>NCT04657068</u>	ART0380	Advanced or metastatic solid tumors w/ATM alterations Colorectal	ATM	North
C4 Therapeutics CFT1946-1101	A Phase 1/2 Open-Label Multicenter Trial to Characterize the Safety, Tolerability, and Preliminary Efficacy of CFT1946 as Monotherapy and Combination therapy in Subjects with BRAF- V600 Mutant Solid Tumors (Shukla)	<u>NCT05668585</u>	CFT1946	BRAF-V600 Mutant mCRC	BRAF-V600	Indy

Lilly J5J-OX-JZZA	Phase 1a/1b Study of LY3962673 in Patients with KRAS G12D- Mutant Solid Tumor (N. Reddy)	<u>NCT06586515</u>	LY3962673	KRAS G12D-Mutant Solid Tumors CRC, PDAC	KRAS G12D	Indy
Janssen 89402638GIC1001	A Phase 1 Study of JNJ-89402638 for Unresectable Metastatic Colorectal Cancer (O'Neil)	<u>NCT06663319</u>	ADC	Unresectable Metastatic CRC	GUCY2C	North Only (South & East Pending)
AbbVie M24-064	An Open Label, Randomized, Controlled, Global Phase 3 Study Comparing ABBV-400 Monotherapy to LONSURF (Trifluridine and Tipiracil) plus Bevacizumab in Subjects with c-Met Over-Expressed Refractory Metastatic Colorectal Cancer (O'Neil)	NCT06614192	ABBV-400 / ADC	c-Met Over-Expressed Refractory Metastatic Colorectal Cancer	c-Met	Indy
Melanoma			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
GV20 Therapeutics GV20-0251-100	GV20-0251-100, An Open-Label Study of GV20-0251 in Patients with Advanced and/or Refractory Solid Tumor Malignancies (O'Neil)	<u>NCT05669430</u>	IGSF8 antibody	Cutaneous melanoma	IGSF8 and others	North and South
C4 Therapeutics CFT1946-1101	A Phase 1/2 Open-Label Multicenter Trial to Characterize the Safety, Tolerability, and Preliminary Efficacy of CFT1946 as Monotherapy and Combination therapy in Subjects with BRAF- V600 Mutant Solid Tumors (Shukla)	<u>NCT05668585</u>	CFT1946	BRAF-V600 Mutant Melanoma (enrolling in Arm A 640mg BID Exploratory Expansion)	BRAF-V600	Indy