



Clinical Trials STAR July 13, 2022 - **ON HOLD**

*STAR studies are for malignancies with a limited population and opened when a specific patient has been identified. The opening process takes approximately four weeks.


Anal		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
20189 - STAR - A Phase 3 Global, Multicenter, Double-Blind Randomized Study of Carboplatin-Paclitaxel With INCMGA00012 or Placebo in Participants With Inoperable Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Anal Canal Not Previously Treated With Systemic Chemotherapy (POD1UM-303/InterAACT 2) (INCMGA 0012-303)	1st line - prior neoadjuvant or adjuvant therapy is permitted if completed > 6 months prior	N/A
Bladder		
20172 - STAR - A Phase 2 study of enfortumab vedotin (ASG-22CE) as monotherapy or in combination with other anticancer therapies for the treatment of urothelial cancer (SGN22E-002).	1st Line Locally Advanced/Metastatic	N/A
Breast		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
14059 - STAR Phase I/II trial of Ibrutinib plus Trastuzumab in HER2-amplified Metastatic Breast Cancer	2nd line/Metastatic	Her2 amplified
Colon Cancer		
19151 - STAR - A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation (849-001) <i>For all solid tumor designations with a G12C mutation.</i>	2nd line/Metastatic - Cohorts A and B, patients must have previous treatment with at least a platinum & checkpoint inhibitor therapy.	Genomic testing for KRAS if not previously performed,, KRAS G12C
20318 - STAR - A Randomized Phase 3 Study of MRTX849 in Combination with Cetuximab Versus Chemotherapy in Patients with Advanced Colorectal Cancer with KRAS G12C Mutation with Disease Progression On or After Standard First-Line Therapy (849-010)	2nd Line	KRAS G12C mutation
Esophageal Cancer/GEJ/Gastric		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
20409-STAR - A Phase 2, Multi-Center, Open-Label Study of Cinrebafusp Alfa (PRS-343) in Combination with Ramucirumab and Paclitaxel in Patients with HER2-Positive Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma and in Combination with Tucatinib in Patients with HER2 Low Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma(PRS-343-PCS_09_20)	1st or 2nd line	HER2+
20171 - STAR - A Phase 3, Multicenter, Double-Blind, Randomized Phase III Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination with Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15)CIBI308A301.	1st Line Locally Advanced/Metastatic	N/A
Head and Neck		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
STAR: Ph1 FIH CUE101 Mono/Combo w/Pembro HNSCC	Recurrent/Mets	HPV16 positive and express p16INK4A
Leukemia/Lymphoma		



Study Name, Phase, & Protocol	TX Line(s)	Biomarker
18263-STAR A Phase 2, Multicenter, Single-arm Study of Zanubrutinib (BGB-3111) in Patients with Previously Treated B-Cell Lymphoma Intolerant of Prior Treatment with Ibrutinib and/or Acalabrutinib (BGB-3111-215)	Minimum of 1 prior line of standard chemotherapy	N/A
20282 - STAR An open label, multi-center Phase IIIb study of asciminib (ABL001) monotherapy in previously treated patients with chronic myeloid leukemia in chronic phase (CML-CP) with and without T315I mutation (AIM4CML)(CABL001AUS04)	2nd line	NGS, T315I
11282 - STAR - A Phase 2 Open-Label Study of Brentuximab Vedotin in Front-Line Therapy of Hodgkin Lymphoma (HL) in Adults age 60 and Above	1st line	N/A
Lung Cancer		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
21239-STAR- A Phase 3, Open-Label, Randomized Study of Amivantamab and Lazertinib in Combination with Platinum-Based Chemotherapy Compared with Platinum-Based Chemotherapy in Patients with EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure (61186372NSC3002)	Locally advanced or metastatic 2nd or 3rd line with most recent treatment being Osimertinib	EGFR
19151 - STAR - A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation (849-001) All Sites can participate in the Ph1b & Ph2**	Treatment Naïve 2nd line	KRAS G12C KRAS G12C and STK11
21498 - STAR: Ph1/2 VS-6766 + Soto KRAS G12C NSCLC-A Phase 1/2 Study of VS-6766 in Combination with Sotorasib in Patients with KRAS G12C mutant Non-Small Cell Lung Cancer (NSCLC) (RAMP 203) (VS-6766-203)	2nd or 3rd line	KRAS G12C
20139- A Phase III, Randomised, Controlled, Multi-centre, 3-Arm Study of Neoadjuvant Osimertinib as Monotherapy or in Combination with Chemotherapy versus Standard of Care Chemotherapy Alone for the Treatment of Patients with Epidermal Growth Factor Receptor Mutation Positive, Resectable Non-small Cell Lung Cancer (NeoADAURA) (D516AC00001)	Neoadjuvant	Mutation in EGFR-TKI sensitivity (Ex19del, L858R), either alone or in combination with other EGFR mutations (ie, T790M, G719X, Exon20 insertions, S7681 and L861Q).
20249 - STAR - A Randomized, Open-label Phase 3 Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared with Carboplatin-Pemetrexed, in Patients with EGFR Exon 20ins Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer (61186372NSC3001)	2nd line or Metastatic	EGFR Exon 20ins activating mutation
20270 - STAR Ph2 MRTX849 Pembro NSCLC KRAS -- A Phase 2 Trial of MRTX849 in Combination with Pembrolizumab in Patients with Advanced Non-Small Cell Lung Cancer with KRAS G12C Mutation (849-007)	Advanced unresectable or Metastatic	KRAS G12C
20331 - STAR - A Phase 2 Study of VS-6766 (Dual RAF/MEK Inhibitor) as a Single Agent and in Combination with Defactinib (FAK Inhibitor) in Recurrent KRAS-Mutant (KRAS-MT) Non-Small Cell Lung Cancer (NSCLC)(VS-6766-202) HOLDING	Metastatic	In Part A of the study, subjects must have either a KRAS-G12V mutation or ANY other KRAS mutation (KRAS-other, including KRAS-G12C & G12D).
21219-RMC-4630-03: A Phase 2, Open-Label, Multicenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects with KRAS G12C Mutation After Failure of Prior Standard Therapies	locally advanced or metastatic KRASG12C NSCLC (not amenable to curative surgery)	KRASG12C

20412 -A Placebo-controlled Double-Blinded Randomized Phase 3 Study of Adjuvant Selpercatinib following Definitive Locoregional Treatment in Participants with Stage IB-IIIa RET fusion-Positive NSCLC (LIBRETTO-432) (J2G-MC-JZJX)	Adjuvant	Central labs for RET testing
Myelofibrosis		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
20177 - STAR - M16-191: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Navitoclax in Combination with Ruxolitinib versus Ruxolitinib in Subjects with Myelofibrosis	1st or 2nd line	N/A
20346 - STAR - A PHASE 2, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY TO EVALUATE SAFETY AND EFFICACY OF SINGLE AGENT SELINEXOR VERSUS TREATMENT OF PHYSICIAN'S CHOICE IN PATIENTS WITH PREVIOUSLY TREATED MYELOFIBROSIS (XPORT-MF-035)	2nd line	MPN Mutation Panel
Ovarian		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
20298 - STAR - A Phase 2 Study of VS-6766 (Dual RAF/MEK Inhibitor) Alone and In Combination with Defactinib (FAK Inhibitor) in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)(VS-6766-201 GOG 3052)	2nd line metastatic	Known KRAS mutation Status
Prostate		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
20138 - STAR - A Phase III Double-Blind, Randomised, Placebo-Controlled Study Assessing the Efficacy and Safety of Capiwasertib + Abiraterone Versus Placebo + Abiraterone as Treatment for Patients with De Novo Metastatic Hormone-Sensitive Prostate Cancer(mHSPC)Characterised by PTEN deficiency (CAPitello-281) D361BC00001	1st line Metastatic	PTEN mutation
20248 - STAR - A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)(67652000PCR3002)	2nd line metastatic	one of the following: BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, PALB2, RAD51B, RAD54L
Solid Tumors		
Study Name, Phase, & Protocol	TX Line(s)	Biomarker
19151 - STAR - A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation (849-001) For all solid tumor designations with a G12C mutation & limited brain mets.	Other solid tumors see Amend 9 flyer	KRAS G12C - other mutations when no other treatment options- Phas2 portion



21270-STAR - A Phase 2 Open-Label, Multicenter Study to Evaluate Efficacy and Safety of ZN-c3 in Subjects with Malignant Tumors Harboring DNA Repair and Cell Cycle Gene Alterations (ZN-c3-005 GOG 3066)	prior standard therapy appropriate for their tumor type and stage of disease, or in the opinion of the Investigator, would be unlikely to tolerate or derive clinically meaningful benefit from appropriate standard of care therapy, or no standard therapy exists for their tumor type/stage. Prior treatment with immune checkpoint inhibitors is allowed.	MRE11, RAD50, or NBN or CCNE1 amplifications
20245 - STAR - CRESTONE : A Phase 2 Study of Seribantumab in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors (ELVCAP-001-01)	2nd line	NRG1 gene fusion
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