

## ENSAYOS CLÍNICOS TUMORES DIGESTIVO

### - COLORRECTAL

#### SMS-0472B

*"A randomized, multicentre, open-label controlled phase II trial of Foxy-5 as neo-adjuvant therapy in subjects with Wnt-5a negative colon cancer"*

<https://clinicaltrials.gov/ct2/show/NCT03883802>

#### BNT 122-01

*"A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection."*

<https://clinicaltrials.gov/ct2/show/NCT04486378>

#### C4221015 (BREAKWATER)

*"an open-label, multicenter, randomized phase 3 study of first-line encorafenib plus cetuximab with or without chemotherapy versus standard of care therapy with a safety lead-in of encorafenib and cetuximab plus chemotherapy in participants with metastatic braf v600e-mutant colorectal cancer"*

<https://clinicaltrials.gov/ct2/show/NCT04607421>

#### C4221022 (SEAMARK)

*"A phase 2, randomized, open-label study of Encorafenib and Cetuximab plus Pembrolizumab versus Pembrolizumab alone in participants with previously untreated BRAF V600E-mutant, MSIH/DMMR metastatic colorectal cancer"*

<https://clinicaltrials.gov/ct2/show/NCT05217446>

#### MOUNTAINEER-03/SGNTUC-029

*"An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer"*

<https://classic.clinicaltrials.gov/ct2/show/NCT05253651>

#### NOUS-209-01

*"A Phase I/II, Multicenter, Open-Label Study of Nous-209 Genetic Vaccine for the Treatment of Microsatellite Unstable Solid Tumors"*

<https://classic.clinicaltrials.gov/ct2/show/NCT04041310>

### **TTD-21-02 (CEBBRA)**

*“Multicenter Phase 2 study to evaluate the efficacy and safety of Cetuximab in combination with Encorafenib plus Binimetinib as induction treatment in BRAF V600E mutated MSS initially resectable or potentially resectable advanced colorectal cancer”.*

<https://classic.clinicaltrials.gov/ct2/show/NCT06207656>

### **61186372GIC2002**

*“A Phase 1b/2, Open-Label Study of Amivantamab Monotherapy and in Addition to Standard-of-Care Chemotherapy in Participants with Advanced or Metastatic Colorectal Cancer”*

<https://clinicaltrials.gov/ct2/show/NCT05379595>

### **219369-AZUR1**

*“A Phase 2, Single-Arm, Open-Label Study with Dostarlimab Monotherapy in Participants with Untreated Stage II/III dMMR/MSI-H Locally Advanced Rectal Cancer”*

<https://clinicaltrials.gov/ct2/show/NCT05723562>

### **219606-AZUR2**

*“A Phase 3, Open-Label, Randomized Study of Perioperative Dostarlimab Monotherapy versus Standard of Care in Participants with Untreated T4N0 or Stage III dMMR/MSI-H Resectable Colon Cancer”*

<https://clinicaltrials.gov/study/NCT05855200>

## **- GÁSTRICO**

### **DS8201-A-U306**

*“a phase 3, multicenter, 2-arm randomized, open-label study of trastuzumab deruxtecan in subjects with her2-positive metastatic and/or unresectable gastric or gastro-esophageal junction (gej) adenocarcinoma subjects who have progressed on or after a trastuzumab-containing regimen (destiny-gastric04)”*

<https://clinicaltrials.gov/ct2/show/NCT04704934>

### **D7986C00001- GEMINI**

*"Novel combinations in participants with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma"*

<https://clinicaltrials.gov/study/NCT05702229>

### **- ESÓGAFO**

#### **MK7902-014**

*"A Phase 3, Randomized Study to Evaluate the Efficacy and Safety of Pembrolizumab (MK-3475) + Lenvatinib (E7080/MK-7902) + Chemotherapy Compared with Standard of Care as First-line Intervention in Participants with Metastatic Esophageal Carcinoma"*

<https://clinicaltrials.gov/ct2/show/NCT04949256>

### **- VIA BILIAR**

#### **INCB 54828-302**

*"A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement"*

<https://clinicaltrials.gov/ct2/show/NCT03656536>

#### **TAS-120-205**

*"Phase 2 Study of Futibatinib 20 mg and 16 mg in Patients with Advanced Cholangiocarcinoma with FGFR2 Fusions or Rearrangements"*

<https://clinicaltrials.gov/study/NCT05727176>

#### **TT420C2308**

*"A Phase III, Randomized, Controlled, Global Multicenter Study to Evaluate the Efficacy and Safety of Oral Tinengotinib versus Physician's Choice in Subjects with Fibroblast Growth Factor Receptor (FGFR)-altered, Chemotherapy- and FGFR Inhibitor-Refractory/Relapsed Cholangiocarcinoma (FIRST-308)"*

<https://classic.clinicaltrials.gov/ct2/show/NCT05948475>

## - **PÁNCREAS**

### **CCL-SBP-101-04**

*"A Randomized, Double-Blind, Placebo-Controlled Study of Nab-Paclitaxel and Gemcitabine With Or Without SBP-101 in Subjects Previously Untreated for Metastatic Pancreatic Ductal Adenocarcinoma"*

<https://clinicaltrials.gov/ct2/show/NCT05254171>

### **TRIPP-FFX**

*"An open-label, multi-centre, randomized study of TaRgeted Intratumoural Placement of Phosphorous-32 (OncoSil™) in addition to FOLFIRINOX chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable locally advanced pancreatic adenocarcinoma"*

<https://clinicaltrials.gov/ct2/show/NCT05466799>

### **P-VCNA-003**

*"A Phase IIb, Open-label, Randomized Study of NabPaclitaxel and Gemcitabine plus/minus VCN-01 in Patients with Metastatic Pancreatic Cancer (VIRAGE)"*

<https://clinicaltrials.gov/ct2/show/NCT05673811>

### **TTD-20-04**

*"Olaparib and durvalumab (MEDI4736) in patients with metastatic pancreatic cancer and DNA Damage Repair genes alterations"*

<https://clinicaltrials.gov/ct2/show/NCT05659914>

### **EF-39 PANOVA-4**

*"EF-39: Pilot, single arm study of Tumor Treating Fields (TTFields, 150kHz) concomitant with atezolizumab, gemcitabine and nab-paclitaxel as first-line treatment for metastatic pancreatic ductal adenocarcinoma (mPDAC)"*

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2022-003157-55/ES>

## **NEUROENDOCRINO**

### **COMPOSE**

*“Lutetium 177Lu-Edotreotide Versus Best Standard of Care in Well-differentiated Aggressive Grade-2 and Grade-3 GastroEnteroPancreatic NeuroEndocrine Tumors (GEP-NETs) - COMPOSE (COMPOSE)”*

<https://classic.clinicaltrials.gov/ct2/show/NCT04919226>

## **TROMBOSIS**

### **ANT-007 (ASTER)**

*“A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to apixaban on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE”*

<https://clinicaltrials.gov/ct2/show/NCT05171049>

### **ANT-008 (MAGNOLIA)**

*“A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE”*

<https://clinicaltrials.gov/ct2/show/NCT05171075>