

## ENSAYOS CLÍNICOS FASE I

### - TUMORES SÓLIDOS

#### **MK6482-016**

*“Estudio de fase 2, abierto y multicéntrico para evaluar la eficacia y la seguridad de pembrolizumab más lenvatinib en combinación con belzutifán en diversos tumores sólidos”*

<https://clinicaltrials.gov/ct2/show/NCT04976634>

#### **PM1183-A-017-20**

*“An Open-Label, Multicenter, Pharmacokinetic Study of Lurbinectedin in Patients with Advanced Solid Tumors and Varying Degrees of Hepatic Impairment”*

<https://clinicaltrials.gov/ct2/show/NCT05101265>

#### **IOV-COM-202**

*“A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN-144 or LN-145) in Patients with Solid Tumors”*

<https://clinicaltrials.gov/ct2/show/NCT03645928?term=IOV-COM-202&rank=1>

#### **CL1-95012-001**

*“A FIRST IN HUMAN PHASE 1/2 OPEN-LABEL, MULTICENTER, DOSE ESCALATION AND EXPANSION STUDY OF SINGLE-AGENT PRS-344/S095012 IN PATIENTS WITH SOLID TUMORS”*

<https://clinicaltrials.gov/ct2/show/NCT05159388>

#### **PM14-A-001-17**

*“Estudio Clínico y Farmacocinético Fase I, Abierto, de Escalada de Dosis de PM14 Administrado por Vía Intravenosa a Pacientes con Tumores Sólidos Avanzados”*

<https://clinicaltrials.gov/ct2/show/NCT05076396>

#### **PM14-A-003-20**

*“Phase Ib Study to Assess the Safety, Tolerability and Efficacy of PM14 in combination with Atezolizumab in Pretreated Patients with Selected Advanced Solid Tumors”*

[Link no disponible](#)

#### **DS8201-A-U106**

*A Phase 1b, multicenter, two-part, open-label study of trastuzumab deruxtecan, an anti-human epidermal growth factor receptor-2 (HER2)-antibody drug conjugate (ADC), in combination with pembrolizumab, an anti-PD-1 antibody, in subjects with locally advanced/metastatic breast or non-small cell lung cancer (NSCLC)*

<https://clinicaltrials.gov/ct2/show/NCT04042701>

#### **LOX-TRK-15002 (BAY2757556/20289)**

*"Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors. (Melanoma, Pulmón, Mama no secretor y Colorectal)"*

<https://clinicaltrials.gov/ct2/show/NCT02576431>

#### **NUVALENT NVL-520-01**

*"A Phase 1/2 Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)"*

<https://clinicaltrials.gov/ct2/show/NCT05118789>

#### **Jacobio JAB21822-1001**

*"A Phase 1/2, Multi-Center, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Evidence of Antitumor Activity of JAB-21822 Monotherapy and Combination Therapy in Adult Patients with Advanced Solid Tumors Harboring KRAS G12C Mutation"*

<https://clinicaltrials.gov/ct2/show/NCT05002270>

#### **- E7386-G000-201**

*"An Open-Label, multicenter, phase 1b/2 study of E7386 in combination with pembrolizumab in previously treated subjects with selected solid tumors"*

#### **KIN-8701**

*"A Phase 1/1b Open-Label, Multicenter, Two-Part Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Antitumor Activity of KIN-2787 in Subjects with BRAF Mutation Positive Solid Tumors Chemotherapy"*

<https://www.clinicaltrials.gov/ct2/show/NCT04913285>

#### **E7386-G000-201**

*"An Open-Label, multicenter, phase 1b/2 study of E7386 in combination with pembrolizumab in previously treated subjects with selected solid tumors"*

<https://clinicaltrials.gov/ct2/show/NCT05091346>

### **CTNO122X2101**

*"An open-label, multi-center, phase I, dose finding study of oral TNO155 in adult patients with advanced solid tumors"*

<https://clinicaltrials.gov/ct2/show/NCT03114319>

### **GS-US-548-5918**

*"Study of Magrolimab in Participants With Solid Tumors"*

<https://clinicaltrials.gov/ct2/show/NCT04827576>

### **XL092-001**

*"A Phase 1 Study in Subjects with Inoperable Locally Advanced or Metastatic Solid Tumors"*

<https://clinicaltrials.gov/ct2/show/NCT03845166?term=XL092&draw=2&rank=1>

### **GCT1042-01**

*"This is an open-label, multicenter phase 1/2 study designed to assess the safety, pharmacokinetics, pharmacodynamics and activity of GEN1042 administered as a monotherapy or in combination in subjects with metastatic or locally advanced solid tumors"*

<https://clinicaltrials.gov/ct2/show/NCT04083599?term=GCT1042&draw=2&rank=2>

### **XL092-001**

*"A Phase 1 Study in Subjects with Inoperable Locally Advanced or Metastatic Solid Tumors"*

<https://clinicaltrials.gov/ct2/show/NCT03845166?term=XL092&draw=2&rank=1>

### **EC VB-N02**

*"A PHASE 1B, OPEN-LABEL, DOSE-ESCALATION TRIAL OF THE SAFETY OF AND ANTIGEN-SPECIFIC IMMUNE RESPONSES ELICITED BY VB10.NEO IN COMBINATION WITH ATEZOLIZUMAB IN SUBJECTS WITH LOCALLY ADVANCED AND METASTATIC TUMORS"*

<https://clinicaltrials.gov/ct2/show/NCT05018273?term=VB-N02&draw=2&rank=1>

### **- SARCOMAS**

#### **TRASTS**

*"Ensayo Clínico Fase I-II abierto, prospectivo y multicéntrico, que explora la combinación de trabectedina y radioterapia en pacientes con sarcoma de tejidos blandos"*

<https://clinicaltrials.gov/ct2/show/NCT02275286?term=TRASTS&rank=1>

### **CEB-01-RLS01-CT**

*"First-in-man clinical trial to assess safety and tolerability of CEB-01 PLGA membrane in patients with recurrent or locally advanced retroperitoneal soft tissue sarcoma after surgery"*

<https://clinicaltrials.gov/ct2/show/NCT04619056>

### **- PULMON**

#### **CAAA601A42101**

*"A Safety Study of [177Lu]Lu-DOTA-TATE in Newly Diagnosed Extensive Stage Small Cell Lung Cancer (ES-SCLC) Patients in Combination With Carboplatin, Etoposide and Tislelizumab"*

<https://clinicaltrials.gov/ct2/show/NCT05142696>

#### **IOR-TPT-IST-002-TOTEM**

*Phase I Clinical Study to Assess Safety and Efficacy of Repotrectinib Combined with Osimertinib in Patients with Advanced, Metastatic E GFR M utant N SCLC (TOTEM)*

<https://clinicaltrials.gov/ct2/show/NCT04772235>

#### **BI1479-0001**

*1479-0001: "An open label, Phase I dose escalation trial, with dose confirmation and expansion, of BI 1810631 as monotherapy in patients with advanced or metastatic solid tumors with HER2 aberrations"*

<https://clinicaltrials.gov/ct2/show/NCT04886804>

### **- GÁSTRICO**

#### **DESTINY-GASTRIC03 (cerrado temporalmente)**

*"A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (DS-8201a) Monotherapy and combinations in Adult Participants with HER-2 Overexpressing Gastric Cancer"*

<https://clinicaltrials.gov/ct2/show/NCT04379596>

### **-C.COLORRECTAL**

#### **ORIGAMI (61186372GIC2002)**

*"Estudio en fase Ib/II abierto de Amivantamab en monoterapia y añadido a la quimioterapia de referencia en pacientes con cáncer colorrectal avanzado o metastásico"*

<https://clinicaltrials.gov/ct2/show/NCT0537959>

- PÁNCREAS

**WO39608**

*“Estudio en paraguas de fase Ib/II, sin enmascaramiento, multicéntrico y aleatorizado para evaluar la eficacia y la seguridad de combinaciones de tratamientos basados en múltiples inmunoterapias en pacientes con adenocarcinoma ductal pancreático metastásico (morphéus-cáncer pancreático)”*

<https://clinicaltrials.gov/ct2/show/NCT03193190?term=WO39608&rank=1>

**D-FR-60010-015 SIRACUSA**

*“A Phase I, Randomised, Open-Label, Single-Dose, Two-Treatment, Two-Way Crossover, Two-Stage Study to Evaluate the Bioequivalence of Onivyde (Irinotecan Liposome Injection) Manufactured at Two Different Sites Administered in Combination with Anti-Cancer Agents in Adult Participants with Metastatic Pancreatic Adenocarcinoma”*

<https://clinicaltrials.gov/ct2/show/NCT05383352>

-HEPATOCARCINOMA

**MIV-818-101**

*A Phase 1/2a Study in 3 Parts (Phase 1a and Phase 1b - Dose Escalations and Phase 2a Expansion Cohorts) to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of MIV-818 in Patients with Liver Cancer Manifestations*

<https://clinicaltrials.gov/ct2/show/NCT03781934>

MELANOMA

**SRP21C101**

*“An Open Label, Multicentre, Phase 1 Study Evaluating the Safety and Pharmacokinetics of ADU-1604 in Adults with Advanced Melanoma (SRP-21C101)”*

<https://www.clinicaltrials.gov/ct2/show/NCT03674502?term=ADU-1604&cntry=ES&city=Madrid&draw=2&rank=1>

-CARCINOMA DE CÉLULAS DE MERKEL

**STUDY KRT-232-103**

*A Phase 2, Open-Label Study Evaluating the Safety and Efficacy of KRT-232 in Patients with p53 Wild-Type (p53WT) Merkel Cell Carcinoma (MCC) Who Have Failed Anti-PD-1 or Anti-PD-L1 Immunotherapy, or in Combination with Avelumab in MCC Patients who are Anti-PD-1 or Anti-PD-L1 Treatment Naïve*

<https://clinicaltrials.gov/ct2/show/NCT03787602>