

## 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>

#### **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](#)

#### **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>

#### **KN-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>

### **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>

### **LOXO-PIK-21001 (PIKASSO)**

*"A Study of LOXO 783 Administered as Monotherapy and in Combination with Anticancer Therapies for Patients with Advanced Breast Cancer and Other Solid Tumors with a PIK3CAH1047R Mutation"*

<https://classic.clinicaltrials.gov/ct2/show/NCT05307705>

### **XB002-001**

*"A Dose-Escalation and Expansion Study of the Safety and Pharmacokinetics of XB002 as Single Agent and Combination Therapy in Subjects with Inoperable Locally Advanced or Metastatic Solid Tumors"*

<https://classic.clinicaltrials.gov/ct2/show/NCT04925284>

### **-CHRO761A12101**

*"Study of HRO761 alone or in combination in cancer patients with specific DNA alterations called Microsatellite Instability – High or Mismatch Repair Deficiency"*

<https://classic.clinicaltrials.gov/ct2/show/NCT05838768>

### **- NVL-655-01**

A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)

<https://classic.clinicaltrials.gov/ct2/show/NCT05384626>

### **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*

<https://clinicaltrials.gov/ct2/show/NCT04657068?term=ART0380&draw=2&rank=1>

### **- M21-404**

*“Estudio de fase 1, de primera administración en el ser humano, para evaluar la seguridad, la farmacocinética y la eficacia de ABBV-400, en monoterapia y en combinación con bevacizumab, en sujetos adultos con tumores sólidos avanzados”*

<https://classic.clinicaltrials.gov/ct2/show/NCT05029882>

#### - 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>

#### - 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 EGFR Mutant NSCLC (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>

##### **BO44426**

*A Phase Ib/II, Open-Label, Multicenter Study Evaluating the Safety, Activity, and Pharmacokinetics of GDC-6036 in Combination With Other Anti-Cancer Therapies in Patients With Previously Untreated Advanced Or Metastatic Non-Small Cell Lung Cancer With a KRAS G12C Mutation*

<https://classic.clinicaltrials.gov/ct2/show/NCT05789082>

### **73841937NSC1001**

*“Estudio Fase I/Ib abierto para evaluar la seguridad y farmacocinética de JNJ- 73841937 (lazertinib), un inhibidor de la tirosinaquinasa del EGFR (TKI-EGFR) de tercera generación, en monoterapia o en combinación con JNJ-61186372, un anticuerpo humano biespecífico frente a EGFR y cMet, en pacientes con cáncer de pulmón no microcítico avanzado”*

<https://clinicaltrials.gov/ct2/show/NCT04077463>

### **- 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**

#### **OMO-103 -02**

*“A Phase 1b Study to evaluate the Safety, Pharmacokinetics, and Anti-Tumour Activity of the Myc Inhibitor OMO-103 administered intravenously in combination with different drugs in Patients with advanced Solid Tumors”*

[https://www.ejancer.com/article/S0959-8049\(22\)00820-6/fulltext](https://www.ejancer.com/article/S0959-8049(22)00820-6/fulltext)

### **C.MAMA**

#### **ELEVATE PROTOCOL STML-ELA-0222 -**

*A Phase 1b/2, Open-Label Umbrella Study to Evaluate Safety and Efficacy of Elacestrant in Various Combinations in Patients with Metastatic Breast Cancer (ELEVATE)*

<https://classic.clinicaltrials.gov/ct2/show/NCT05563220>

### **C4891023**

*TACTIVE-U: an interventional safety and efficacy phase 1b/2, openlabel umbrella study to investigate tolerability, pk, and antitumor activity of arv-471 (pf-07850327), an oral proteolysis targeting chimera, in combination with other anticancer treatments in participants aged 18 years and over with er+ advanced or metastatic breast cancer: substudy a-c4891006 (arv-471 in combination with abemaciclib) and sub-study bc4891023 (arv-471 in combination with ribociclib)*

<https://classic.clinicaltrials.gov/ct2/show/NCT05548127>

<https://classic.clinicaltrials.gov/ct2/show/NCT05573555>

### **- PRÓSTATA**

### **CELC-G-201**

*A Phase 1/2, Open-Label, Dose Escalation and Dose Expansion Study of Gedatolisib in Combination with Darolutamide in Metastatic Castration-Resistant Prostate Cancer (mCRPC)*

<https://classic.clinicaltrials.gov/ct2/show/NCT06190899>

### **GLIOBLASTOMA**

### **CAAA603C12101**

*"Phase 1b Dose Finding Study Assessing Safety and Activity of [177Lu]Lu-NeoB in Combination with Radiotherapy and Temozolomide in Subjects with Newly Diagnosed Glioblastoma with MGMT methylated and unmethylated promoter status."*

<https://classic.clinicaltrials.gov/ct2/show/NCT05739942>