

## 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>

#### 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>

#### 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>

### **-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>

### **-SRP-22C102- Sairopa**

*An Open-Label, Multicenter, Multi-Arm Phase 1 Study Evaluating the Safety and Pharmacokinetics of ADU-1805 in Adults with Advanced Solid Tumors*

### **- 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>

### **-M24-427**

*“A Phase 1 Open-Label Study to Evaluate the Efficacy and Safety of ABBV-400 in Select Advanced Solid Tumor Indications”*

<https://clinicaltrials.gov/study/NCT06084481>

### **-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 Tumour*

### **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/study/NCT04042701>

### **-HERTHENA-PanTumor01 (U31402-277)**

*A Phase 2, Multicenter, Multicohort, Open-Label, Proof of Concept Study of Patritumab Deruxtecan (HER3-DXd; U3-1402) in Subjects With Locally Advanced or Metastatic Solid Tumors*

<https://clinicaltrials.gov/study/NCT06172478>

### **- 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 E GFR M utant N SCLC (TOTEM)*

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

#### **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>

#### **-SPLFIO-174**

*“A phase1b/2, multicenter, open label platform study of select immunotherapy combinations in adult participants with previously untreated advanced non-small cell lung cancer (NSCLC) with high PD-L1 expression”*

<https://clinicaltrials.gov/study/NCT06162572>

#### **-DEBIO0123-SCLC-104**

*“A Phase 1 dose-escalation and expansion study to assess safety and preliminary antitumor activity of **Debio 0123** in combination with carboplatin and etoposide in adult participants with small cell lung cancer that recurred or progressed after previous standard platinum-based therapy”*

<https://clinicaltrials.gov/study/NCT05815160>

#### **- 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>

#### **-CL1-95029-002**

*Phase 1b/2 trial of S095029 in combination therapy in participants with advanced MSI-H/dMMR gastroesophageal junction/gastric cancer”*

<https://clinicaltrials.gov/study/NCT06116136>

## -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)

### **-20230223**

*"A Phase 1B/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG193 Alone or in Combination With Other Therapies in Subjects With Advanced Gastrointestinal, Biliary Tract or Pancreatic Cancers With Homozygous MTAP Deletion"* Fase Ib: Gastrointestinal, Biliar y Páncreas.

## 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/NCT05573555>

## GLIOBLASTOMA

### **CAAA603C12101**



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*“Phase Ib 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>

### **-CT- P51 1.1**

*“A Double-Blind, Randomized, Three-arm, Active-Controlled, Parallel-Group, Phase 1 Study Evaluating Pharmacokinetic Similarity of Three Formulations of Pembrolizumab (CT-P51, EU-Approved Keytruda, and US-licensed Keytruda) as Adjuvant Therapy in Patients with Completely Resected Stage IIB, IIC, and III Melanoma”*