Ensayos Clínicos Cabeza y Cuello abiertos a reclutamiento en España (Actualizado agosto_2025)
Información Pública obtenida a partir de: Clinical trials.gov; EU Clinical Trials Register; REEC (AEMPS)

EuCT number	NCT	STUDY-Code	TITLE	PHASE	INDICATION	STATUS	DRUGS	SITES	SPONSOR	
2024-516779-33-00	5784012	TTCC-2022-01 RADIAN	Phase Ib/II Non-randomized Non-comparative Two-cohort Study of Niraparib and Dostarlimab Plus (Chemo) Radlotherapy in LocallyAdvanced; Head and Neck Squamous Cell Carcinoma **(RADIAN)**	**Phase 1b/II**	Multi-center, open-label, non-randomized, non-comparative two-cohort study for patients with **locally-advanced** squamous cell carcinoma arising from the larynx, hypopharynx, oropharynx (Stage III, IVA and IVB according to 8th TNM/AJCC ed.) and oral cavity (unresectable, stage IVB according to 8th TNM/ American Joint Committee on Cancer (AJCC). **Recruiting Cohort B**	**RECRUITING**	Dostarlimab Niraparib Radiation Therapy	ICO Hospitalet H.U. Clínic (BCN) ICO Badalona H.U. Vall d´Hebron (BCN) C.H. Navarra (Pamplona) H. Clinico de Valencia H. 12 de Octubre	**Grupo Español de Tratamiento de Tumores de Cabeza y Cuello (TTCC)**	
2024-514953-31-00	6856213	TTCC-2022-02 ERBIOTAX	TTCC-2022-02: a Phase II, Multicenter, Randomized Study of Cetuximab Plus/ Minus Weekly Paclitaxel **After Progression to First-Line Pembrolizumab Plus Platinum-5FU** in Subjects with Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck **(ERBIOTAX)**	**Phase II**	The study aims to evaluate the efficacy of weekly cetuximab combined with paclitaxel (Arm A) or cetuximab monotherapy (Arm B) after progression to pembrolizumab plus platinum / 5-FU. The efficacy of treatment will be assessed through objective response rate (ORR).	**RECRUITING**	Cetuximab Paclitaxel	H.U. Clinico San Carlos(Madrid) ICO-Hospitalet H.U. 12 Octubre H.U. Infanta Leonor(Madrid) H.U.M. Valdecilla(Santander) H.U. Navarra C.O. Galicia H.U.Virgen Valme(Sevilla) H.U.Virgen Rocio(Sevilla) H.U. Canarias (Tenerife) C.H. Salamanca	**Grupo Español de Tratamiento de Tumores de Cabeza y Cuello (TTCC)**	
LOCALLY-ADVANCED H&N										
2023-508613-17-00	6256588	221530	A Study of Dostarlimab vs Placebo After Chemoradiation in Adult Participants With Locally Advanced Unresected Head and Neck Squamous Cell Carcinoma **(JADE)**	**Phase III**	A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Evaluate Dostarlimab as Sequential Therapy After Chemoradiation in Participants With Locally Advanced Unresected Head and Neck Squamous Cell Carcinoma.	RECRUITING	Dostarlimab Placebo	H.U.Marques Valdecilla (Santander) C.H. Navarra C.H. Salamanca H. U. Miguel Servet (Zaragoza) H. Lucus Augusti (Lugo) H.U. Cruces (Bilbao) H. U. 12 Octubre (Madrid) H.U.La Paz (Madrid) H. Clinico San Carlos (Madrid) H.U. Jerez de la Frontera (Cadiz) ICO-Hospitalet H. Vall d Hebron(BCN)	GlaxoSmithKline	
2023-506294-36-00	6129864	D798EC00001	A Phase III, Randomized, Open-Label, Multi-Center, Global Study of Volrustomig (MEDI5752) as Sequential Therapy Versus Observation in Participants With Unresected LocallyAdvanced (Head and Neck Squamous Cell Carcinoma), Who Have Not Progressed Following Definitive Concurrent Chemoradiotherapy **(eVOLVE-HNSCC)**	**Phase III**	The main purpose of this study is to assess the efficacy and safety of volrustomig compared to observation in participants with unresected locally advanced head and neck squamous cell carcinoma (LA-HNSCC) who have not progressed after receiving definitive concurrent chemoradiotherapy (cCRT)	RECRUITING	Volrustomig	ICO Badalona H. Vall d Hebron(BCN) H. Clinic (BCN) H. Clinico San Carlos (Madrid) H.U.Ramon y Cajal (Madrid) H. General Valencia H. U. La Fe (Valencia) H. U. Gregorio Marañon (Madrid) H. U. Jaen	AstraZeneca	

2024-520386-31-00	4892173	NANORAY-312	A Phase 3 Study of NBTXR3 Activated by Investigator's Choice of Radiotherapy Alone or Radiotherapy in Combination With Cetuximab for Platinum-based Chemotherapy-Ineligible Elderly Patients With LA-HNSCC	**Phase III**	This is a global, open-label, randomized, 2-arm, Investigator's choice Phase 3 (Pivotal Stage) study to investigate the efficacy/performance and safety of NBTXR3/RT±cetuximab versus RT±cetuximab in treatment-naïve, platinum-ineligible, elderly participants with LA-HNSCC.	RECRUITING	JNJ-90301900 (NBTXR3) Cetuximab Radiation Therapy	H.U.Cruces(Bilbao) C.Hospitalario Navarra H.U.M. Valdecilla(Santander) H. Clínic (BCN) H.U. 12 Octubre (Madrid) H.U. Vall d Hebron(BCN) ICO Hospitalet H.U. Lucus Augusti(Lugo) F.Jimenez Diaz(Madrid) H.Sanchinarro(Madrid) H.Regional Malaga H.U. Virgen del Rocio(Sevilla) I.Valenciano de Oncologia H.General Valencia	Johnson & Johnson Enterprise Innovation Inc.	
2022-502787-20-00	5280314	MK-3475-E40	Phase II, Multi-cohort Trial of Neoadjuvant and Post-surgery IO102-IO103 and Pembrolizumab in Patients With Selected Resectable Tumors in Squamous Cell Carcinoma of Head and Neck.	**Phase II**	This is a multicenter, multi-arm trial evaluating anti-tumor activity, safety, and immune infiltration of IO102-IO103 in combination with pembrolizumab as neoadjuvant and post-surgery treatment. This proof-of-concept trial will include patients with resectable tumors in at least 2 indications.	RECRUITING	IO102-IO103 Pembrolizumab	H. Clinico Valencia H. Ramon y Cajal (Madrid) H. Quirón Dexeus (BCN) ICO-Badalona	IO Biotech	
RECURRENT-METASTATIC H&N										
2023-510323-30-00	6525220	MCLA-158-CL03	This is Phase 3 randomized, open-label study to evaluate the efficacy and safety of petosemtamab plus pembrolizumab vs pembrolizumab in **first-line treatment** of recurrent or metastatic PD-L1+ head and neck squamous cell carcinoma.	**Phase III**	Previous treatments with anti PD-(L)1 or anti-EGFR therapies are not allowed. In the case of cetuximab, patients who have received cetuximab with radiotherapy as a local treatment and PD was >1 year after the last dose of cetuximab are eligible.	RECRUITING	Petosemtamab Pembrolizumab	3 sites Madrid 2 sites Barcelona Marbella Valencia C.H. Pamplona CUN	Merus N.V.	
2023-506308-24-00	6082167	XL092-305	A Phase 2/3, Randomized, Double-Blind, Controlled Study of Zanzalintinib (XL092) in Combination With Pembrolizumab vs Pembrolizumab in **First-Line Treatment of Subjects With PD-L1 Positive** Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma **(STELLAR-305)**	**Phase II/III**	This is a multicenter, randomized, double-blind, controlled Phase 2/3 trial of zanzalintinib in combination with pembrolizumab versus zanzalintinib-matched placebo in combination with pembrolizumab in subjects with PD-L1 positive recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) incurable by local therapies who have not received prior systemic therapy for recurrent or metastatic disease.	RECRUITING	Zanzalintinib Zanzalintinib-matched Placebo Pembrolizumab	5 Sites Madrid 1 Site BCN ICO-Girona 1 Site Coruña 1 Site Pamplona 1 Site Sevilla 1 Site Zaragoza 1 Site Valencia	Exelixis	
2024-515538-34-00	6295731	INBRX106-01-201	A Phase 2/3, Randomized Study of INBRX-106 Combined With Pembrolizumab Versus Pembrolizumab **as First Line Treatment** for Patients With Recurrent or Metastatic (R/M) Head and Neck Squamous Cell Carcinoma (HNSCC) Expressing PD-L1 (CPS ≥20) (HexAgon-HN)	**Phase II/III**	This seamless phase 2/3 randomized controlled study will evaluate the efficacy and safety of the hexavalent OX40 agonist antibody INBRX-106 combined with the anti-PD-1 antibody pembrolizumab versus pembrolizumab (+ placebo in phase 3) as first-line treatment for patients with locally advanced recurrent or metastatic head and neck squamous cell carcinoma (R/M HSNSCC) incurable by local therapies, expressing PD-L1 with a combined proportion score (CPS) ≥20.	RECRUITING	INBRX-106 Pembrolizumab	H.Quiron Salud Barcelona	Inhibrx Biosciences, Inc	
2023-503428-24-00	6062420	219885	A Platform Study of Novel Immunotherapy Combinations **as First-Line Treatment** in Participants With PD-L1 Positive Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck- **GALAXIES H&N-202**	**Phase II**	The primary purpose of the study is to evaluate the antitumor activity and safety of novel immunotherapy combinations compared with dostarlimab in participants with Programmed death ligand 1 (PD-L1) positive Recurrent/Metastatic (R/M) Head and Neck Squamous Cell Carcinoma (HNSCC).	RECRUITING	Dostarlimab Belrestotug Nelistotug GSK4381562	H. Ramon y Cajal (Madrid) H. 12 Octubre (Madrid) ICO-Hospitalet H.U. Jaen H. Puerta de Hierro (Madrid) C.H. Salamanca H.Miguel Servet (Zaragoza) H. Quirón-Madrid & Barcelona H. Vall d'Hebron(BCN) H.U.M.Valdecilla(Santander) H. Clinico San Carlos (Madrid) I.Valenciano de oncologia H. La Milagrosa (Madrid)	GlaxoSmithKline	

2024-512671-12-00	4534205	BNT113-01	An Open Label Phase II Randomized Trial of BNT113 in Combination With Pembrolizumab Versus Pembrolizumab Monotherapy **as a First Line** Therapy in Patients With Unresectable Recurrent, or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) Which is **Positive for Human Papilloma Virus 16 (HPV16+)** and Expresses PD-L1 **(AHEAD-MERIT)**	**Phase II**	A Clinical Trial Investigating the Safety, Tolerability, and Therapeutic Effects of BNT113 in Combination With Pembrolizumab Versus Pembrolizumab Alone for Patients With a Form of Head and Neck Cancer Positive for Human Papilloma Virus 16 and Expressing the Protein PD-L1 (AHEAD-MERIT)	RECRUITING	BNT113 Pembrolizumab	H.U. Clínic (BCN) H.U. La Paz (Madrid) H.U. Puerta de Hierro (Madrid) C.H. Jaén C.U.N ICO Girona H. Regional de Málaga H.U. Son Espases (P.Mallorca) Start_F.J.Díaz (Madrid) H.La Fe (Valencia) H.Miguel Servet (Zaragoza)	BioNTech SE	
2024-517091-38-00	6806852	1501-0002	A Phase Ib Open Label Randomised Clinical Trial to Evaluate Safety and Efficacy of BI 770371 in Combination With Pembrolizumab With or Without Cetuximab Compared With Pembrolizumab Monotherapy **for the First-line Treatment** of Patients With Metastatic or Recurrent Head and Neck Squamous Cell Carcinoma (HNSCC)	**Phase Ib**	Participants are put into 3 groups randomly. Each group receives a different combination of study medicines. All study medicines are given as an infusion into a vein at the study site.	RECRUITING	BI 770371 Pembrolizumab Cetuximab	H.U. Vall d' Hebron H. U. Virgen Victoria (Malaga) H. Clinico Valencia	Boehringer Ingelheim	
2023-510307-22-00	4958239	1463-0001	An Open Label, Phase I Dose-finding and Expansion Study of BI 765179 as Monotherapy and in Combination With Ezabenlimab (BI 754091) in Patients With Advanced Solid Cancers, and BI 765179 in Combination With Pembrolizumab **in First-line PD-L1-positive** Metastatic or Incurable, Recurrent Head and Neck Squamous Cell Carcinoma (HNSCC)	**Phase I**	Participants can stay in the study up to 3 years (Part 1) or 2 years (Part 2) if they benefit from treatment and can tolerate it. The doctors regularly check the participants' health and note any health problems that could have been caused by the study treatment.	RECRUITING	BI 765179 Ezabenlimab Pembrolizumab	H.Clinico San Carlos (Madrid) H. Vall d Hebron (BCN) ICO-Badalona CUN	Boehringer Ingelheim	
2023-505606-42-00	6064877	AV-299-23-301	A Multicenter, Randomized, Double Blind, Placebo - Controlled, Phase 3 Study of Ficlatuzumab in Combination With Cetuximab in Participants With Recurrent or Metastatic (R/M) **HPV -Negative** Head and Neck Squamous Cell Carcinoma. **(FIERCE-HN)**	**Phase III**	The purpose of this study is to compare the efficacy and safety of ficlatuzumab plus cetuximab compared to placebo plus cetuximab in participants with recurrent/metastatic (R/M) HPV-negative Head and Neck Cancer. **Exclusion Criteria:** Participants who have received **> 2 prior lines of anticancer therapy.**	RECRUITING	Ficlatuzumab Cetuximab Placebo	H.U.Vinalopo(Alicante) H. Clinico Valencia H. M. Valdecilla H.U. La Paz H.U. Vall d'Hebron ICO-Hospitalet ICO-Badalona H.Torrejon(Madrid) H.Quiron(Malaga) H.Sanchinarro H.U.Jerez Frontera(Cadiz)	AVEO Pharmaceuticals, Inc.	
2023-504478-39-00	5815927	EORTC-2014-HNCG	Pembrolizumab and Radiotherapy for Oligometastatic Head and Neck Cancer (PROLoNg)	**Phase III**	This is a randomized open-label multicentre phase III superiority study of the effect of adding SABR to the standard of care treatment pembrolizumab on progression free survival in patients with oligometastases of a squamous cell carcinoma of the head and neck (SCCHN), histological confirmation of the primary disease at first diagnosis, and PD-L1 CPS ≥1	RECRUITING	Pembrolizumab **Radiation:** stereotattic ablation radiotherapy (SABR)	H. Clinico San Carlos H. Ramón y Cajal H. Dr. Negrin (Gran Canaria) ICO-Hospitalet H. Vall d'Hebron	European Organisation for Research and Treatment of Cancer - EORTC	
2023-510322-32-00	6496178	MCLA-158-CL02	A Phase 3 Study to Evaluate Petosemtamab Compared With Investigator's Choice Monotherapy in Previously Treated Head and Neck Squamous Cell Carcinoma Patients	**Phase III**	This is a phase 3 open-label, randomized, controlled, multicenter study to compare petosemtamab vs investigator's choice monotherapy in HNSCC **patients for the second- and third-line treatment** of incurable metastatic/recurrent disease.	RECRUITING	Petosemtamab Investigator's Choice	3 sites Madrid Barcelona Valencia C.H. Pamplona CUN	Merus N.V.	
2023-508418-40-00	6385080	61186372HNC2002	A Study of Amivantamab Alone or in Addition to Other Treatment Agents in Participants With Recurrent/Metastatic Head and Neck Cancer **(OrigAMI-4)**	**Phase II**	The purpose of this study is to determine safety and preliminary efficacy of amivantamab monotherapy, amivantamab in addition to pembrolizumab, and amivantamab in addition to paclitaxel in participants with recurrent/metastatic head and neck cancer. The study will also confirm the recommended Phase 2 combination dose (RP2CD) for amivantamab in addition to paclitaxel.	RECRUITING	Amivantamab Pembrolizumab Paclitaxel Carboplatine	H.12 Octubre H. Ramon y Cajal ICO - Hospitalet H. Vall d'Hebron	Janssen Research & Development, LLC	

2024-513121-22	6727565	GS-US-699-7184	A Phase 2 Platform Study of Novel Combination Therapies in Participants With Head and Neck Squamous Cell Carcinoma	**Phase II**	This platform study will begin with a substudy targeting first-line (1L) recurrent or metastatic (r/m) HNSCC regardless of programmed cell death ligand 1 (PD-L1) expression status (Substudy-01), and new substudies may be added in the future targeting different study populations of HNSCC.	RECRUITING	Domvanalimab Zimberelimab Paclitaxel Carboplatin	H. U. Virgen del Rocio (Sevilla)	Gilead Sciences	
2022-503055-26-00	6016920	VB-C-03	A Phase 1/2a, Open-label, Dose-finding Trial to Evaluate Safety, Immunogenicity, and Anti-tumor Activity of VB10.16 and Pembrolizumab in Patients With Unresectable Recurrent or Metastatic **HPV16-positive** Head-Neck Squamous Cell Carcinoma.	**Phase I/IIA**	The trial is designed to investigate VB10.16, an investigational therapeutic DNA vaccine in combination with another medicine, pembrolizumab, which is the standard of care for patients with previously untreated metastatic or resectable recurrent PD-L1 positive HNSCC. The study is divided in 2 parts: a phase 1, dose escalation part, testing 3 different doses of VB10.16 in combination with a standard fixed dose of pembrolizumab	RECRUITING	VB10.16 Pembrolizumab	ICO-Hospitalet H. del Mar (BCN) H. Virgen Nieves (Granada) M.D.Anderson (Madrid)	Nykode Therapeutics ASA	
2024-511477-29-00	6648096	IRSSP-001	Afatinib in Patients with **Fanconi Anemia** (FA) and Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) **(AFAN)**	**Phase Ib/II**	The main hypothesis, based on preclinical evidence, is that treatment with afatinib, an epithelial growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), could be an effective treatment option to control cancer for patients with FA - HNSCC.	RECRUITING	Afatinib	H.U. Sant Pau (Barcelona)	Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau	
Solid Tumors: Included H&N Cancer Cohort										
2023-507641-29-00	6172478	U31402-277	**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	**Phase II**	This study is designed to assess the safety and efficacy of HER3-DXd monotherapy in subjects with refractory locally advanced or metastatic solid tumors who have been **previously treated with ≥1 prior line of systemic anticancer therapy.**	RECRUITING	HER3-DXd	H.Ramón y Cajal H. 12 Octubre H. G.Marañon H.Regional Malaga H.U. Virgen Macarena(Sevilla) H.Clinic de Valencia H. Clinic BCN H.U.Sant Pau H.U.Vall Hebron	Daiichi Sankyo	
2024-514461-19-00	4868877	MCLA-129-CL01	Phase 1/2 Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-c-MET Bispecific Antibody, in Patients With Advanced NSCLC and Other Solid Tumors (H&N..)	**Phase I/II**	A phase 1/2 open-label multicenter study will be performed with an initial dose escalation part to determine the MTD and/or the RP2D of MCLA-129 as monotherapy	RECRUITING	MCLA-129 Osimertinib Chemotherapy	H. U. Vall d'Hebron (BCN) H. Sant Pau (BCN) H. Gregorio Marañón (Madrid) H. 12 Octubre (Madrid) H. La Fé (Valencia) I.Valenciano Oncologia (IVO) C.U.N Start_F.J.Diaz(Madrid) Start_Sanchinarro(Madrid) Next_Oncology H.M. Delfos (BCN)	Merus N.V.	
2024-513627-16-01	3526835	MCLA-158-CL01	Phase 1/2 Dose Escalation and Cohort Expansion Study Evaluating MCLA-158 (Petosemtamab) as Single Agent or in Combination in Advanced Solid Tumors.	**Phase I/ II**	This is a Phase 1/2 open-label, multi-center, multi-national study with an initial dose escalation part to determine the RP2D of MCLA-158 single agent in patients with mCRC.	RECRUITING	MCLA-158 MCLA-158 + Pembro MCLA-158 + FOLFIRI MCLA-158 + FOLFOX	H. 12 Octubre (Madrid) C. H. Navarra I.Valenciano Oncologia (IVO) H. Vall d'Hebron (BCN) CUN	Merus N.V.	

2023-503651-10-00	4895709	CA052-002	A Phase 1/2 Study of BMS-986340 as Monotherapy and in Combination With Nivolumab in Participants With Advanced Solid Tumors.	**Phase I/ II**	The purpose of this study is to assess the safety, tolerability, and recommended dose(s) of BMS-986340 as monotherapy and in combination with nivolumab in participants with advanced solid tumors.	RECRUITING	BMS-986340 BMS-936558-01 Docetaxel	ICO-Badalona H. Vall d'Hebron (BCN) H. V. de la Victoria (Málaga) H. U. 12 Octubre (Madrid) Start_Sanchinarro(Madrid) Start_F.J.Diaz(Madrid) C.U.N	Bristol-Myers Squibb	
2023-505334-10-01	5592626	CP-START-001	A Phase 1/2, First-in-Human, Open-Label, Dose Escalation and Expansion Study of STAR0602, a Selective T Cell Receptor (TCR) Targeting, Bifunctional Antibody-fusion Molecule, in Subjects with Unresectable, **Locally Advanced,** or **Metastatic** Solid Tumors That Are Antigen-rich **(START-001)**	**Phase I/II**	This Phase 1/2 study consists of two parts: Phase 1 Dose Escalation and Phase 2 Dose Expansion for Advanced Solid Tumors. Virally associated tumors: **- Papillomavirus Infection** **- Epstein-Barr Virus Infections**	RECRUITING	STAR0602	H.Vall d'Hebron Next Quiron -BCN Next Quiron-Madrid CUN H. Clinico Valencia Start-Fjimenez Diaz	Marengo Therapeutics, Inc.	
UNK	4585750	KEYNOTE-D79	A Phase 1/2 Open-label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of PC14586 in Patients With **Locally Advanced** or **Metastatic** Solid Tumors Harboring a TP53 Y220C Mutation. **(PYNNACLE)**	**Phase I/II**	This Phase 1/2 study will assess the safety, tolerability, and efficacy of multiple dose levels of PC14586 (INN: rezatapopt) alone (monotherapy) and in combination with pembrolizumab in participants with advanced solid tumors containing a TP53 Y220C mutation.	RECRUITING	Rezatapopt Pembrolizumab	H. U. Vall d'Hebron (BCN) Start_F.J.Diaz(Madrid) Start_Sanchinarro(Madrid) Next_Oncology (Quiron-BCN) H. Clinico de Valencia H. 12 Octubre (Madrid)	PMV Pharmaceuticals, Inc	
2024-510655-36-00	4180371	BT5528-100	Phase I/II Study of the Safety, Pharmacokinetics, and Preliminary Clinical Activity of BT5528 in Patients With Advanced Malignancies Associated With EphA2 Expression.	**Phase I/ II**	This clinical trial is evaluating a drug called BT5528 alone and in combination with nivolumab in participants with advanced solid tumors historically known for expression of EphA2	RECRUITING	BT5528 Nivolumab	ICO Hospitalet H. Vall d'Hebron (BCN) H. 12 Octubre (Madrid) Start_Sanchinarro (Madrid) Start_F.J.Diaz (Madrid)	BicycleTx Limited	
2023-506228-10-00	6305247	CLIN-01194-450	An Open-label, Phase I/IIa First-in-human, Dose Escalation and Cohort Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetic, Pharmacodynamic and Antitumour Activity of ERK1/2 Inhibitor IPN01194 as Single Agent in Adult Participants With Advanced Solid Tumours	**Phase I/IIA**	The purpose of this study is to determine the appropriate dosage, safety and effectiveness of the study drug, IPN01194 in adults with advanced solid tumours. The participants in this study will have advanced solid tumours. 'Advanced solid tumours' refers to cancers that can occur in several places, including cancers in organs or tissues that have spread from their original site to nearby tissues or other parts of the body. In this study, all participants will receive the study drug, which will be taken by mouth (orally).	RECRUITING	IPN01194 IPN01194	H. Vall d'Hebron Start_F.J.Diaz (Madrid) M.D.Anderson (Madrid)	Ipsen	
2023-506539-14-00	5983432	BL-B01D1-LUNG-101	Study to Evaluate BL-B01D1 in Patients With Metastatic or Unresectable Non-Small Cell Lung Cancer (NSCLC) and Other Solid Tumors	**Phase I**	The objective of this study is to evaluate the safety, tolerability, and efficacy of BL-B01D1 in patients with Metastatic or Unresectable Non-Small Cell Lung Cancer (NSCLC) and **Included Cohort:** -Nasopharyngeal cancer. -Head and Neck cancer.	RECRUITING	BL-B01D1	Star_Sanchinarro (Madrid) Start_F.J. Díaz (Madrid)	SystImmune Inc.	
2022-502381-25-01	5544929	CKFA115A12101	A Phase I, Open-label, Multi-center Study of KFA115 as a Single Agent and in Combination With Pembrolizumab in Patients With Select Advanced Cancers	**Phase I**	The purpose of this study is to characterize the safety and tolerability of KFA115 and KFA115 in combination with pembrolizumab in patients with select advanced cancers, and to identify the maximum tolerated dose and/or recommended dose. **Included Cohort :** -Cutaneous Melanoma -Nasopharyngeal Carcinoma -Squamous Cell Carcinoma of Head and Neck	RECRUITING	KFA115 Pembrolizumab	H. Vall d'Hebron (BCN)	Novartis Pharmaceuticals	

2022-501684-40-00	5007782	**GS-US-570-6015**	A Phase 1 Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of GS-1811, an Afucosylated Anti-CCR8 Monoclonal Antibody, as Monotherapy and in Combination With an Anti–PD-1 Monoclonal Antibody in Adults With Advanced Solid Tumors	**Phase I**	Head and Neck Squamous Cell Carcinoma, Non-Small-Cell Lung Cancer, Gastric an	RECRUITING	Denikitug Zimberelimab	H.U. Vall d'Hebron H. 12 Octubre MD Anderson(Madrid) Start_Sanchinarro Next-Oncology_Quiron Madrid	Gilead Sciences Inc.	
2023-504807-94-00	**5768139**	**STX-478-101**	First-in-Human Study of STX-478, a Mutant-Selective PI3Kα Inhibitor as Monotherapy and in Combination With Other Antineoplastic Agents in Participants With Advanced Solid Tumors	**Phase I**	Study STX-478-101 is a multipart, open-label, phase 1/2 study evaluating the safety, tolerability, pharmacokinetics (PK), and preliminary antitumor activity of STX-478 in participants with advanced solid tumors with P13Ka mutations.	RECRUITING	STX-478 Fulvestrant Ribociclib Palbociclib	Start-Sanchinarro Start-Delfos (BCN) Next Oncology-Quiron(Madrid) H. U. Vall d'Hebron Start-F Jimenez Diaz H. Clinico San Carlos(Madrid)	Scorpion Therapeutics, Inc.	
2023-505346-26-01	**5683418**	**TOS-358-001**	A Study to Evaluate the Safety and Tolerability of the Covalent Phosphoinositide-3-Kinase (PI3K)-alpha Inhibitor, TOS-358, in Adult Subjects with Select Solid Tumors	**Phase I**	The main questions it aims to answer are: -what is the maximum tolerated dose and recommended dose for phase 2? -how safe and tolerable is TOS-358 at different dose levels when taken orally once or twice per day?	RECRUITING	TOS-358	Start-Sanchinarro Start-Delfos (BCN) Next Oncology-Quiron(Madrid & BCN) H. U. Vall d'Hebron Start-F Jimenez Diaz H. Clinico San Carlos(Madrid) CUN H. Clinico Valencia	Totus Medicines	
2022-501570-18-00	**5647122**	**D9350C00001**	A Phase I, Multicenter, Open-label, First-in-Human, Dose Escalation and Expansion Study of AZD9592 as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumors.	**Phase I**	The study consists of several study modules, each evaluating the safety, tolerability, preliminary efficacy, pharmacokinetics (PK), pharmacodynamics, anti-tumor activity, and immunogenicity of AZD9592, as monotherapy or in combination with anti-cancer agents.	RECRUITING	AZD9592 Osimertinib 5-Fluorouracil (5-FU) Leucovorin Bevacizumab	H. Vall d'Hebron(BCN) H. Virgen del Rocio (Sevilla) Start_F J Diaz (Madrid)	Astra Zeneca	
2023-506604-18-00	**5208762**	**SGNPDL1V-001**	A Phase 1 Study of SGN-PDL1V in Advanced Solid Tumors.	**Phase I**	This study will have **three parts.** **Parts A and B** of the study will find out how much SGN- PDL1V should be given to participants. **Part C**_ will use the dose found in Parts A and B to find out how safe SGN-PDL1V is and if it works to treat solid tumor cancers.	RECRUITING	PF-08046054 Pembrolizumab	ICO Hospitalet H. Vall d'Hebron(BCN) Start_Sanchinarro (Madrid) Next-Oncology (BCN)	Seagen, a wholly owned subsidiary of Pfizer	
2023-508469-34-00	**4389632**	**SGNB6A-001**	A Phase 1 Study of SGN-B6A in Advanced Solid Tumors.	**Phase I**	The study will have **two parts:** **Part A** of the study will find out how much SGN-B6A should be given to participants. **Part B** will use the dose found in Part A to find out how safe SGN-B6A is and if it works to treat solid tumors.	RECRUITING	Sigvotatug vedotin Pembrolizumab Cisplatin Carboplatin	H.U. Vall d´Hebron (BCN) Start_Sanchinarro (Madrid) H.M.Valdecilla (Santander) H. 12 Octubre (Madrid) H.M. Nou Delfos (BCN) Next_Quiron (BCN) H. U. de Elche H. U. Ramon y Cajal (Madrid) H.U de Jerez (Cadiz)	Seagen, a wholly owned subsidiary of Pfizer	
2024-511286-11-00	**5238883**	**HFB-200301-01**	A Phase 1a/1b, Open-Label, Multi-Center, Dose Escalation and Expansion Study of HFB200301 (TNFR2 Agonist Antibody) as a Single Agent and in Combination With Tislelizumab (Anti-PD-1 Antibody) in Adult Patients With Advanced Solid Tumors	**Phase I**	The purpose of this study is to test the safety and tolerability of HFB200301 as a single agent and in combination with tislelizumab in patients with advanced cancer.	RECRUITING	HFB200301 Tislelizumab	H. Vall d'Hebron(BCN) H. 12 Octubre (Madrid) H. Clinico Valencia	HiFiBiO Therapeutics	

2023-509867-26-00	6238479	LOXO-ENC-23001	A Phase 1 Trial Investigating LY4101174, an Antibody-Drug Conjugate Targeting Nectin-4, in Participants With Recurrent, Advanced or Metastatic Solid Tumors	**Phase Ia/Ib**	The purpose of this study is to find out whether the study drug, LY4101174, is safe, tolerable and effective in participants with select advanced or metastatic solid tumors. The study is conducted in two parts - phase Ia (dose-escalation, dose-optimization) and phase Ib (dose-expansion). The study will last up to approximately 4 years.	RECRUITING	LY4101174	H. 12 Octubre H. Vall d'Hebron H. Virgen del Rocio MD Anderson-Madrid	Eli Lilly and Company	
2023-509632-26-00	6330064	DS7300-203	A Phase 1B/2 Pan-Tumor, Open-Label Study To Evaluate The Efficacy And Safety Of Ifinatamab Deruxtecan (I-DXd) In Subjects With Recurrent Or Metastatic Solid Tumors **(IDeate-PanTumor02)**	**Phase Ia/IIb**	This study will evaluate the efficacy and safety of I-DXd in participants with **recurrent or metastatic solid tumors previously treated with 1 or more systemic therapies for the selected tumor indication**. The study will be divided into 2 parts: Stage 1 and Stage 2. Each cohort starts with Stage 1 and may continue to Stage 2 if sufficient safety and efficacy data are observed.	RECRUITING	Ifinatamab deruxtecan	H.U. 12 Octubre H.U. Gregorio Marañon H. Clinico San Carlos H.U. La Paz H. Virgen Macarena H. Clinic de Barcelona ICO-Hospitalet H.U. Vall d'Hebron	Daiichi Sankyo	
Observationals & Traslational Studies H&N Cancer										
UNK	6998888	ONCOCAARING	Determining the Effectiveness of Remote Monitoring of Cancer Patients With Oral Cancer Treatment Using Caaring® Software (ONCOCAARING)	Prospective Case-Control	**This is a randomized study with two arms.** **Online telemonitoring group:** The follow-up of these patients will be carried out prospectively remotely through the Caaring® platform. **And Prospective Control group:** The data of these patients are collected prospectively for their routine medical visits for 12 weeks after their inclusion.	RECRUITING	**Device:** software Caaring (remote monitoring app)	H. Sanchinarro(Madrid) H.Monteprincipe(Boadilla) H. Puerta del Sur (Mostoles)	Persei Vivarium	
N.A	5059444	02-MX-003	ORACLE: Observation of ResiduAl Cancer With Liquid Biopsy Evaluation	NA	The purpose of ORACLE is to demonstrate the ability of a novel ctDNA assay developed by Guardant Health to detect recurrence in individuals treated for early-stage solid tumors. It is necessary that ctDNA test results are linked to clinical outcomes in order to demonstrate clinical validity for recurrence detection and explore its value in a healthcare environment subject to cost containment.	RECRUITING	Diagnostic Test: Guardant Reveal	13 Sites in Spain	Guardant Health, Inc.	
N.A	5106608	PBM_CANCER21	Photobiomodulation Therapy With M-health Tool for the Management of Oral Health and Quality of Life in Head and Neck Cancer Patients: LAXER Study. **Condition:** **- Head and Neck Cancer** **- Head and Neck Neoplasms** **- Xerostomia**	NA	**Participants who meet the inclusion and exclusion criteria will be randomized to one of the three study groups** using a random number generation program (www.randomizer.org). The randomization sequence will be prepared by a member external to the investigation to respect the masking in terms of randomization of the participants, thus reducing the risk of bias during the evaluations. Therefore both patients and evaluator will be masked.	RECRUITING	Energy density photobiomodulation (7.5 J/cm2) Energy density photobiomodulation (3 J/cm2) Sham placebo	U. de Granada	Universidad de Granada	
N.A	5562375	3011202123121	Predictive Value of GOCCLES® (Glasses for Oral Cancer Curing Light Exposed Screening), Device for **Early Diagnosis of Oral Potentially Malignant Disorders**	NA	Oral potentially malignant disorders (OPMDs) are chronic pathologies which can suffer dysplastic alterations and evolve into oral cancer. The diagnosis of those pathologies is commonly done by visual inspection, which is not capable of determining the presence or not of dysplasia. Furthermore, this type of diagnosis depends greatly on the expertise and training of the professional.	RECRUITING	**Device:** GOCCLES **Diagnostic Test:** Toluidine blue stain **Procedure:** Biopsy	U. Rey Juan Carlos	Universidad Rey Juan Carlos	
N.A	5483374	INT 43/21	The Observational Clinical Registry of the European Reference Network on Rare Adult Solid Cancers: the Protocol for the Rare Head and Neck Cancers **(EURACAN)**	**Cohort Prospective**	Head and Neck Cancer Nasopharynx Cancer Nasal Cavity and Paranasal Sinus Cancer Salivary Gland Cancer Middle Ear Carcinoma	RECRUITING	N.A	F. Profesor Novoa Santos A Coruña	Fondazione IRCCS Istituto Nazionale dei Tumori, Milano	

NA	05117775	HNC-TACTIC	Towards A Better Paradigm for **Head and Neck Cancer Treatment Applying Artificial Intelligence:** an International Cohort Study of Electronic Health Records. HNC-TACTIC.	NA	The present study aims to describe the clinical characteristics of patients with HNSCC in a real-world setting by analyzing readily available information in the Electronic Health Records (EHRs). This study will gain a deep insight of the clinical characteristics and real-world outcomes of patients with all stages (early, locally advanced, and metastatic) of HNSCC. It will focus on developing two predictive models to apply in the clinical setting, one for electing patients with high-risk of recurrence after radical treatment, and the second one for selecting recurrent or metastatic patients who could benefit from immunotherapy.	RECRUITING	No intervention - Just description and predictive models	Savana Research S.L	Savana Research & Head and Neck Cancer International Group (HNCIG)	
NA	4098146	SMDR_RP_v2.0	International, Multicenter, Prospective Registry to Collect Data on Patients Undergoing Segmental Mandibular Defect Reconstruction (SMDR) Following Oral Squamous Cell Carcinoma (OSSC) Resection	Prospective Case-Control	Prospective will be collected in a minimum of 300 patients presenting with an acquired segmental mandibular defect ≥ 4 cm secondary to OSSC removal and who require mandibular reconstruction.	RECRUITING	Surgical Resection and Reconstruction	H.U. 12 de Octubre (Cirugia Oral y Maxilofacial)	AO Innovation Translation Center	