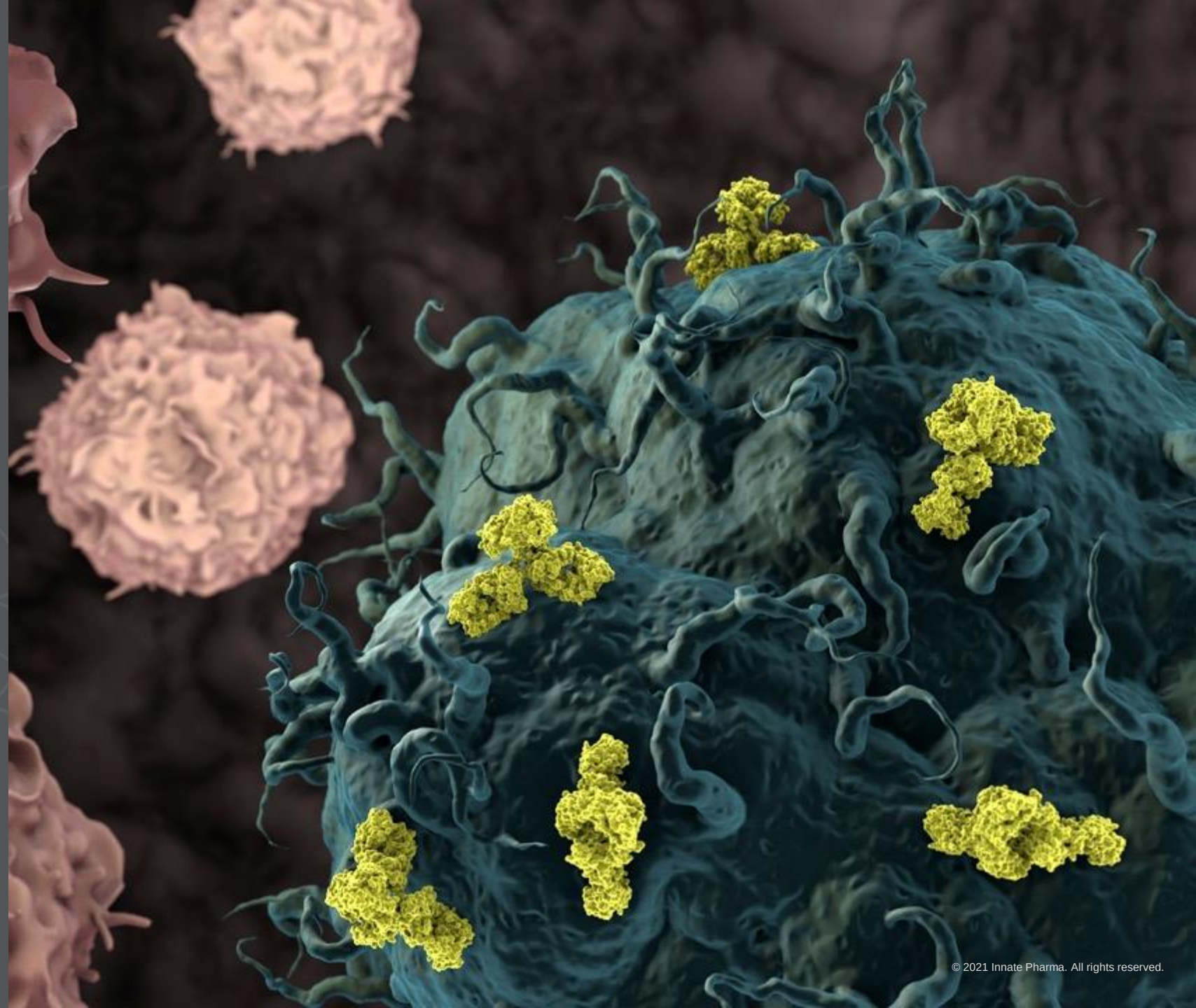
innate pharma

Clinical Trials Appendix

PARIS: IPH.PA NASDAQ: IPHA



Monalizumab (NKG2A mAb): HNSCC

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 3 INTERLINK-1 NCT04590963	AstraZeneca	Recurrent or Metastatic HNSCC, 2L	600	Arm 1: • monalizumab + cetuximab Arm 2: • placebo + cetixumiab	Primary endpoints: • OS Secondary endpoints: • PFS, ORR, DoR
Phase 1/2 IPH2201-203 NCT02643550	Innate Pharma	Recurrent or Metastatic HNSCC, post IO and/or platinum or naive	140	Dose Escalation (post plat) • Monalizumab + cetuximab Expansion cohort 1 (post IO/plat), 2 (naive) • Monalizumab + cetuximab Expansion cohort 3 (naive) • Monalizumab + cetuximab + durvalumab	Primary endpoints: • Occurrence of Dose Limiting Toxicities • Objective Response Rate Secondary endpoints: • ORR, DoR, PFS, OS
Phase 2 UPSTREAM NCT03088059	EORTC	Recurrent or Metastatic after first line platinum-based chemotherapy HNSCC	340	Arm B1 to B6: see Biomarker-based Study in R/M HNSCC - Full Text View - ClinicalTrials.gov Arm I1 (PD(L)-1 naïve or resistant • Monalizumab monotherapy Arm I2 (PD(L)1 pretreated • Monalizumab + durvalumab or SoC	Primary endpoints: • Progression Free Survival Rate • Objective Response Rate Secondary endpoints: • PFS, RR, RD, OS, Toxicity…

Monalizumab (NKG2A mAb): NSCLC

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 2 NeoCOAST NCT03794544	AstraZeneca	Resectable early stage (I to IIIA) NSCLC	80	Arm 1: • Neoadjuvant durvalumab monotherapy Arm 2: • Neoadjuvant durvalumab with novel agents including monalizumab	Primary endpoints: • Major Path. Resp Rate Secondary endpoints: • Feasibility to surgery, AE, CR, PK, immunogenicity
Phase 2 NeoCOAST-2 NCT05061550	AstraZeneca	Resectable early stage (II to IIIA) NSCLC	140	Arm 1: • Durvalumab + Oleclumab + chemotherapy Arm 2: • Durvalumab + Monalizumab + chemotherapy	Primary endpoints: • pathological Complete Response (pCR) • Adverse Events and Serious Adverse Events Secondary endpoints: • EFS, DFS, surg. res., mPR, ORR, OS, Ser con., ADA, baseline PD-L1 exp., ctDNA
Phase 3 (Planned) COAST	AstraZeneca	Unresectable (stage III) NSCLC	TBD	TBD	TBD
Phase 2 PIONeeR NCT03833440	AP-HM	Advanced stage or recurrent NSCLC	120	Arm 1: • Durvalumab + monalizumab Arm 2: • Durvalumab + MEDI9447 Arm 3: • Durvalumab + ADF6748 Arm 4: • Docetaxel	Primary endpoints: • 12-week Disease Control Rate Secondary endpoints: • ORR, PFS, OS, DoR

Monalizumab (NKG2A mAb): others

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 1/2 D419NC00001 NCT02671435	AstraZeneca	Advanced solid tumours	381	Escalation phase • Monalizumab + durvalumab Expansion phase • Monalizumab + durvalumab Exploration phase • Durvalumab +monalizumab + SoC with or without biologic agent	Primary endpoints: • Safety • Exploration Phase: Objectivs Response per RECIST Secondary endpoints: • OR, DC, DoR, PFS, OS, immunogenicity, PK, PD
Phase 1 PIRAT NCT02921685	Institut Paoli-Calmettes	Hematologic Malignancies	18	Arm 1: • Monalizumab monotherapy	Primary endpoints: • Occurrence of Dose Limiting Toxicities Secondary endpoints: • Incidence of acute GVHD • NRM, DFS, OS

Lacutamab (KIR3DL2 mAb)

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 2 TELLOMAK NCT03902184	Innate Pharma	R/R Sezary Syndrome Stage IB-IV Mycosis Fungoides	Up to 150	Cohort 1: R/R Sezary Syndrome • Lacutamab monotherapy Cohort 2: Mycosis Fungoides KIR3DL2+ • Lacutamab Monotherapy Cohort 3: Mycosis Fungoides, KIR3DL2- • Lacutamab Monotherapy	Primary endpoints: • Objective Response Rate Secondary endpoints: • AE, QoL, PFS, OS, DoR, Immunogenicity, PD, PK
Phase 2 KILT NCT04984837	LYSA	R/R Peripheral T Cell Lymphoma	56	Arm 1: • Lacutamab + GEMOX Arm 2: • GEMOX	Primary endpoints: • Median modified Progression-Free Survival Secondary endpoints: • AE, OS, CRR, DoR, Immungenicity, PD, PK
Phase 1b (Planned)	Innate Pharma	R/R Peripheral T Cell Lymphoma	TBD	Monotherapy Lacutamab	TBD

IPH6101/SAR443579 (CD123/NKp46/CD16a)

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 1/2 NCT05086315	Sanofi	B-cell Acute Lymphoid Leukemia High Risk-Myelodisplasia	82	Arm 1: • Dose Escalation: SAR443579 administered intravenously at escalating dose levels. • Dose Expansion: SAR443579 administered intravenously at the recommended dose and schedule determined from the dose escalation.	Primary endpoints: • Incidence of dose-limiting toxicity (DLT) • Proportion of participants who have a CR (Complete Remission) + CRi (Complete Remission with Incomplete Hematological Recovery) Secondary endpoints: • Recommended Phase 2 dose • Treatment-emergent adverse events • Cmax, AUC0-T • Incidence of anti-drug antibody • Anti-leukemic activity • Proportion of participants with CR, CRh, Cri, MLFS • Time interval from first documented evidence of CR until PD • Time interval from date of first administration to induction failure, relapse or death • Proportion of survivors from the first administration to death • Rate of HSCT • Time from first administration to discontinuation excluding remission

Adenosine Pathway

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 1 IPH5201 (CD39) NCT04261075	AstraZeneca	Advanced Solid Tumors	204	Dose escalation • IPH5201 monotherapy Dose escalation • IPH5201 + durvalumab Dose escalation • IPH5201 + durvalumab + oleclumab	Primary endpoints: • Adverse effect • Clinically significant laboratory values as a measure of safety • ECG abnormalities Secondary endpoints: • OR, DC, Half-life of IPH5201, Cmax, AUC, immunogenicity
Phase 1 (Planned) IPH5301 (CD73)	Innate Pharma	Metastatic Cancer Metastatic Breast Cancer Metastatic Pancreatic Cancer Metastatic Gastric Cancer Metastatic Lung Cancer Metastatic Ovary Cancer Oesophageal Cancer Endometrial Cancer Advanced Solid Tumor	27	IPH5301 Alone or in combination with chemotherapy and trastuzumab	Primary endpoints: • Occurrence of dose limiting toxicity (DLT) of IPH5301 in monotherapy in the dose escalation and in combination with paclitaxel and trastuzumab in the expansion cohort (time frame: 1 month)

Avdoralimab (C5aR1 mAb)

Trials	Sponsor	Population	Patients	Design	Endpoints
Phase 2 NCT04563923	CHU Nice	Bullous Pemphigoid	40	Arm 1: • Avdoralimab + Clobetasol proprionate cream Arm 2: • Clobetasol proprionate cream	Primary endpoints: • Complete Clinical Remission Secondary endpoints: • Delay • Initial Clinical Remission