Gilead and Kite Pipeline.



Active and planned clinical trials

Click row or phase bar to view clinical trial study designs in the indicated research area.

The safety and efficacy of investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that investigational agents and/or uses will receive Health Authority approval and/or become commercially available.

Our scientific focus areas target:

Tumour-intrinsic cell death Immune-mediated tumour/cell killing Tumour-permissive microenvironment

Oncology

ESEA	RCH AREA	MOLECULE(S)	PHASE 1	PHASE 2	PHASE 3
HEMATOLOGICAL MALIGNANCIES	1L high-risk LBCL (ZUMA-23)	Axicabtagene ciloleucel	NCT05605899		
	R/R DLBCL	KITE-197 (next-gen CD19 CAR-T)	NCT06079164)	
	R/R DLBCL	KITE-363 (CD19/20 bicistronic)	NCT04989803		
	R/R DLBCL	KITE-753 (CD19/20 bicistronic)	NCT04989803)	
	2L+ high-risk FL (ZUMA-22)	Axicabtagene ciloleucel	NCT05371093		
	R/R Pediatric ALL/NHL (ZUMA-4)	Brexucabtagene autoleucel	NCT02625480		
	R/R MM (iMMagine-3) ^a	Anitocabtagene autoleucel	NCT06413498		
	R/R MM (iMMagine-1) ^a	Anitocabtagene autoleucel	NCT05396885		
	R/R MM (Phase 1) ^a	Anitocabtagene autoleucel	NCT04155749		
BREAST	1L mTNBC, PD-L1- (ASCENT-03)	Sacituzumab govitecan (SG)	NCT05382299		
	1L mTNBC, PD-L1+ (ASCENT-04) ^b	Sacituzumab govitecan + pembro	NCT05382286		
	Adjuvant TNBC (ASCENT-05) ^c	Sacituzumab govitecan + pembro	NCT05633654		
	HR+/HER2- chemo-naïve mBC (ASCENT-07)	Sacituzumab govitecan	NCT05840211		
0	1L mNSCLC, PD-L1 TPS≥50% (EVOKE-03)b	Sacituzumab govitecan + pembro	NCT05609968		
THORACIC	2L ES-SCLC (EVOKE-SCLC-04)	Sacituzumab govitecan	NCT05502237		
	1L mNSCLC, PD-L1 all comers (STAR-121) ^d	Domvanalimab + zimberelimab + chemo	NCT05186974		
	1L mNSCLC (EVOKE-02) ^b	Sacituzumab govitecan + pembro ± chemo	NCT04262856		
	Stage 2-3 resectable NSCLC, 1-2L mNSCLC (VELOCITY-Lung) ^d	Zim ± dom ± etruma ± chemo/SG combinations	NCT05633667		
	1L/2L+ mNSCLC (EDGE-Lung) ^d	Zim ± dom ± quemli ± chemo combinations	NCT06801834		
	1L r/m HNSCC, PD-L1 all comers (VELOCITY-HNSCC)	Zimberelimab + chemotherapy ± domvanalimab	NCT06727565		
OB B	1L/2L+ mUC (TROPHY U-01, multicohort)	Sacituzumab govitecan + combinations	NCT03547973		
<u>.</u>	1L upper GI (STAR-221) ^{d,e}	Domvanalimab + zimberelimab + chemotherapy	NCT05568095		
	1L/2L+ upper GI (EDGE-Gastric) ^{d,f}	Dom + zim ± quemli + chemo combinations	NCT05329766		
	2L+ mCRC (ARC-9) ^{d,g}	Etruma + zim + chemo ± bev combinations	NCT04660812	1b/2	
	1-2L mPDAC (ARC-8) ^{d,h}	Zimberelimab ± quemliclustat + chemotherapy	NCT04104672)	
GYN	2L+ mEC (ASCENT-GYN-01)i	Sacituzumab govitecan	NCT06486441		
	Solid tumours (EVER-132-003)	Sacituzumab govitecan	NCT05119907		ı
OTHER SOLID TUMOURS	Solid tumour basket study (TROPiCS-03) ⁱ	Sacituzumab govitecan	NCT03964727		ı
	Solid tumours	GS-9716 (MCL-1) + chemo or SG	NCT05006794		
	Solid tumours	GS-1811 (CCR8) ± zim	NCT05007782		
	Solid tumours	GS-4528 (IL-2 variant) ± zim	NCT05840224		
	Solid tumours	GS-0201 (PARP1) ± SG	NCT06167317		
	Solid tumours	GS-9911 (DGKα) ± zim	NCT06082960		
	Solid tumours	GS-2121 (undisclosed MoA) ± zim	NCT06532565		
	Solid tumours ^k	GS-0321 (IL18BP) ± zim	NCT06759649		
	Solid tumours	XTX301 (IL-12)	NCT05684965		
	Glioblastoma ^m	CAR-T EGFR IL13Ra2	NCT05168423		
	Neuroblastoma ⁿ	CAR-T GPC2	NCT05650749		

Non-oncology

Multiple indications

KITE-363 (CD19/20 bicistronic)

Preclinical

Multiple targets

Optionable Partner Programs^o

Arcus: 2 clinical stage programs: Advanced Cancers

MacroGenics: 1 clinical stage program: Advanced cancers

Targets

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GS-9716	GS-0201	SG	Anito-cel	Axi-cel, Brexu-cel	KITE-197	KITE-363, KITE-753	GS-9911	GS-4528	XTX301	Zim	Dom	EGFR IL13Ra2 CAR-T			Quemli	GS-1811	GS-2121	GS-0321
MCL-1	PARP1	Trop-2	ВСМА	CD19	CD19 Next-gen CAR-T	CD19/20 bicistronic	DGKα	IL-2 variant	IL-12	PD-1	TIGIT	EGFR IL13Ra2	GPC2	A _{2A} R/A _{2B} R	CD73	CCR8	undisclosed MoA	IL18BP

"In collaboration with Arcellx, Inc. bln collaboration with Merck Sharp & Dohme. In collaboration with Alliance Foundation Trials, LLC and National Surgical Adjuvant Breast and Bowel Project Foundation, Inc. In collaboration with Arcus Biosciences. "STAR-221: dom + zim + FOLFOX/CAPOX vs nivo + FOLFOX/CAPOX. 'EDGE-Gastric: (IL) dom + zim + FOLFOX, zim + FOLFOX and (2L) dom + zim, zim + quemli. BARC-9: etruma + zim + FOLFOX vs FOLFOX ± bevacizumab, etruma + zim + FOLFOX ± bevacizumab vs rego, and etruma + zim + quemli. BARC-8: quemli + zim + gem/nab-pac. In collaboration with the Gynecologic Oncology Group (GOG) Foundation, the European Network of Gynaecological Oncological Trial Groups (ENGOT) and the Asia-Pacific Gynecologic Oncology Trials Group (APGOT). TROPICS-03: mNSCLC, mSCLC, mHNSCC, mEC. Operationalized by Compugen. Also referred to as COM503. 'Operationalized by Xilio Development, Inc. In collaboration with University of Pennsylvania. In collaboration with Children's Hospital of Philadelphia. Optionable Partner Programs: Selected programs listed are optionable partner programs. Gilead has not opted into these programs unless otherwise noted.

1L, first line; 2L, second line; A_{2A}R/A_{2B}R, adenosine 2A receptor/adenosine 2B receptor; AD, autoimmune diseases; ALL, acute lymphoblastic leukemia; BC, breast cancer; BCMA, B-cell maturation antigen; Bev, bevacizumab; CAPOX, capecitabine + oxaliplatin; CAR, chimeric antigen receptor; CCR8, chemokine receptor 8; CD19/20, cluster of differentiation 19/20; Chemo, chemotherapy; CRC, colorectal cancer; DGKα, diacylglycerol kinase alpha; DLBCL, diffuse large B-cell lymphoma; Dom, domvanalimab; EC, endometrial cancer; EGFR, epidermal growth factor receptor; ES-SCLC, extensive-stage small cell lung cancer; Etruma, etrumadenant; FL, follicular lymphoma; FOLFOX, FOLinic acid, Fluorouracil and OXaliplatin; gem/nab-pac, gemcitabine/nab-paclitaxel; GI, gastrointestinal; GPC2, Glypican 2; GU, genitourinary; GYN, gynecological; HER2, human epidermal growth factor receptor 2; HNSCC, head and neck squamous cell carcinoma; HR, hormone receptor; IL-2/12, interleukin-2/12; IL13Ra2, interleukin-13 receptor subunit alpha 2; IL18P, interleukin-18 binding protein; LBCL, large B-cell lymphoma; m, metastatic; MCL-1, myeloid cell leukemia-1; MM, multiple myeloma; MoA, mechanism of action; NCT, national clinical trial; NHL, non-Hodgkin lymphoma; Nivo, nivolumab; NSCLC, non-small cell lung cancer; PARP1, poly adenosine diphosphate (ADP) ribose polymerase 1; PD-(L)1, programmed cell death (ligand) 1; PDAC, pancreatic ductal adenocarcinoma; Pembro, pembrolizumab; Quemli, quemliclustat; Rego, regorafenib; r/m, recurrent/metastatic; R/R, relapsed/refractory; SCLC, small cell lung cancer; SG, sacituzumab govitecan; TIGIT, T cell immunoreceptor with immunoglobulin (Ig) and immunoreceptor tyrosine-based inhibitory motif (ITIM) domains; TNBC, triple-negative breast cancer; TPS, tumour proportion score; Trop-2, trophoblast cell surface antigen 2; UC, urothelial cancer; Zim, zimberelimab.

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