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2021 ASCO Data Discussion

June 2021

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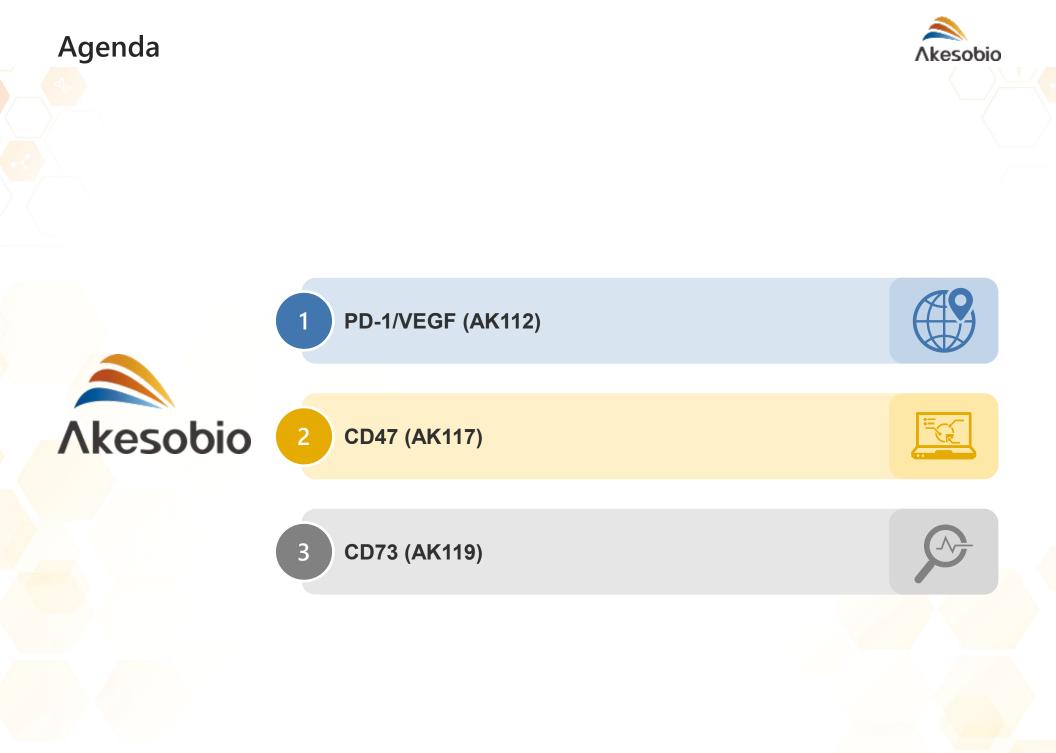
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AK112 PD-1/VEGF bispecific

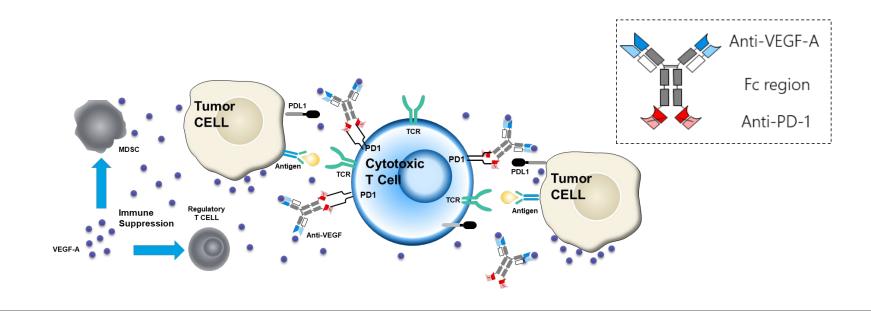
First-in-class



AK112 (PD-1/VEGF) – Mechanism Of Action



- Combination of anti-VEGF with immune checkpoint inhibitor therapy is postulated to produce complementary and synergistic antitumor effects.
- Combination therapies involving PD-(L)1 and VEGF inhibitors have been approved for the treatment of selected patients with metastatic non-small cell lung carcinoma (NSCLC), advanced renal cell carcinoma, advanced endometrial carcinoma and unresectable hepatocellular carcinoma.
- Given the strong correlation between VEGF and PD-1 expression in the tumor microenvironment, the simultaneous blockade of these 2 targets by AK112 as a single agent might achieve higher target binding specificities and synergistically produce enhanced anti-tumor activity compared to co-administration of anti-PD-(L)1 and anti-VEGF therapies.





Safety And Efficacy Of AK112, An Anti-PD-1/ VEGF-A Bispecific Antibody, In Patients With Advanced Solid Tumors In A Phase I Dose Escalation Study

Jermaine Coward¹, Anna Mislang², Sophia Frentzas³, Charlotte Lemech⁴, Adnan Nagrial⁵, Xiaoping Jin⁶, Baiyong Li⁶, Zhongmin Maxwell Wang⁶, Kon Yew Kwek⁶, Yu Xia⁶;

¹ ICON Cancer Care, South Brisbane, Australia; ² Adelaide Cancer Centre, Kurralta Park, Australia; ³ Monash Health, Melbourne, Australia; ⁴ Scientia Clinical Research, Randwick, Australia; ⁵ Blacktown Hospital Cancer and Haematology Centre, Blacktown, Australia; ⁶ Akeso Biopharma, Inc., Zhongshan, China



ASCO ABSTRACT #2515 – safety data (Phase Ia)

- As of 6 April 2021, 42 subjects were enrolled in 6 cohorts ranging from 0.3mg/kg to 30mg/kg
 - 10mg/kg (n=13) and 20mg/kg Q2W (n=18)
- No DLTs and no drug-related death up to 30mg/kg Q2W (inclusive)
 - Most common TRAEs (≥5%) were as expected including arthralgia (19%), fatigue (14.3%), hypertension(11.9%), diarrhoea (11.9%), rash (11.9%), pruritus (7.1%) and headache (7.1%)

	Categories	AK112 All dose levels (N = 42)	AK112 20 mg/kg Q2W (N = 18)	IMmotion151 mRCC ¹ (Atezo 1200 mg + Bev 15mg/kg Q3W)
	TRAE	27 (64.3%)	10 (55.6%)	91%
П	≥ Grade 3 TRAE	8 (19.0%)	3 (16.7%)	40%
	Drug-related SAE	1 (2.4%)	0	Not reported
	TRAEs leading to discontinuation	2 (4.8%)	1 (5.6%)	5%

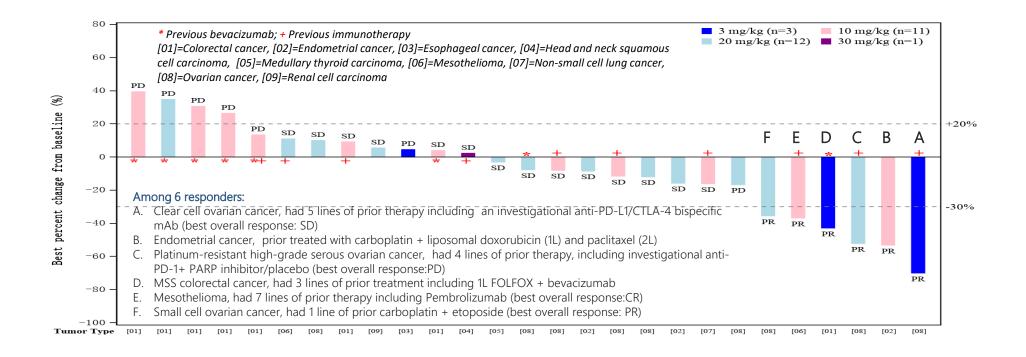
TRAE: treatment-related adverse event; Atezo: Atezolizumab; Bev: Bevacizumab; RCC: renal cell carcinoma

AK112 demonstrates good safety profile and is well-tolerated

ASCO ABSTRACT #2515 – Prelimary efficacy data (Phase Ia)



AK112 demonstrated encouraging anti-tumor activity at doses ≥3mg/kg in patients with various tumor types that have been heavily pretreated (including with bevacizumab or ICI) and resistant/refractory to standard therapies

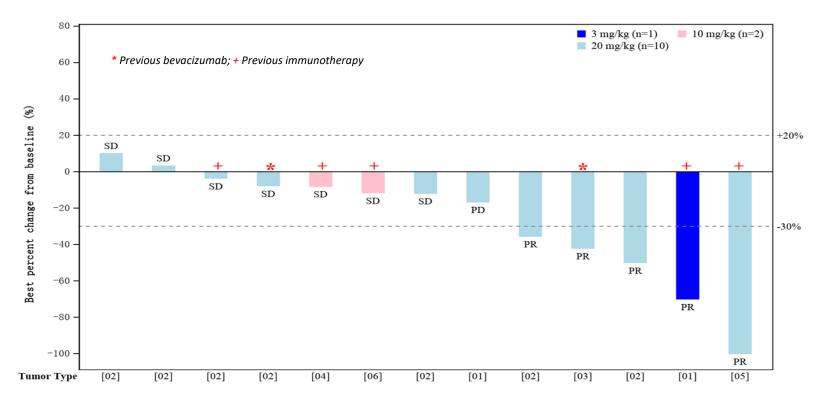


For dose levels ≥3 mg/kg, ORR was 22.2% (6/27) and DCR was 74.1% (20/27)

AK112 (PD-1/VEGF) – Prelimary efficacy data (Phase Ia)



Platinum-resistant Ovarian Cancer



[01]=Clear Cell Cancer Of Ovary, [02]=Epithelial Ovarian Cancer, [03]=Fallopian Tube Cancer, [04]=Granulosa Cell Tumour, [05]=High Grade Serous Ovarian Carcinoma, [06]=Ovarian Cancer

ORR = 38.5% (5/13), DCR = 92.3% (12/13)

AK112 (PD-1/VEGF) – clinical development plan



We are executing a global clinical development strategy for AK112. Started Phase I trial for the treatment of advanced solid tumors in Australia in October 2019.

							Status	
Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Phase la	Phase Ib/ll	Pivotal/ Phase III	NDA Submitted
			+Chemo	1L EGFRwt NSCLC/ EGFR-TKI failure NSCLC			FPI: Feb.07,2021	
			+Chemo	1L ES-SCLC			FPI: April.23,202	1
AK112	PD-1 / VEGF	Global	Mono	1L NSCLC			FPI: May.20,202	1
			Mono	OC/CC/EC			FPI: April.04,202	1
			Mono 🄇	Adv. solid tumors			FPI: Oct.02,2019	
			Mono	Adv. solid tumors/RCC/HCC			FPI: Oct.21,2020	
			+PARPi	Platinum sensitive OC (gBRCA wt)			FPI: June 30,202	1 (est)
			+Chemo	1L TNBC				
			+Chemo	1L Platinum sensitive OC				
			+AK117 (CD47)	Adv. solid tumors				

NSCLC: Non Small Cell Lung Cancer ES-SCLC: Extensive Stage-Small Cell Lung Cancer OC: Ovarian Cancer CC: Cervical Cancer EC: Endometrial Cancer RCC: Renal Cell Carcinoma HCC: Hepatocellular Carcinoma TNBC: Triple Negative Breast Cancer



AK117 CD47 antibody





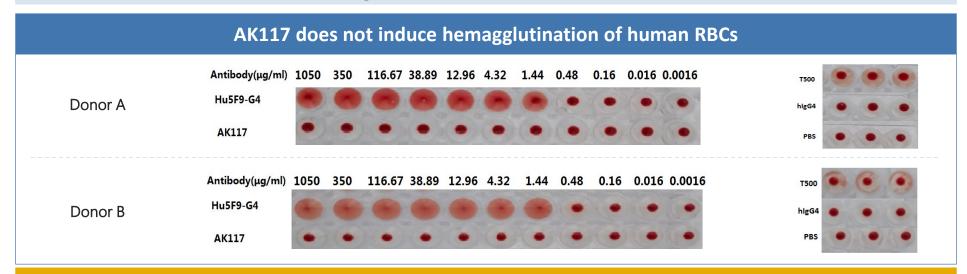
Safety Of AK117, An Anti-CD47 Monoclonal Antibody, In Patients With Advanced Or Metastatic Solid Tumors In A Phase I Study

Hui Kong Gan¹, Jermaine Coward², Anna Mislang³, Rasha Cosman⁴, Adnan Nagrial⁵, Xiaoping Jin⁶, Baiyong Li⁶, Zhongmin Maxwell Wang⁶, Kon Yew Kwek⁶, Dennis Xia⁶, Yu Xia⁶

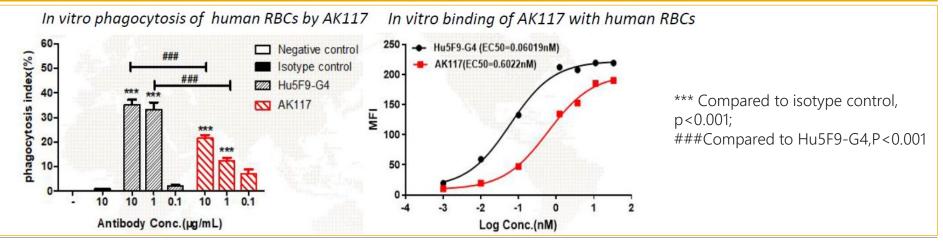
¹ Austin Health, Heidelberg, Australia; ² ICON Cancer Care, South Brisbane, Australia; ³ Adelaide Cancer Centre, Kurralta Park, Australia; ⁴ St Vincent's Hospital, Sydney, Australia; ⁵ Blacktown Hospital Cancer and Haematology Centre, Blacktown, Australia; ⁶ Akeso Biopharma, Inc., Zhongshan, China

ASCO ABSTRACT # 2630 – Differentiated characteristics of AK117

- AK117 is a noval humanized IgG4 monoclonal antibody (mAb) targeting CD47, a macrophage immune checkpoint that allows tumor cells to evade immune destruction by phagocytic cells.
- Preclinical data suggest that the risk of anemia is reduced with AK117 compared to Hu-5F9 and AK117 does not cause hemaglutination.



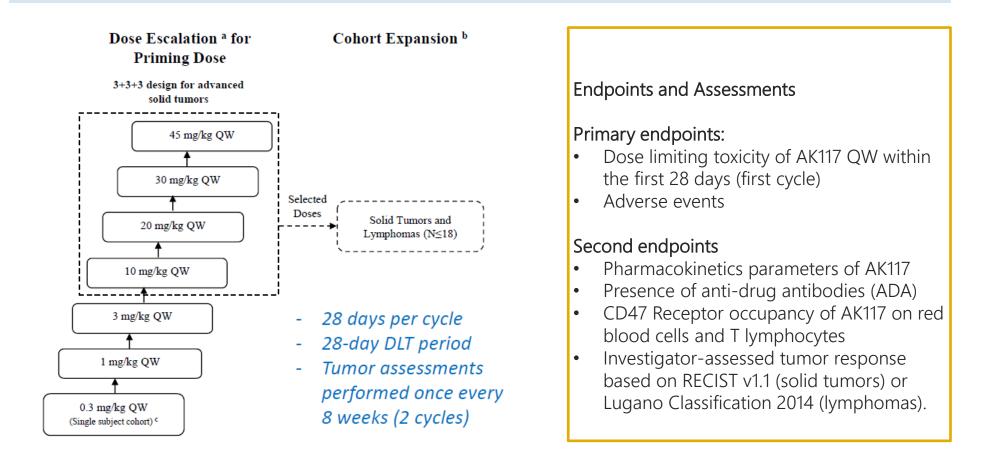
Significantly weaker phagocytosis (left) and binding activity (right) to human RBCs



ASCO ABSTRACT # 2630 – Study Design

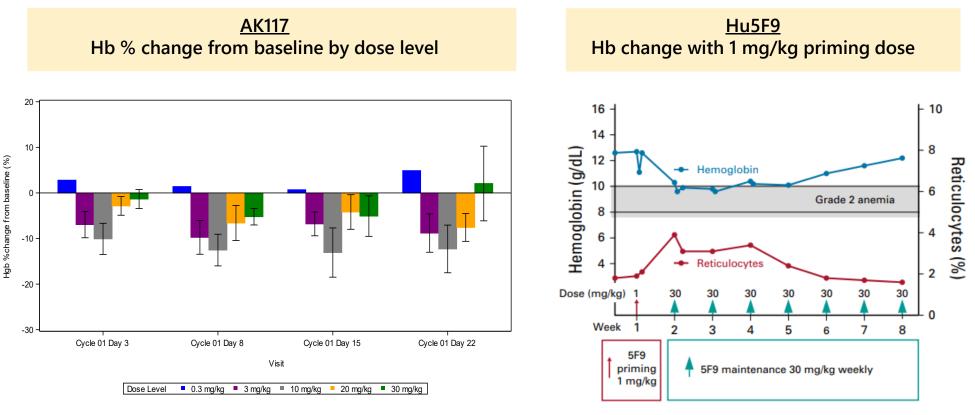


- A first-in-human, Phase 1a/1b, multicenter, open label, single arm, dose escalation and dose expansion study of AK117 in advanced or metastatic solid tumors or lymphomas
- In Part A, patients with resistant/refractory advanced or metastatic solid tumors were administered escalating doses of AK117 monotherapy (dose range 0.3 to 45mg/kg QW).
- An accelerated titration (first cohort) followed by 3+3+3 design was used to assess the safety and tolerability of AK117 monotherapy.



AK117 (CD47) – no significant reductions in hemoglobin (Hb)



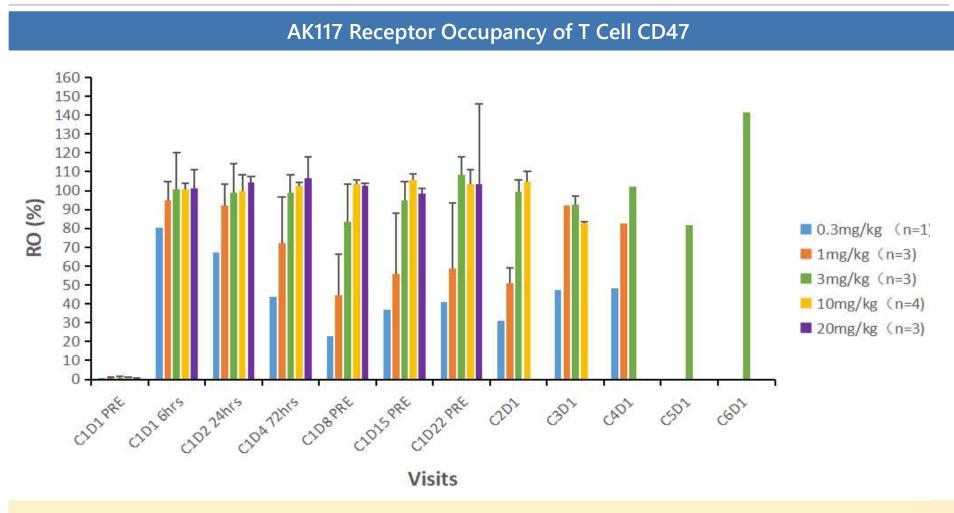


Source: Branimir I Sikic, et al. 2018 ASCO

- AK117 does not require administration of a priming dose
- ✓ AK117 at up to 30 mg/kg, inclusive, does not cause significant reduction in hemoglobin levels
- Safety evaluation of 45mg/kg QW cohort is in progress
- In comparison, an approximately 20% reduction in hemoglobin levels was observed with a 1 mg/kg priming dose of Hu5F9

AK117 (CD47) – maximal T-cell receptor occupancy at 3mg/kg QW





✓ AK117 demonstrated dose dependent increase in CD47 RO on peripheral T cells.

 AK117 achieved consistent maximal saturation of CD47 on peripheral T cells after just 2 doses at 3mg/kg QW.

AK117 (CD47) – clinical development plan



AK117 is a potential best-in-class anti-CD47 mAB with eliminated hemagglutination effect

					Status			
Drug Candidate	Target	Comm. Rights	Mono/Combo	Indication	Phase la	Phase Ib/II	Pivotal/ Phase III	NDA Submitted
	CD47	047 Global	Mono	Solid tumor/ lymphoma	FPI: May.11	,2020		
			+AK104 (PD-1/CTLA-4)	Adv. solid tumors	FPI: Jun.5,2	2021		
			+azacitidine 🔇	MDS		FPI: May.28	3,2021	
			+azacitidine	AML		FPI: Jul.2,20	021	
A 1/117			+azacytidine +venetoclax	AML				
AK117			+AK112 (PD-1/VEGF)	Adv. solid tumors (1L PD-L1 CPS>1 HNSCC)				
			+rituximab	R/R Lymphoma				
			+trastuzumab± pacilitaxel	≥2L Her2+ GC 1L Her2+ Breast Cancer				
			+adriamycin	1L Soft Tissue Sarcoma				
			+AK112/AK104+Chemo	1L NSCLC/HNSCC/OC/GC/CRC	2			

= In planning



AK119 CD73 antibody





A Phase I Study Of AK119, An Anti-CD73 Monoclonal Antibody, In Combination With AK104, An Anti-PD-1/CTLA-4 Bispecific Antibody, In Patients With Advanced Or Metastatic Solid Tumors

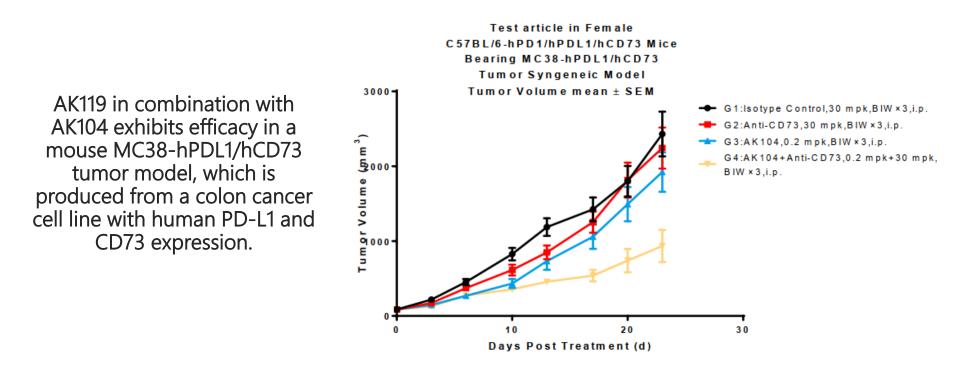
Ben Markman¹, Amy Hsin-Chieh Hsieh², Jim Coward³, Matteo S. Carlino⁴, Sophia Frentzas⁵, Xiaoping Jin⁶, Baiyong Li⁶, Zhongmin Maxwell Wang⁶, Kon Yew Kwek⁶, Yu Xia⁶

¹ Alfred Hospital, Melbourne, Australia; ² Icon Cancer Centre, Windsor Gardens, Australia; ³ ICON Cancer Care, South Brisbane, Australia; ⁴ Westmead Hospital, Sydney, Australia; ⁵ Monash Health, Melbourne, Australia;

• 6 Akeso Biopharma, Inc., Zhongshan, China



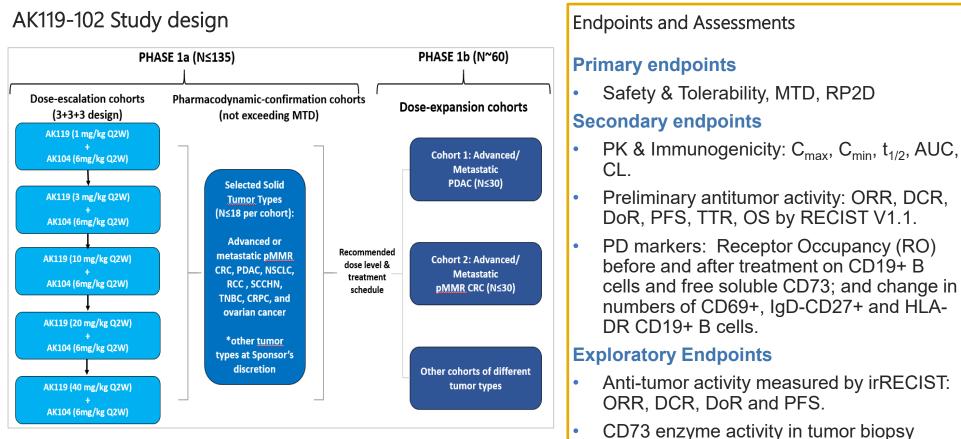
- AK119 is a humanized IgG1 monoclonal antibody (mAb) that selectively binds to and inhibits the ectonucleotidase activity of CD73.
- In order to reduce antibody-mediated effector functions (including antibody-dependent cellmediated cytotoxicity and complement dependent cytotoxicity) from eliminating immune cells, two amino acid mutations were introduced at the Fc end of AK119.



In mouse tumor model, AK119 + AK104 in combination have shown synergistically enhanced anti-tumor activity compared to anti-CD73 monotherapy or ICIs alone.

ASCO ABSTRACT # 2675

- The study was initiated in late 2020.
- No dose limiting toxicity at AK119 (1mg/kg) + AK104 (6mg/kg) Q2W. Safety evaluation of the second cohort [AK119 (3mg/kg) + AK104 (6mg/kg) Q2W] is in progress.



Abbreviations: CRC, colorectal cancer; CRPC, castration-resistant prostate cancer; MSS, metastatic microsatellite stable; NSCLC, non-small-cell lung cancer; PDAC, pancreatic ductal adenocarcinoma; pMMR, mismatch repair-proficient; RCC, renal cell cancer; SCCHN, squamous cell cancer of head and neck; TNBC, triple negative breast cancer.

• CD73/PD-L1 expression in tumor tissue.

tissue obtained before and after treatment.



AK119 (CD73) – clinical development plan



		Comm. Rights		Indication	Status			
Drug Candidate	Target		Mono/Combo		Phase la	Phase lb/ll	Pivotal/ Phase III	NDA Submitted
			Mono 🤇	Healthy Subjects				
		_	+AK104 (PD-1/CTLA-4)	Adv. solid tumors NSCLC/OC/PDAC				
AK119	CD73	D73 Global	+AK104 (PD-1/CTLA-4) +Chemo	1L NSCLC/OC/PDAC				
			+AK112 (PD-1/VEGF) ±Chemo	Adv. solid tumors NSCLC/OC/PDAC				





