



康方生物科技(開曼)有限公司  
Akeso, Inc.

# 3Q 2020 Business Update Presentation

November 2020



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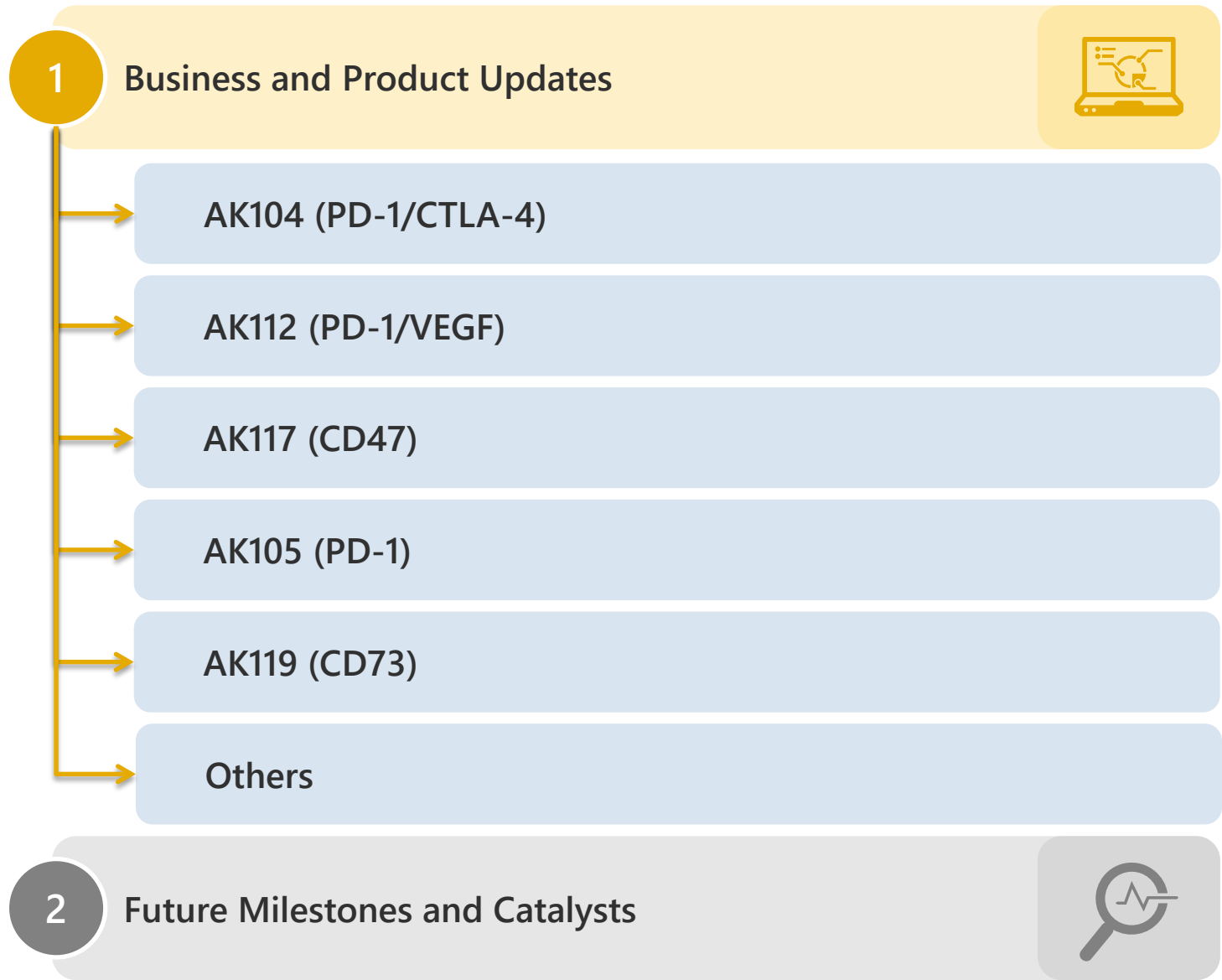
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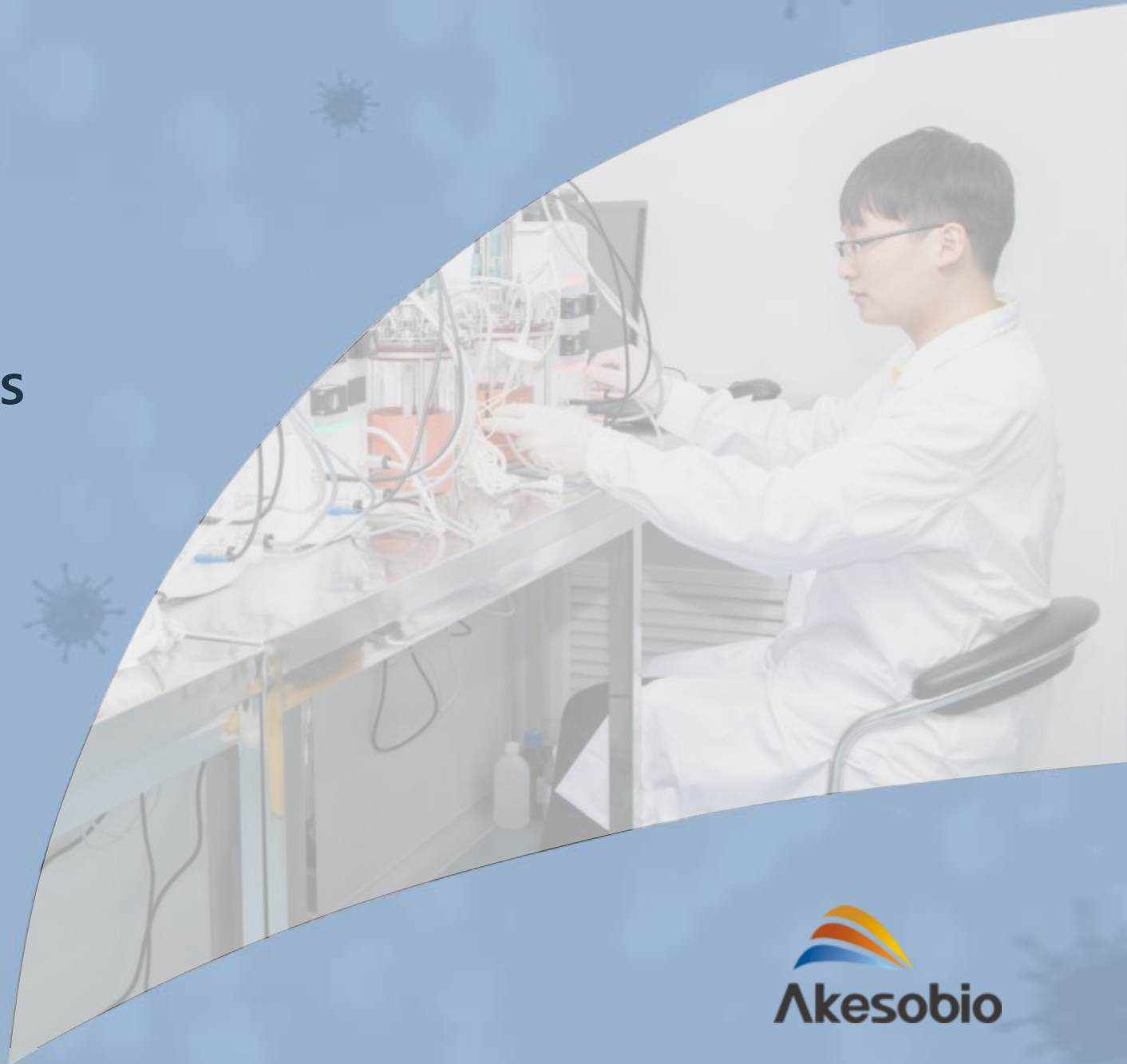
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## SECTION 1

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# Business and Product Updates



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## Major Clinical Program Advancements

### 1. PD-1/CTLA-4 (AK104)

- October, NMPA Breakthrough Therapy Designation, for 2L/3L cervical cancer
- August, FDA FTD, for 2L/3L cervical cancer

### 2. PD-1 (AK105)

- October, FDA FTD, for 3L NPC
- Completion of Patient Enrollments
  - for 3L NPC, reached key endpoints
  - in combination with chemotherapy for 1L SQ NSCLC

2

## Data Readouts

1. **Sept, 2020 ESMO: oral presentation** of AK104 for treating Advanced Mesothelioma
2. **Oct, 2020 CCI (中国肿瘤免疫医疗会议): oral presentation** of PD-1/CTLA-4 (AK104), PD-1/VEGF (AK112)
3. **Nov, 2020 SITC:** 6 abstracts to be published
  - Late-Breaking Abstract (LBA): PD-1 for cHL, NPC
  - CD73 (AK119) for COVID-19
  - CD47 (AK117), PD-1/CD73 (AK123), TIGIT (AK127)

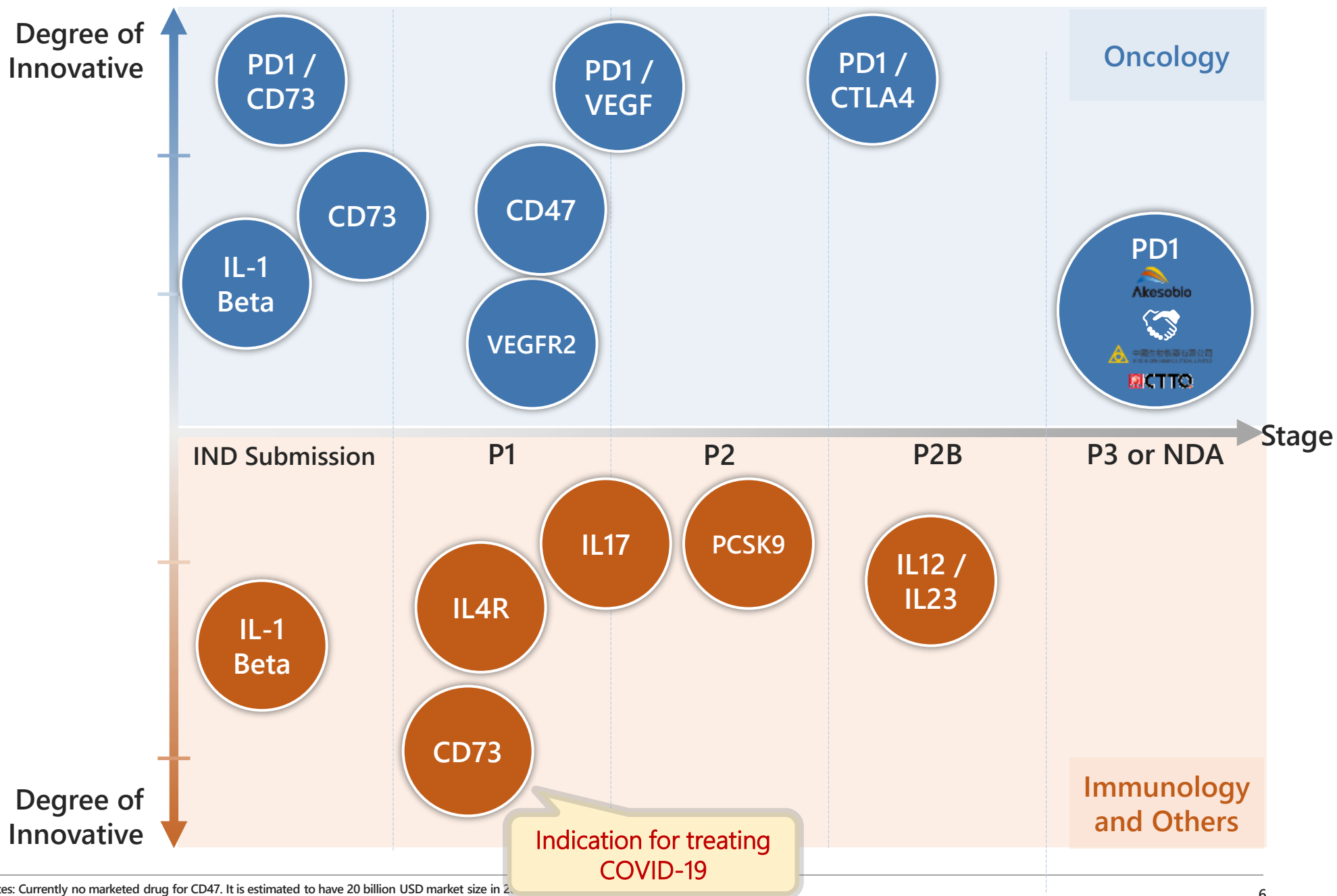
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## Addition of Senior Management Members

1. **Non-oncology program leader: Dr. Jason Ni**
2. **Commercialization head: Mr. Shi Wenjun**



# Akeso clinical pipeline landscape

























## Our selected IND-enabling drug candidates




In addition to our clinical-stage drug candidates, as of 30, October 2020, we are also developing over five drug candidates in IND-enabling stage, including but not limited to:

Assets	Target(s)	Comm. Rights	Therapeutic Areas
AK114	IL-1beta	Global	Oncology/ Inflammatory disease
AK123	PD-1 / CD73	Global	Oncology
AK127	TIGIT	Global	Oncology
AK129	PD-1 / LAG3	Global	Oncology

# 1 Cadonilimab (PD-1/CTLA-4, AK104) – clinical development plan

Focusing on combo trials for large indications and mono trials for unmet medical needs for fast approval

Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Status				
					Phase I	Phase II	Pivotal	NDA Submitted	
					Phase Ia	Phase Ib			
AK104	PD-1 / CTLA-4	Global	Mono 	2L/3L cervical cancer					
			Mono	3L NPC					
			+XELOX 	1L GC or GEJ adenocarcinoma					
			+Lenvatinib 	1L HCC					
			+Chemo 	1L NSCLC					
			+Anlotinib 	1L NSCLC and 2L/3L NSCLC (PD-(L)1 R/R)					
			Mono 	2L HCC					
			Mono 	2L ESCC					
			Mono	≥2L melanoma (PD-(L)1 naive or R/R)					
			Mono	≥2L PTCL					
			Mono 	2L/3L NSCLC (PD-(L)1 R/R)					
			Mono	Adv. solid tumors					
			Mono 	Adv. solid tumors					

 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within Next Quarter

 Large indications 
  Registration trial

 Global trial

## ■ 2L/3L cervical cancer

- Expected to **submit an NDA** for AK104 (PD-1/CTLA-4) in 2L/3L cervical cancer **in 2021**



# 1 Cadonilimab (PD-1/CTLA-4) – safety data summary

**New cut off date: July**

**Consistent better safety profile compared to PD-1 and CTLA-4 combination therapy**

Categories	AK104 All dose levels (N = 228)	AK104 6mg/kg (N = 141)	AK104 15mg/kg (N = 12)	Checkmate-214 RCC <sup>1</sup> (Nivo 3mg/kg +Ipi 1 mg/kg)	Checkmate-067 Melanoma <sup>2</sup> (Nivo 1mg/kg +Ipi 3 mg/kg)	Checkmate-227 <sup>3</sup> (Nivo 3mg/kg +Ipi 1 mg/kg Q6W)
Drug-related TRAE	147 (64.5%)	86 (61.0%)	9 (75.0%)	93%	96%	77%
≥ Grade 3 TRAE	29 (12.7%)	11 (7.8%)	1 (8.3%)	46%	59%	33%
Drug-related SAE	25 (11.0%)	10 (7.1%)	2 (16.7%)	Not reported	48.6%	Not reported
TRAEs leading to discontinuation	15 (6.6%)	8 (5.7%)	2 (16.7%)	22%	39%	18%

\* Our dose-escalation level has expanded to 15mg/kg Q3W (n=12) and 25mg/kg Q3w (n=3) and ongoing

**Previous cut off date: Feb**

Categories	All dose levels (N = 184)	6mg/kg (N = 101)	10mg/kg (n=17)	450mg (N = 50)	Checkmate-214 RCC <sup>1</sup> (Nivo 3mg/kg +Ipi 1 mg/kg)	Checkmate-067 Melanoma <sup>2</sup> (Nivo 1mg/kg +Ipi 3 mg/kg)	Checkmate-227 <sup>3</sup> (Nivo 3mg/kg +Ipi 1 mg/kg Q6W)
Drug-related TRAE	124 (67.4%)	75 (74.3%)	9 (52.9%)	29 (58.0%)	93%	96%	77%
≥ Grade 3 TRAE	24 (13.0%)	10 (9.9%)	2 (11.8%)	9 (18.0%)	46%	59%	33%
Any irAE	68 (37.0%)	44 (43.6%)	4 (23.5%)	15 (30.0%)	90%	Not reported	Not reported
≥ Grade 3 irAE	13 (7.1%)	6 (5.9%)	0 (0.0%)	5 (10.0%)	27%	Not reported	Not reported
Treatment-related SAE	22 (12.0%)	9 (8.9%)	3 (17.6%)	7 (14.0%)	Not reported	48.6%	Not reported
TRAEs leading to discontinuation	12 (6.5%)	6 (5.9%)	0 (0.0%)	6 (12.0%)	22%	39%	18%

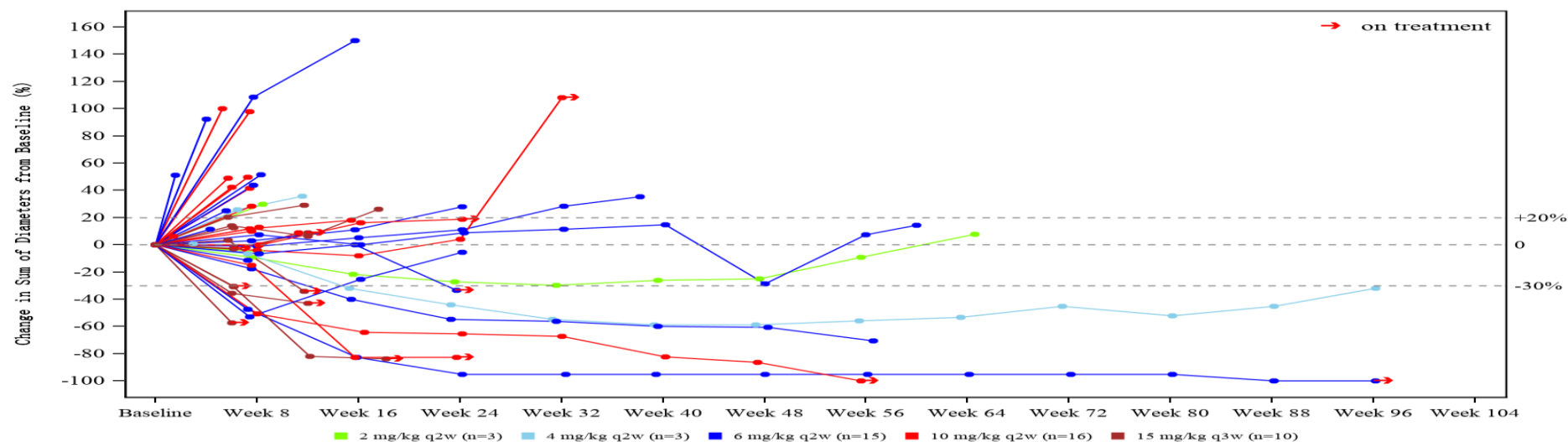
Abbreviation: irAE = immune-related adverse event; SAE= serious adverse event; TRAE =treatment-related adverse event; RCC = renal cell carcinoma; Nivo = nivolumab; Ipi = ipilimumab

Source:

1. Motzer RJ, NEJM 2015; NICE 2018; <https://www.nice.org.uk/guidance/ta581/documents/committeepapers>, 2. Wolchok, JD, NEJM 2017, 3. Solange P, ESMO 2019

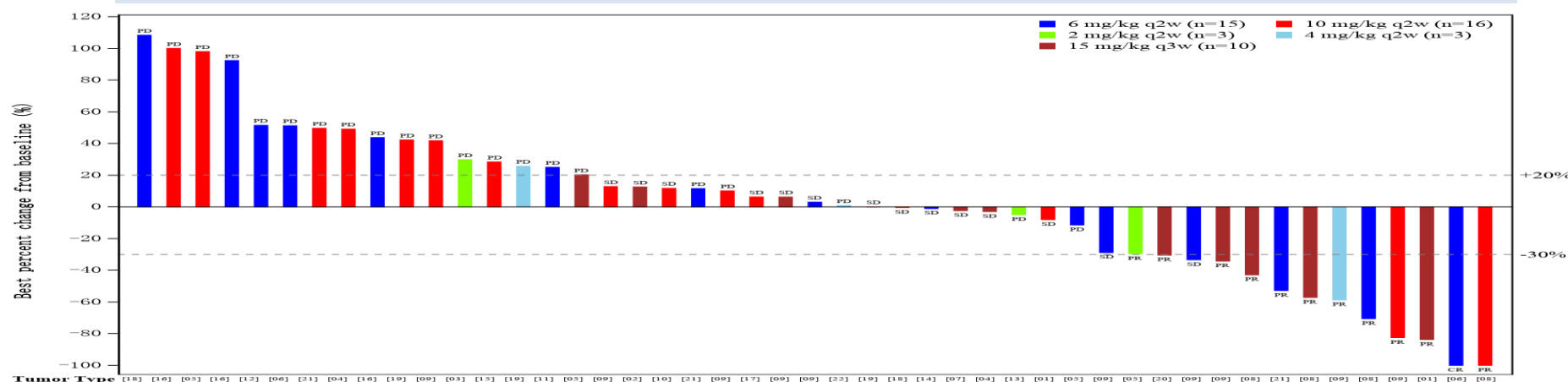
**AK104 continued to show favourable safety profile with larger patient pool and higher dosing volume**

## Anti-tumor activity of Cadonilimab in Australia Phase 1a trial (N=47, $\geq 2$ mg/kg) (N =40 at previous cut off date)



**ORR = 25.5% (12/47), DCR = 55.3% (26/47)**

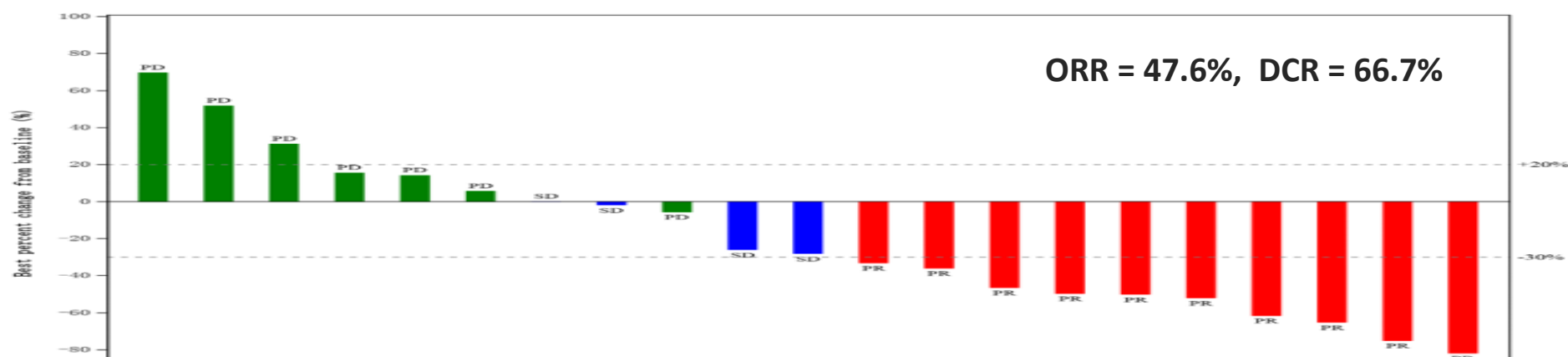
**(ORR = 17.5% (7/40), DCR = 55.0% (22/40) at previous cut off date)**



[01]=Cervical cancer, [02]=Cholangiocarcinoma, [03]=Duodenal cancer, [04]=Endometrial cancer, [05]=Gastric cancer, [06]=Large cell neuroendocrine carcinoma, [07]=Leiomyosarcoma, [08]=MSI-H/dMMR colorectal cancer, [09]=Mesothelioma, [10]=Metastatic thymus carcinoma, [11]=Ovarian cancer, [12]=Pancreatic cancer, [13]=Rectal cancer, [14]=Renal cell carcinoma, [15]=SCCHN, [16]=SCLC, [17]=Salivary gland carcinoma, [18]=Sarcoma, [19]=Sarcomatoid carcinoma, [20]=Small cell neuroendocrine carcinoma, [21]=Triple negative breast cancer, [22]=Urachal carcinoma

# 1 Cadonilimab (PD-1/CTLA-4) – clinical data summary (cont'd)

2L/3L Cervical Cancer: encouraging efficacy was shown from initial clinical studies (up-to-July evaluable patients)



**Cadonilimab showed superior efficacy in cervical cancer  
in comparison to either PD-1 plus CTLA-4 combination therapy or PD-1 mono-treatment.**

Sponsor	Treatment	Indications	Number of Pts	ORR	DCR
Akesobio	<b>Cadonilimab (AK104)<sup>1</sup></b> (PD-1/CTLA-4)	Recurrent/Metastatic Squamous Cervical Cancer(failure after SOC)	31 <sup>(1)</sup>	47.6%	66.7%
Agenus	Balstilimab+Zalifrelimab <sup>2</sup> (PD-1+CTLA-4)	Recurrent/Metastatic Cervical Cancer	143	21.6%	NA
Agenus	Balstilimab <sup>2</sup> (PD-1)	Advanced Cervical Cancer (failure after SOC)	160	14%	NA
Merck	Pembrolizumab <sup>3</sup> (PD-1)	Advanced Cervical Cancer (failure after SOC)	77 (PD-L1+)	14.3%	31.2%
			15 (PD-L1-)	0.0%	20.0%
BMS	Nivolumab 3 + Ipilimumab 1 mg/kg <sup>4</sup>	Recurrent/Metastatic SCC Cervical Cancer	26 (PST*)	23.1%	53.8%
BMS	Nivolumab 1 + Ipilimumab 3 mg/kg <sup>4</sup>	Recurrent/Metastatic SCC Cervical Cancer	22 (PST*)	36.4%	72.7%

1. Data cutoff date: July, 2020, 31 patients enrolled with 21 patients evaluable for efficacy. The efficacy data as of today remain consistent with the data in July.

2. Presented at: 2020 ESMO Congress; September 20, 2020; virtual. Abstract LBA34.

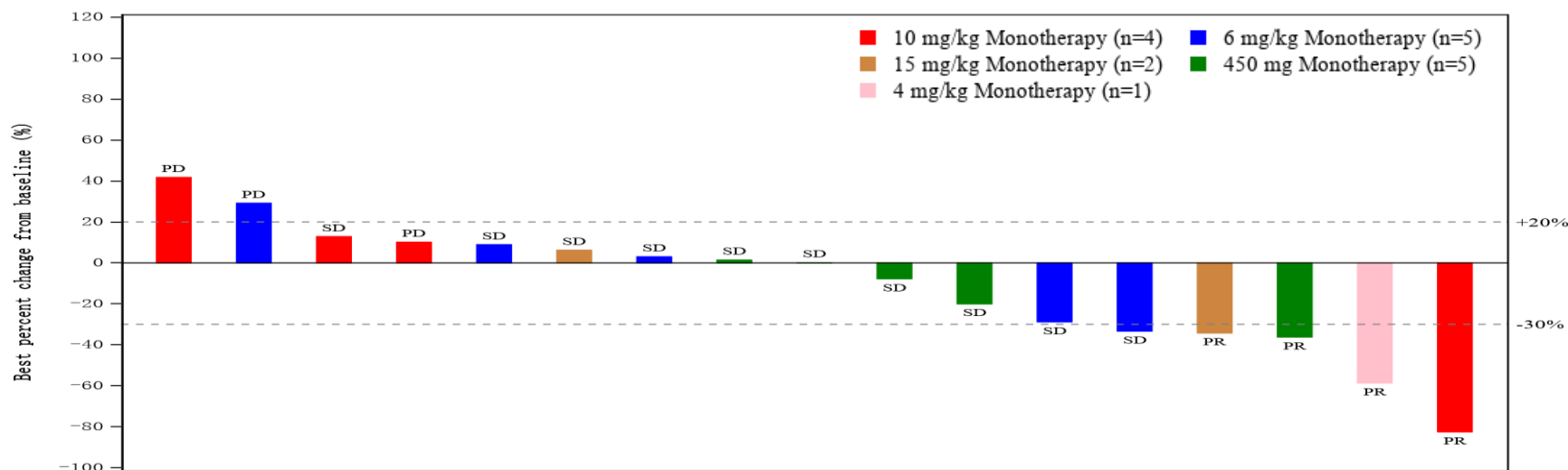
3. Chung HC, et al, Journal of Clinical Oncology, 2019, 37, no.17, 1470-1478.

4. Naumann R. Efficacy and safety of nivolumab (Nivo) + ipilimumab (Ipi) in patients (pts) with recurrent/metastatic (R/M) cervical cancer: Results from CheckMate 358. Proffered Paper, Abstract 5630. ESMO 2019.

\* PST: Prior Systemic Therapy

## Encouraging efficacy was shown from initial clinical studies

### ≥2L Mesothelioma (N=17)



**ORR = 24%, DCR = 88%**

Treatment	Lines of therapy	No. of pts	ORR	DCR (At 12 Week)
AK104 (PD-1/CTLA-4 bispecific)	≥2L	17	24%	88%
Nivolumab+ Ipilimumab <sup>1</sup>	≥2L	61	28%	52%
Nivolumab <sup>2</sup>	≥2L	63	19%	40%

AK104 up to 10 mg/kg Q2W or 15 mg/kg Q3W in mesothelioma patients is safe and well-tolerated.

- ≥ Grade 3 TRAE: 16.7% vs 26% for Nivo + Ipi
- TRAE leading to discontinuation: 5.6% for AK104 vs 21% for Nivo + Ipi
- No treatment-related AE leading to death AK104 vs 5% for Nivo + Ipi

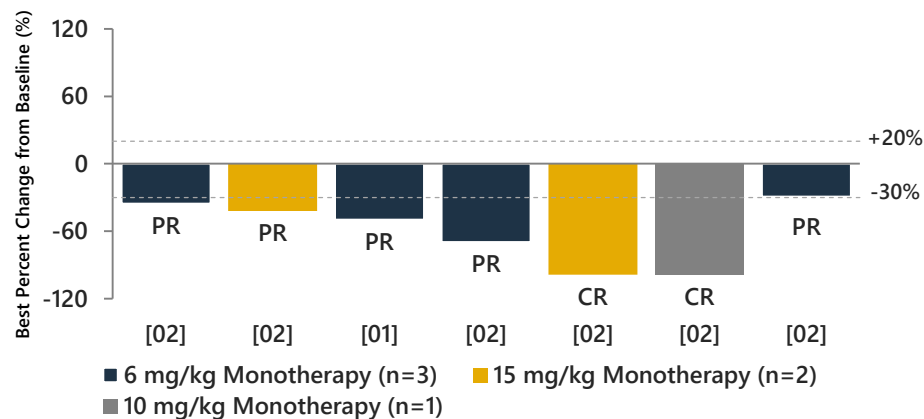
1. IFCT-1501 MAPS2, Nivolumab With (without) ipilimumab Sep2020.

2. IFCT-1501 MAPS2, Nivolumab Sep2020.

# 1 Cadonilimab (PD-1/CTLA-4) – clinical data summary (cont'd)

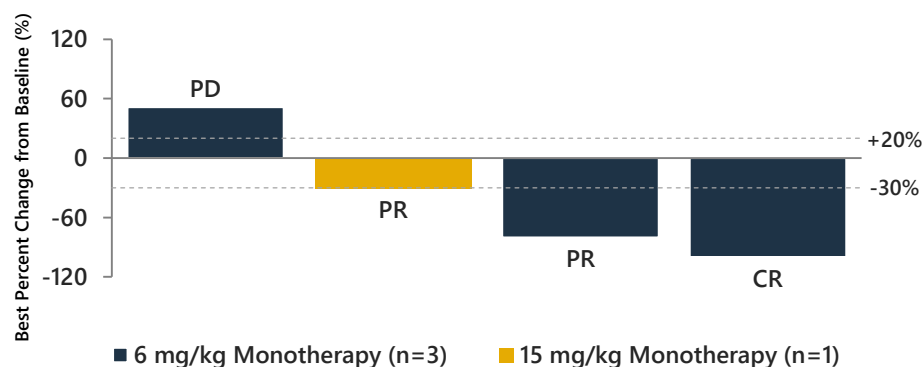
## Very encouraging efficacy was shown from initial clinical studies

### ≥3L MSI-H tumors (N=7)



**ORR = 100% with 2 CRs**

### Neuroendocrine Carcinoma (N=4)

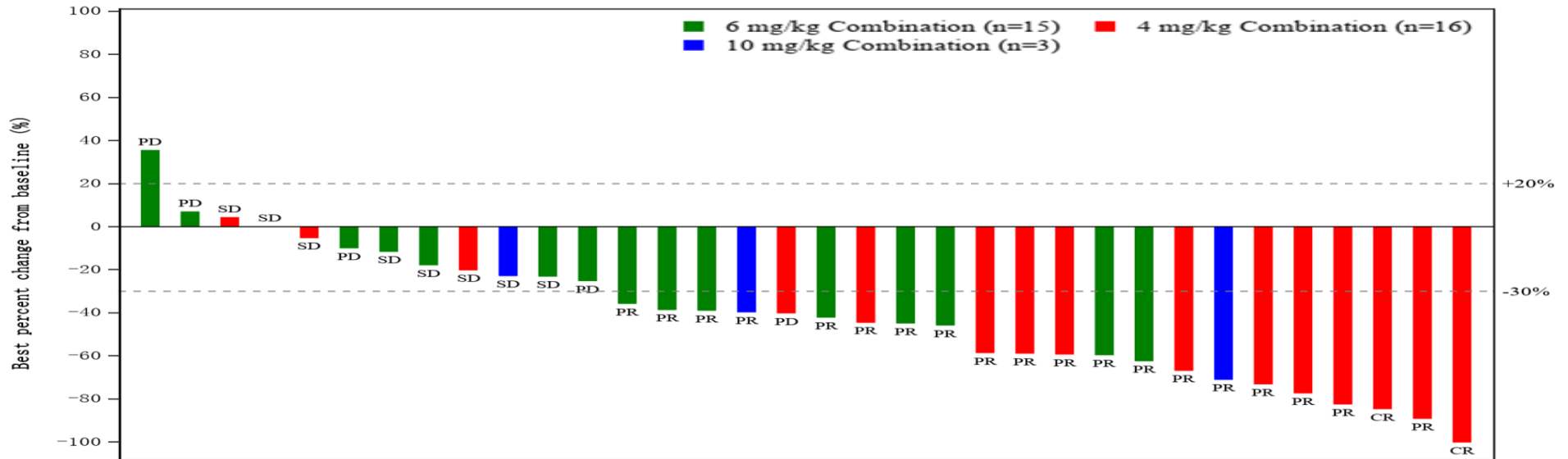


**ORR = 75% with 1 CR**

Sponsor	Treatment	Lines of therapy	No. of pts	MSI-H Tumor type	ORR	CR rate
Akesobio	AK104 (PD-1/CTLA-4 bispecific)	≥3L	7	CRC (6) BTC (1)	<b>100%</b>	<b>28.6%</b>
BMS	Nivolumab+ Ipilimumab <sup>1</sup>	≥2L	82	CRC (82)	56%	13%
BMS	Nivolumab <sup>3</sup>	≥2L	53	CRC(53)	32%	9%
Merck	Pembrolizumab <sup>4</sup>	≥3L	61	CRC(61)	33%	3.3%
Merck	Pembrolizumab <sup>5</sup>	≥2L	63	CRC(63)	33%	7.9%
Alphamab	KN035 <sup>2</sup> (PD-L1)	≥1L	103	CRC (65) GC(18) Other (20)	34.0%	4.9%

1. Checkmate-142, Cohort 2. Nivolumab label Oct2020; 2. KN035: 2020 ASCO; 3. Checkmate-142, Cohort 1, Nivolumab label Oct2020; 4. Keynote-164 Cohort A, J Clin Oncol 2019; 5. Keynote-164 Cohort B, J Clin Oncol 2019; 6. Keynote-158 J Clin Oncol 2019.

## 1L Gastric Cancer or GEJ (34 evaluable patients with 60 patients already enrolled)



**Cadonilimab in combination with Chemo showed better efficacy and improved 6 month PFS rate in comparison to PD-1 plus chemo combination therapy**

	Pembro + Chemo PD-L1(+) (N=257)	Tislelizumab + Chemo (N=15)	Cadonilimab + Chemo
ORR	48.6%	46.7%	61.7% (21/34) <sup>(2)</sup>
6 month PFS rate	53% <sup>(1)</sup>	/	76.5% (N=18, 4mg/kg cohort)
Median PFS (months)	6.9	6.1	7.8 (N=18, 4mg/kg cohort)

Source: Pembrolizumab KEYNOTE-062 JAMA Oncol. Published online September 3, 2020.  
Beigun PD-1 : Clin Cancer Res September 1 2020 (26) (17) 4542-4550

(1) Estimated from KM curve

(2) For all dose level

PFS :Progression Free Survival



# 1 Cadonilimab (PD-1/CTLA-4) – clinical summary

- **First-in-Class Bispecific PD-1/CTLA-4 Antibody**

- Consistent higher level of target-binding avidity compared to anti-PD-1 & anti-CTLA-4 co-administration
- Potential next generation of prevailing immune-oncology drug
- **Fast-track designation approval by US FDA and break-through therapy designation by China NMPA for 2L/3L cervical cancer**

- **Excellent Safety Profile**

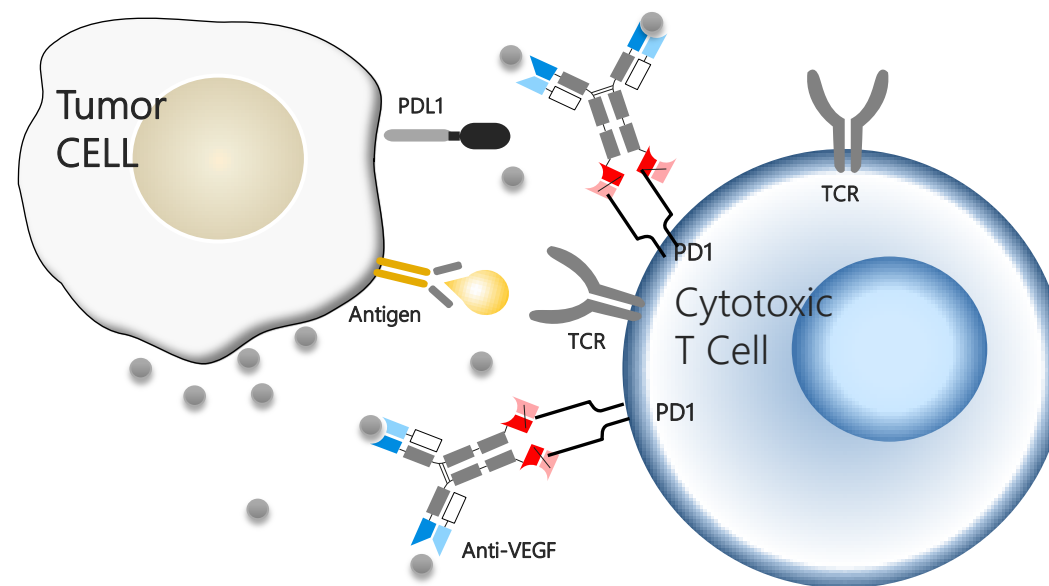
- Cadonilimab is **safe and well-tolerated at 10 mg/kg Q2W and 15 mg/kg Q3W**. Better safety profile compared to co-administration of anti-PD-1 & anti-CTLA-4 therapies
- The incidence rates of **TRAEs above grade 3 were approximately 1/3 that of anti-PD-1 & CTLA-4 combination therapies**

- **Superior Efficacy**

- Cadonilimab also showed **very encouraging efficacy** in heavily-treated patients with advanced solid tumors treated selected refractory/relapsed tumors
- We are **progressing** Cadonilimab **Phase 2 combo studies in large tumor indications** (i.e. NSCLC, GC and HCC)

- 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.




## Mechanism of Action



## 2 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.

- Dose escalation phase (Phase Ia) to determine the maximum tolerated dose (MTD)
- Dose expansion phase (Phase Ib) in subjects with selected tumor types with AK112 at the RP2D

Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Status				
					Phase I		Phase II	Pivotal	NDA Submitted
					Phase Ia	Phase Ib			
AK112	PD-1 / VEGF	Global	Mono 	Adv. solid tumors					
			Mono	Adv. solid tumors					

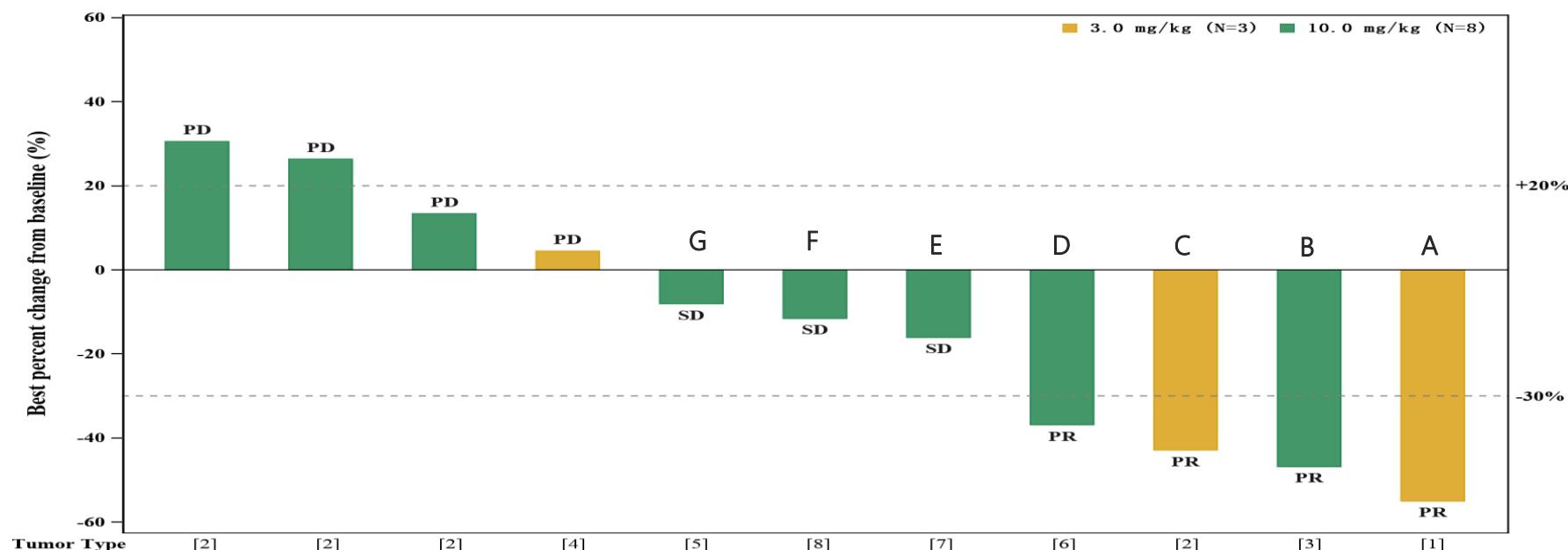
 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within Next Quarter

 Global trial

- We have obtained IND approval from NMPA in Aug 2020, started Phase I/II in China, and expect to enroll patients soon

## 2 AK112 (PD-1/VEGF) – clinical data summary

### Exciting Anti-Tumor Activity During Dose Escalation in PD-1 Non-responsive or PD-1 Pre-treated Tumors



[1]:Clear Cell Ovarian Cancer; [2]:Colorectal Cancer; [3]:Endometrial Cancer; [4]:Esophageal Cancer;

[5]:Granulosa Cell Tumor; [6]:Mesothelioma; [7]:Non-Small-Cell Lung Cancer (NSCLC); [8]:Ovarian Cancer

**ORR = 36% (4/11), DCR = 64% (7/11)**

A: Ovarian cancer, prior treatment with an investigational anti-PD-L1/CTLA-4 bispecific. Best overall response: PD.

B: Endometrial cancer, prior treatment with carboplatin + liposomal doxorubicin (1L) and paclitaxel (2L). Best overall response for both lines: PD .

C: MSS CRC, 3 lines of prior treatment including 1L FOLFOX + bevacizumab. Best overall response: PR.

D: Mesothelioma, prior treated with Pembrolizumab. Best overall response: CR.

E: NSCLC, prior treatment with Nivolumab. Best overall response: PD.

F: Ovarian cancer, prior treatment with Penpulimab (PD-1). Best overall response: SD.

G: Granulosa cell tumor, 4 lines of prior treatment including 3L Tisellizumab (PD-1). Best overall response: SD

Data cutoff date: September 28, 2020

- AK117 has the **same target as Gilead's Magrolimab (Hu5H9-G4)**
- AK117 binds to CD47 and blocks its interaction with SIRP $\alpha$  on the membranes of macrophages, thus promoting the phagocytosis of macrophages to tumor cells.
- AK117 does not induce hemagglutination (血凝反应) based on its designed low binding activity to red blood cells (RBCs).



**Robust anti-tumor efficacy  
with activities similar or  
better than Hu5F9**



**With eliminated RBC  
hemagglutination**



**With superior safety in both  
pre-clinical and current  
clinical studies**

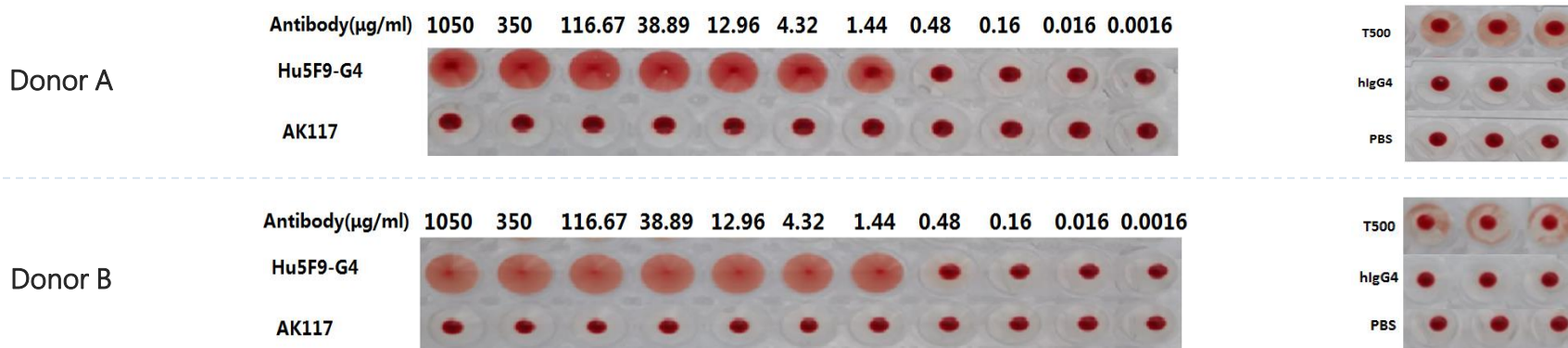
**AK117 is a potential best-in-class anti-CD47 mAB with eliminated hemagglutination effect**

### 3 AK117 (CD47) – Pre-clinical data summary

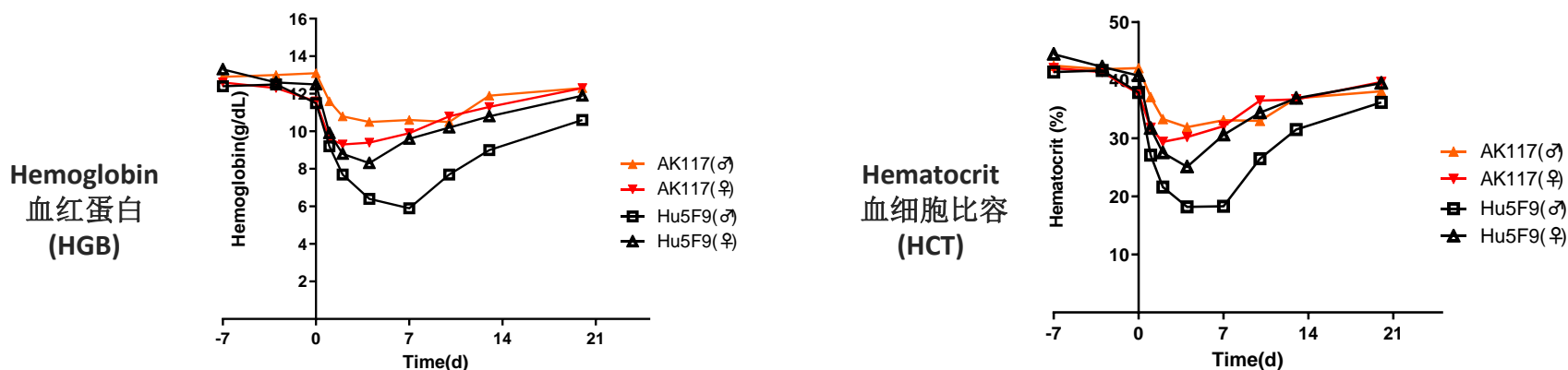
- Excellent safety profile

- AK117 shows lower promotion of phagocytosis to human RBCs and B cells vs Hu5F9-G4;
- AK117 has weakened binding activity to RBCs and B cells in comparison to Hu5F9-G4;
- AK117 has no hemagglutination of human RBCs.

#### AK117 does not induce hemagglutination of human RBCs



#### HGB and HCT level after single dose of AK117 in cynomolgus monkeys



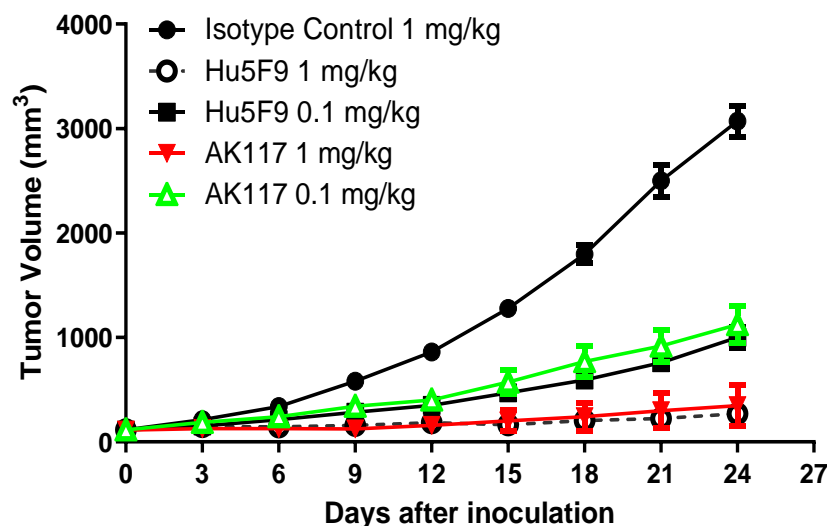
- AK117 caused a transient anemia right after injection, but quickly remained to normal.



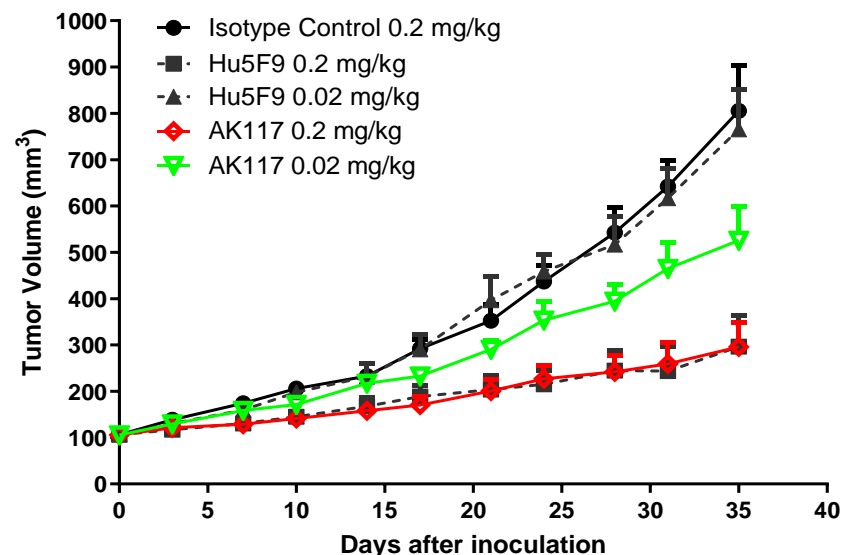
### 3 AK117 (CD47) – Pre-clinical data summary

#### Bioactivity in-vivo

##### SCID/Beige mouse with subcutaneous Raji tumor









##### SCID/beige mouse model with subcutaneous MDA-MB-231 tumor



- AK117 produces anti-tumor activity from tumor volume inhibition in two different mouse models.
- **Great activity**
  - AK117 shows comparable antigen binding activity to Gilead's Magrolimab (Hu5F9-G4);
  - AK117 shows comparable anti-tumor activity to Gilead's Magrolimab (Hu5F9-G4) in mouse models;

### 3 AK117 (CD47) – clinical development plan

Drug Candidate	Target	Comm. Rights	Mono/Combo	Indication	Status				
					Phase I		Phase II	Pivotal	NDA Submitted
					Phase Ia	Phase Ib			
AK117	CD47	Global	Mono	Solid tumor/ Lymphoma					
			+rituximab	CD20+ NHL			In planning		
			+PD-1	HNSCC			In planning		
			+HER2	HER2+GC			In planning		
			+azacitidine	AML, MDS			In planning		

 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within 1H 2021

#### Clinical development in advanced solid tumor / lymphoma

- Dose escalation has completed 0.3mg/kg, 1mg/kg, 3mg/kg, 10mg/kg cohorts, **and ready for dosing 20mg/kg cohort**. MAD dose of 45 mg/kg.
- **No drug-related effect on hemoglobin and reticulocytes, or drug-related anemia were observed so far.** Subjects have been dosed at 10mg/kg QW without need for a priming dose.

## 4 Penpulimab (PD-1, AK105) – clinical development plan

Focusing on combo trials with Chemo or Anlotinib for large indications, combined with monotherapy trials for niche indications for rapid approval

Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Status				
					Phase I		Phase II	Pivotal	NDA Submitted
					Phase Ia	Phase Ib			
AK105	PD-1	Global	Mono	3L R/R cHL					Completed
			→ Mono	≥3L NPC			In Progress		
			+Chemo	1L non-SQ NSCLC				In Progress	
			+Anlotinib	1L non-SQ NSCLC				In Progress	
			+Chemo	1L SQ NSCLC				In Progress	
			+Anlotinib	1L HCC				In Progress	
			+Anlotinib	2L GC				In Progress	
			+Anlotinib	dMMR			In Progress		
			+Chemo with/without anlotinib	1L NPC			In Progress		
			+Chemo	1L ESCC				In Progress	
			+Anlotinib	NSCLC, SCLC, HNC, thyroid cancer, mesothelioma and thymic cancer			In Progress		
			+Anlotinib	ESCC, UC, GC/GEJ, cholangiocarcinoma, neuroendocrine tumor (NET)			In Progress		
			Mono	Adv. solid tumors	In Progress				
			+Chemo with/without anlotinib	Neoadjuvant/adjuvant NSCLC			In Progress		

= Completed; 
 = Completed Patient Enrollment; 
 = In Progress; 
 = To Be Initiated within Next Quarter; 
 Large indications; 
 Registration trial

Global trial

- 3L R/R cHL
  - Expected to receive NDA approval in 2021
- ≥3L NPC
  - Expected to submit NDA in 1H 2021
- 1L SQ NSCLC
  - Expected to submit NDA for Penpulimab in combination with chemotherapy in 2021

## 4 Penpulimab (PD-1) – efficacy profile (cHL)

### Efficacy Profiles - Better Efficacy

**Penpulimab's ORR and CR rate for cHL were better than sintilimab, camrelizumab, pembrolizumab and nivolumab**

Response	Penpulimab (N=85) <sup>a</sup>	Sintilimab (N=96) <sup>b</sup>	Camrelizumab (N=75) <sup>b</sup>	Pembrolizumab (N=210) <sup>d</sup>	Nivolumab (N=258) <sup>b</sup>
<b>CR, %</b>	48.2%	28.0%	31.8%	27.6%	14%
<b>ORR, % (95% CI)</b>	89.4% (80.8%, 95% )	78.7% (67.7%, 87.3% )	77.3% ( 65.3%, 86.7%)	71.9% (65.3%, 77.9%)	69% (63%, 75%)
<b>6m DOR, % (95% CI) <sup>c</sup></b>	88.8% (78.9%, 94.2%)	82.4% (73.0%, 91.8%)	85.9% ( 72.6%, 93.0%)	--	--
<b>6m PFS, % (95% CI) <sup>c</sup></b>	87.8% (78.5%, 93.3%)	81.1% (72.2%, 90.0%)	84.6% (73.2%, 91.4%)	--	--

a: Data cut-off date: Aug 4, 2020

b: All efficacy results were obtained from their respective package insert

c: Based on Kaplan-Meier estimate

d: Chen R, Zinzani PL, etc. Blood. Oct 2019

## 4 Penpulimab (PD-1) – safety profile (cHL)

### Safety Profiles - Better Safety

**Penpulimab was safe and well-tolerated in Chinese cHL patients, and had potential safety advantages as compared to sintilimab and camrelizumab**

	Penpulimab (N=94) <sup>a</sup>	Sintilimab (N=96) <sup>b</sup>	Camrelizumab (N=75) <sup>b</sup>
Treatment related AE (TRAE) (%)	96.8%	99.0%	100.0%
TRAE (≥ Grade 3) (%)	19.1%	33.3%	26.7%
Treatment related SAE (%)	8.5%	21.9%	12.0%
TRAE leading to discontinuation (%)	4.3%	6.3%	5.3%
TRAE leading to treatment Interruption (%)	14.9%	31.3%	29.3%

a: Data cutoff date: Aug 4, 2020, TRAE including “unlikely related”

b: Safety results were obtained from their respective package insert

## 4 Penpulimab (PD-1) – efficacy profile (NPC)

### Efficacy Profiles - Comparison with other anti-PD-1 mAbs

**For NPC, Penpulimab's ORR was better than Nivolumab, Pembrolizumab and Toripalimab**

Response	Penpulimab <sup>a</sup> (N=111)	Nivolumab <sup>b</sup> (N=44)	Pembrolizumab <sup>c</sup> (N=27)	Toripalimab <sup>d</sup> (N=190)
<b>ORR, %</b>	27.9%	20.5%	/	20.5%
<b>ORR for PD-L1(+)<sup>e</sup></b>	41.9%	33%	25.9%	27.1%
<b>ORR for PD-L1(-)<sup>e</sup></b>	19.7%	13%	/	19.4%
<b>DCR, %</b>	49.5%	37.0%	77.8%	41.6%

a Date cutoff : Sep 18 2020, Including 1 confirmed complete response, 29 confirmed partial response and 1 ongoing response awaiting confirmation

b Nivolumab: J Clin Oncol 2018 May 10;36(14):1412-1418

c Pembrolizumab: Keynote 028, Hsu C 2017 J Clin Onco 35:4050-4056

d Toripalimab: POLARIS-02 2020 ASCO, 48 pts were PD-L1 positive and 134 pts were PD-L1 negative

e 43 pts were PD-L1 positive (TPS≥50%) and 66 pts were PD-L1 negative (TPS < 50%)



## 4 Penpulimab (PD-1) – safety profile (NPC)

### Safety Profiles - Comparison with other anti-PD-1 mAbs

**Penpulimab is safe and well-tolerated in NPC pts, and has potential safety advantages compared with other anti-PD-1 mAbs**

	Penpulimab <sup>a</sup> N=130	Nivolumab <sup>b</sup> N=45	Pembrolizumab <sup>c</sup> N=27	Toripalimab <sup>d</sup> N=190
<b>TRAE (%)</b>	80.0%	/	74.1%	92.6%
<b>≥ Grade 3 TRAE (%)</b>	15.4%	22.2%	29.6%	27.9%
<b>Treatment-related SAE (%)</b>	10.8%	/	/	/
<b>TRAE leading to discontinuation (%)</b>	3.1%	/	/	7.9%

a Date cutoff : Sep 18 2020. TRAE including adverse events considered as unlikely related to study drug by the investigator.

b Nivolumab: J Clin Oncol 2018 May 10;36(14):1412-1418

c Pembrolizumab: Keynote 028, Hsu C 2017 J Clin Onco 35:4050-4056

d Toripalimab: POLARIS-02 2020 ASCO

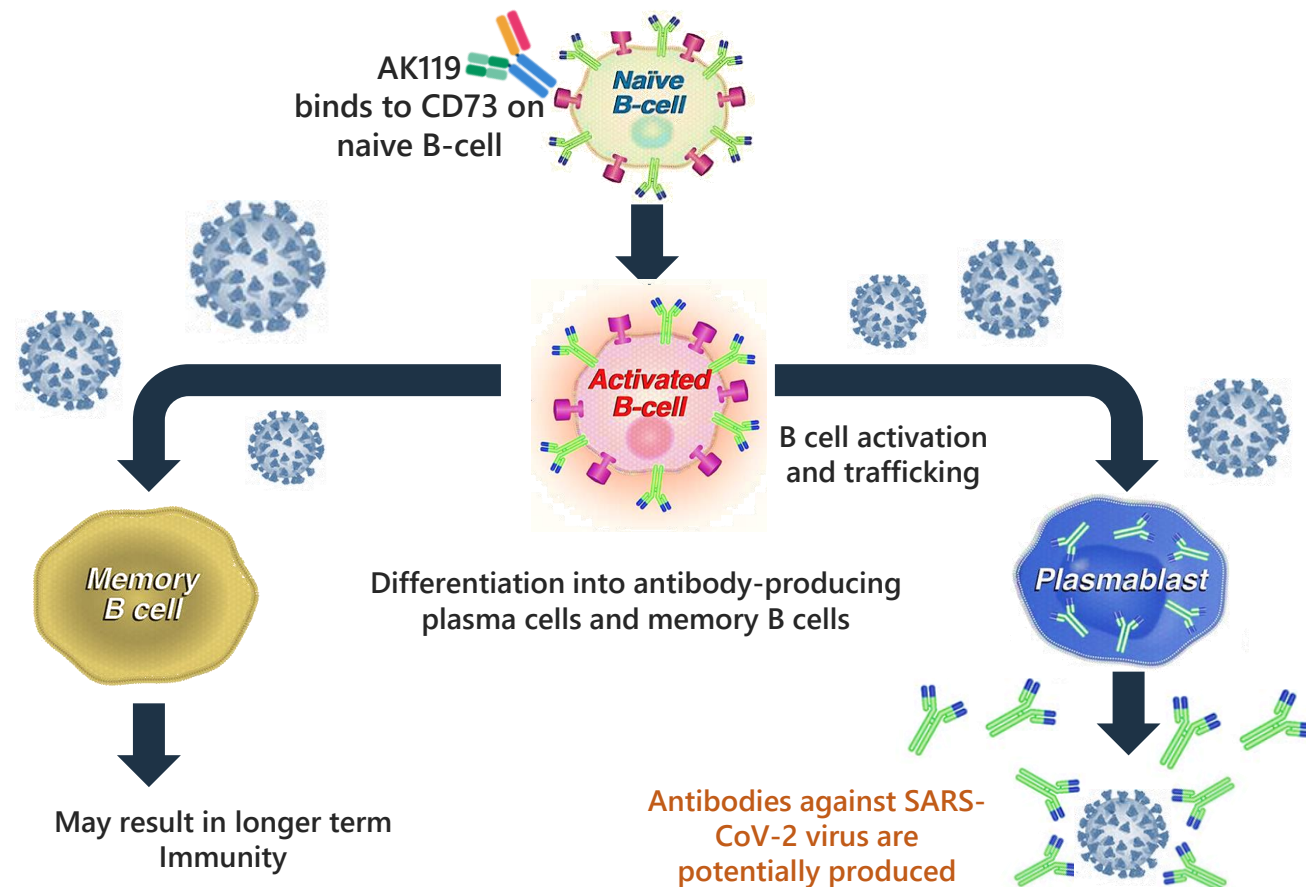
## 4 Penpulimab (PD-1) – clinical summary

- **Filed the NDA for Penpulimab in China for classical Hodgkin's lymphoma (cHL)**
- **Comprehensive development plans for penpulimab in NSCLC**
  - 1L sqNSCLC: + chemo vs chemo (Phase 3)
  - 1L non-sqNSCLC: + chemo vs chemo (Phase 3)
  - 1L non-sqNSCLC: + anlotinib vs chemo (Phase 3)
  - Neoadjuvant/adjuvant NSCLC: + chemo, + anlotinib (Phase 2)
- **Penpulimab demonstrates potential best-in-class safety profile**
  - Relatively lower incidence rate of  $\geq$  Grade 3 irAEs (e.g., pneumonitis 0.2%, hepatitis 0.9%, no colitis, pancreatitis or myocarditis observed)
  - Over 600 patients treated in China and Australia with patients treated for more than 2 years
- **Penpulimab profile is clinically similar or superior to approved anti-PD-1 agents**
  - >80% ORR and 49% CR rate in late-line cHL
  - 49% ORR in combination with chemo in 1L NSCLC
  - ~ 20% ORR in late line GI cancers (e.g., HCC, gastric and cholangiocarcinoma)
- **Penpulimab ready for global development**
  - US IND granted by FDA in March, 2018
  - US fast track application in metastatic NPC granted in Oct, 2020

## 5 AK119 (CD73) – antibody drug for COVID-19 treatment

*We want to contribute to the fight against COVID-19 by leveraging our immunology assets to find solutions to this pandemic as matter of priority*

- AK119 activates the immune system to fight COVID-19 via binding to immune cells and stimulating B cell activation and humoral immunity
- AK119 could enhance antibody production against SAR-CoV-2 virus in Humans
- **Completed regulatory and ethics submissions in New Zealand for AK119 for a COVID-19 trial in HV**

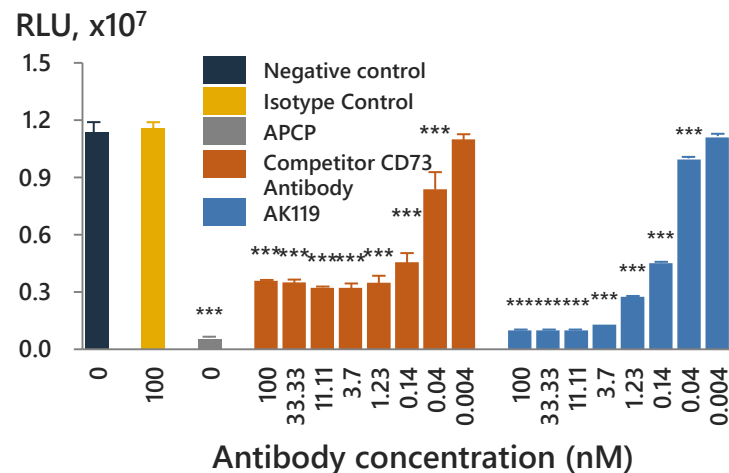


- CD73 expressed on immune cells in various tissue and in the vasculature creates an immune suppressive environment through adenosine generation

- AK119 is a full antagonist of CD73 activity, thus causing full scale B cell activation compared to leading competitor antibody in clinical development

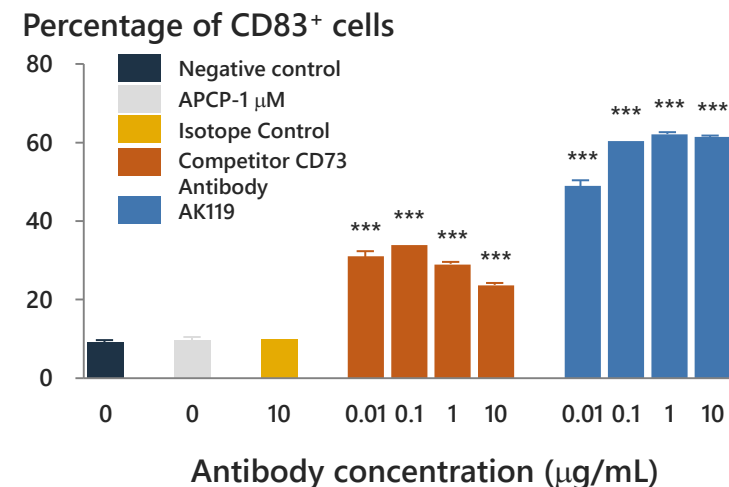
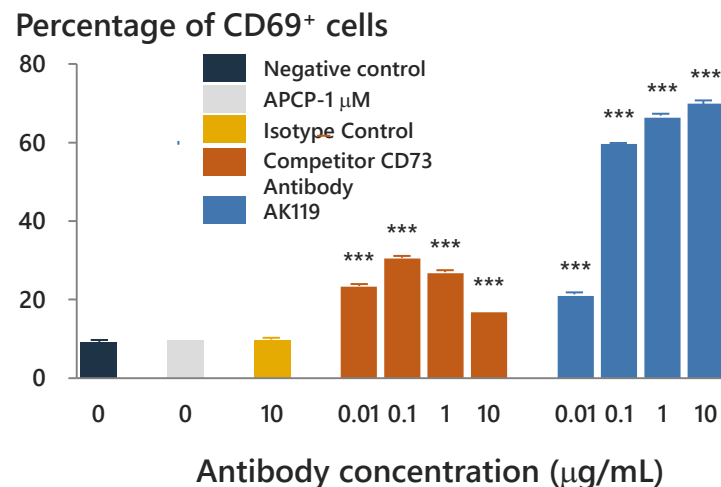
- A CD73 antibody with similar profile has been shown to dramatically enhance antibody production against SARS-CoV-2 in human

# AK119 (CD73) - stimulates B cell activation and humoral immunity



- CD73 expressed on immune cells in various tissues and in the vasculature create an immune suppressive environment through adenosine generation
- AK119 is a **full** antagonist of CD73, generating complete blockade of CD73 activity

## AK119 stimulation of B cells: elevation of CD69 and CD83 expression



## 5 AK119 (CD73) – clinical development plan

Our development of AK119 is aimed at the treatment of COVID-19 and solid tumors.

Drug Candidate	Target	Comm. Rights	Mono/Combo	Indication	Status				NDA Submitted
					Phase I		Phase II	Pivotal	
					Phase Ia	Phase Ib			
AK119	CD73	Global	Mono	COVID-19	<div><div></div></div>				
			Mono	COVID-19		<div><div></div></div>			
			+AK104	Solid tumors	<div><div></div></div>				
			+AK104	2L PDAC		<div><div></div></div>			
			+AK104	3L MSS CRC		<div><div></div></div>			
			+AK104 +Gem/Nab-Pac	1L PDAC		<div><div></div></div>			

 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within 1H 2021

### ■ COVID-19

- Phase 1a study in healthy volunteers is in progress
- Expected to initiate phase 1b study in mild to moderate COVID-19 patients in 1H 2021

### ■ Solid tumors

- Expected to initiate phase 1 study of AK119 in combination with AK104 in cancer patients (especially in PDAC, and MSS CRC) in 1H 2021

## 6 Other clinical stage products (cont'd)

### AK101 IL-12/IL-23



- Immunology
- Currently in phase 2b for Moderate-to-Severe Psoriasis. Wrapping up phase 2b study and analyzing phase 3 trial design soon
- Planning to initiate phase 1b/2 for UC soon
- Expect data readouts in next 12 months

### AK120 Anti-IL-4R



- Immunology
- Dupixent developed by Sanofi/Regeneron is expected to realize USD2bn revenue in 2019
- First healthy subject was dosed with AK120 in Phase I study in New Zealand (June 2020)
- First patient with severe atopic dermatitis in phase 1b trial was dosed in October in New Zealand
- Expect data readouts in next 12 months

### AK102 PCSK9



- Cardiovascular
- Four phase 2 trials for various indications well underway including HoFH, HeFH, and Hypercholesterolemia
- Active Phase III preparation is underway to ensure our timeline
- Potential first domestically developed PCSK9 drug
- Expect data readouts in next 12 months



## 6 Other clinical stage products (Cont'd)

### AK109 Anti-VEGFR-2



- Oncology
- First patient was dosed with AK109 in Phase I study in China (June 2020)
- Plan to conduct combo studies with AK104 in 2021
- Expect data readouts in next 12 months

### AK111 Anti-IL-17

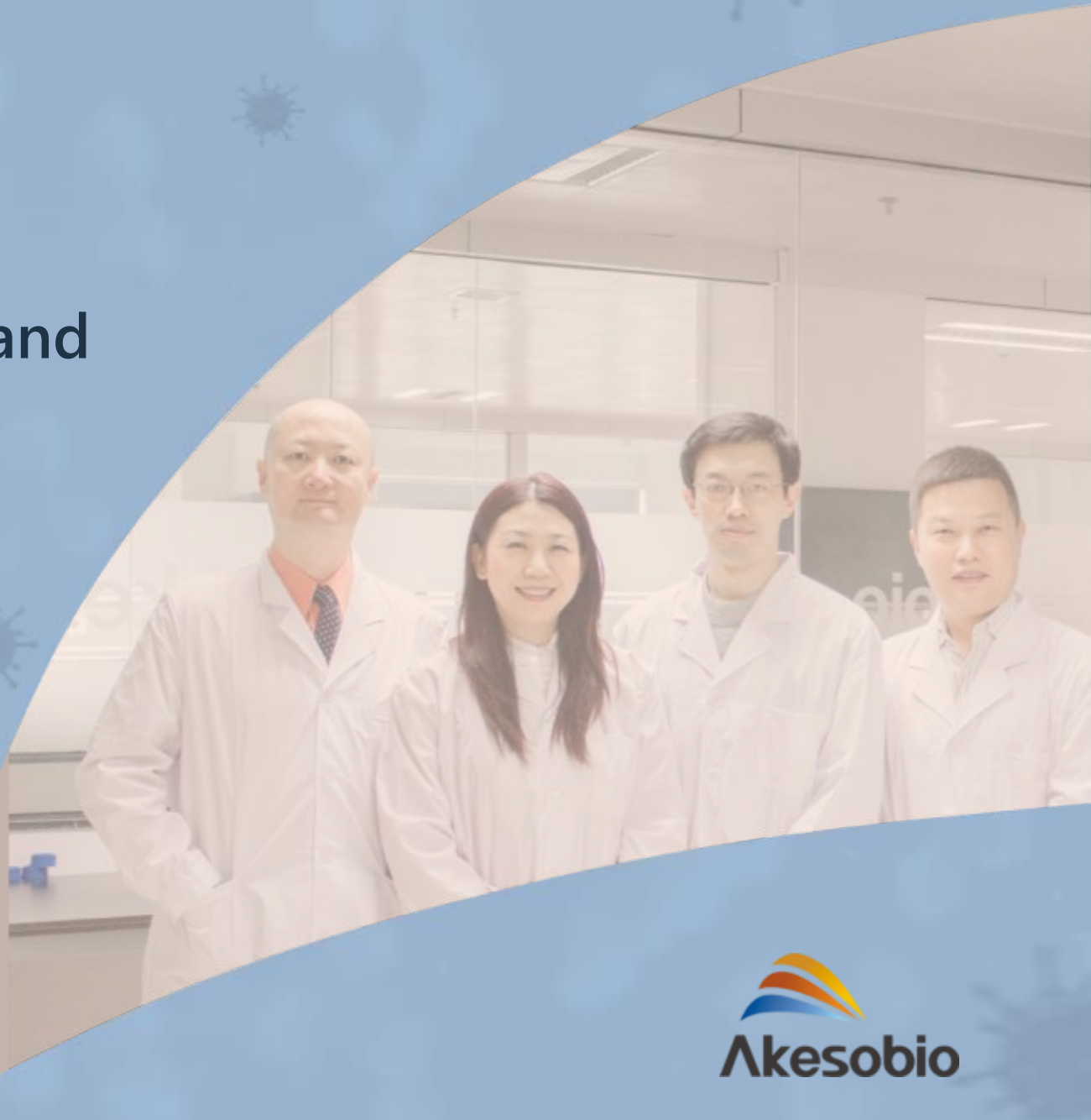


- Immunology
- First patient with moderate-to-severe plaque psoriasis was dosed with AK111 in Phase Ib study in China (June 2020)
- Expect data readouts in next 12 months

## SECTION 2

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# Future Milestones and Catalysts



## Clinical Advancement

- 1 **Receive NDA approval** for Penpulimab in 3L R/R cHL in 2021
- 2 **File NDA** for Penpulimab in  $\geq 3$ L NPC in 1H 2021
- 3 **File NDA** for Penpulimab in combination with chemotherapy for 1L squamous NSCLC in 2021
- 4 **File NDA** for AK104 (PD-1/CTLA-4) in 2L/3L cervical cancer in 2021
- 5 **Data readouts for various clinical development programs** in the next 12 months
- 6 AK114 (IL-1beta): **First-in-human** in 1H 2021

# Future milestones and catalysts (cont'd)

## Early Stage Assets

- 7 Advance at least one pre-clinical compound in our pipeline into clinic in 2021

## Commercialization

- 8 Commercialization of Penpulimab with CTTQ in 2021
- 9 Actively explore value-accretive strategic partnerships both in China and globally
- 10 Build an experienced and strong commercial team of approximately 300-500 personnel in 2021

## Manufacturing

- 11 Complete the phase 1 installation of Guangzhou manufacturing facility, which expects to house up to 20,000L bioreactor capacity, and commence operation by 1H 2021
- 12 Start the construction of the new manufacturing facility to add 40,000L bioreactor capacity in Zhongshan in 2H 2020

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# *Appendix*

## Q&A



## 7 Ebdarokimab (IL-12/IL-23, AK101) – clinical development plan

Our development of AK101 is aimed at the treatment of autoimmune diseases with unmet medical needs, including psoriasis and UC.

Drug Candidate	Target	Comm. Rights	Indication	Status				
				Phase I		Phase II	Pivotal	NDA Submitted
				Phase Ia	Phase Ib			
AK101	IL12 / IL23	Global	Moderate-to-severe plaque psoriasis					
			Moderate-to-severe UC					

 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within Next Quarter





### ■ Moderate to severe Psoriasis

- Two Phase IIb dose-ranging studies are in progress to evaluate AK101 optimal dose and dosing schedule
- Expected to initiate Phase III in 2021

### ■ UC

- Plan to initiate Phase Ib for UC in 2H 2020
- FDA IND was granted in October 2019. We are actively exploring co-development/licencing opportunities globally

We have initiated four Phase II trials in patients for various indications in China

Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Status			
					Phase I		Phase II	Pivotal
					Phase Ia	Phase Ib		
<u>Ebronucimab (AK102)</u>	PCSK9	Global	AK102 / Placebo+ Statin / Ezetimibe	HoFH				
			AK102/ Placebo+ Statin / Ezetimibe	HeFH				
			AK102/ Placebo+ Statin / Ezetimibe	Hypercholesterolemia				
			AK102/ Placebo+ Statin / Ezetimibe	HoFH、HeFH、Hypercholesterolemia				

 = Completed; 
  = Completed Patient Enrollment; 
  = In Progress; 
  = To Be Initiated within Next Quarter

### ■ Hypercholesterolemia

- Enrolled the first patient in Phase II trial for hypercholesterolemia with high cardiovascular risk in 1H 2020, the last patient will be in 2020.10

### ■ Heterozygous Familial Hypercholesterolemia (HeFH)

- Enrolled the first patient in Phase II trial for HeFH in 2020

### ■ Homozygous Familial Hypercholesterolemia (HoFH)

- Initiated Phase II trial in patients with HoFH in 2019