Alphamab Oncology Update

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Clinical Progress

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(1)	Alphamab Oncology Announces Two IND Application Approvals for new therapies of KN026 from NMPA CDE						
	May 13, 2020 论 回家药品监督管理局 Ational Medical Products Administration	Alphamab Oncology has received approvals for two IND applications for new therapies of KN026 from the Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) of China. First IND application is approved to apply lyophilized dosage of KN026 for treatment of HER2-positive or HER2 expression solid tumors, including in combination with docetaxel as first-line treatment to metastatic recurrent HER2-positive or HER2 expression breast cancer. Second IND application is approved to conduct clinical trials on evaluating of the effectiveness, safety and tolerance of KN046 in combination with KN026 for HER2-positive or HER2 expression solid tumors in Phase Ib clinical study [View details]					
(2)	2 Alphamab Oncology Announces Two IND Application Approvals for new therapies of KN046 from NMPA CDE						
	May 13, 2020 修 国家药品监督管理局 National Medical Products Administration	Alphamab Oncology has received approvals for two IND applications for new therapies of KN046 from the Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) of China. First IND application is aims to conduct clinical trials on KN046 in combination with Ningetinib Tosylate for the treatment of solid tumors and blood tumors, including but not limited to the treatment of hepatocellular carcinoma (HCC). Second IND application is approved to conduct clinical trials on evaluating of the effectiveness, safety and tolerance of KN046 in combination with KN026 for HER2-positive. [View details]					
3	Alphamab Oncology Presents Phase I Clinical Data of KN046 at the 2020 ASCO Annual Meeting						
	May 29, 2020	Alphamab Oncology has achieved promising results for the Phase I clinical trials of KN046 (PD-L1/CTLA4 bispecific antibody) and the clinical data was presented at the ASCO Annual Meeting. KN046 has shown exciting preliminary clinical results in patients with advanced solid tumors who previously failed immuno-checkpoint inhibitor treatment. It would be further validating the efficacy of K046 as monotherapy and combos with other drugs in late stage cancer patients who have failed PD-1 treatments. [View details]					
(4)	Alphamab Oncology Pre	esents Phase I Clinical Data of KN026 at the 2020 ASCO Annual Meeting					
	May 29, 2020	Alphamab Oncology has achieved promising results for the Phase I clinical trials of KN026 (HER2 bispecific) and the clinical data was presented at the ASCO Annual Meeting. The results of Phase I clinical trials show KN026 has encouraging anti-tumor activity in HER2-positive breast cancer patients					
	ASCO [®] AMERICAN SOCIETY OF CLINICAL ONCOLOGY	who progressed after multiple lines of anti-HER2 treatment. Based on the favorable efficacy, clinical trials would be conducted as first line therapy in HER2-positive solid tumors as soon as possible. [View details]					
5	-	Alphamab Oncology Announces Positive Clinical Data for Subcutaneous Injectable anti-PD-L1 Antibody KN035 at the 2020 ASCO Annual Meeting					
	May 29, 2020	Alphamab Oncology's partner 3D Medicines presented Phase II clinical results of KN035 (the subcutaneous injection PD-L1 antibody) from the treatment of advanced solid tumors with					

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microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) as monotherapy, and a combination therapy with KN035 plus chemotherapy for advanced gastric or gastroesophageal junction (G/GEJ) cancer in China. The company plans to submit BLA in China by the end of 2020. View details

Alphamab Oncology Presents Clinical Data for KN026 at the 2020 AACR Annual Meeting

June 22, 2020

AMERICAN AMERICAN ASSOCIATION for Cancer Research

Alphamab Oncology announced that the clinical study of the anti-HER2 bispecific antibody KN026 was shared at the AACR Annual Meeting. In order to determine the target concentration, researchers explored the anti-tumor activity under different KN026 exposures at various initial tumor volume and different proliferation rates based on preclinical PK-PD data and tumor growth parameters in breast cancer patients. View details

Preliminary Clinical Data Publication Plan

Year	Month	Conference	Title		
2020	November	(site)	KN046-IST-02 KN046+KN026 in HER2-positive solid tumors		
2021	January	ASCO [®] Gastrointestinal	KN046-IST-02 KN046+KN026 in HER2-positive CRC and GC/GEJ		
		ASCO Cancers Symposium	KN046-IST-01 ESCC (CRT)		
2021	January	2020 World Conference	KN046-201		
		on Lung Cancer Singapore	KN046-AUS-001 Thymic cancer		
2021	April	American Association for Cancer Reasoch	KN046-203		
	June		KN046-202		
2021		ASCO	KN026-202		
			KN026-203		
2021	21 September ESVO		KN046-204		

Essay must be accepted for submission

The results of clinical trials can not be predicted
 2020 WCLC conference is postponed to 2021, January

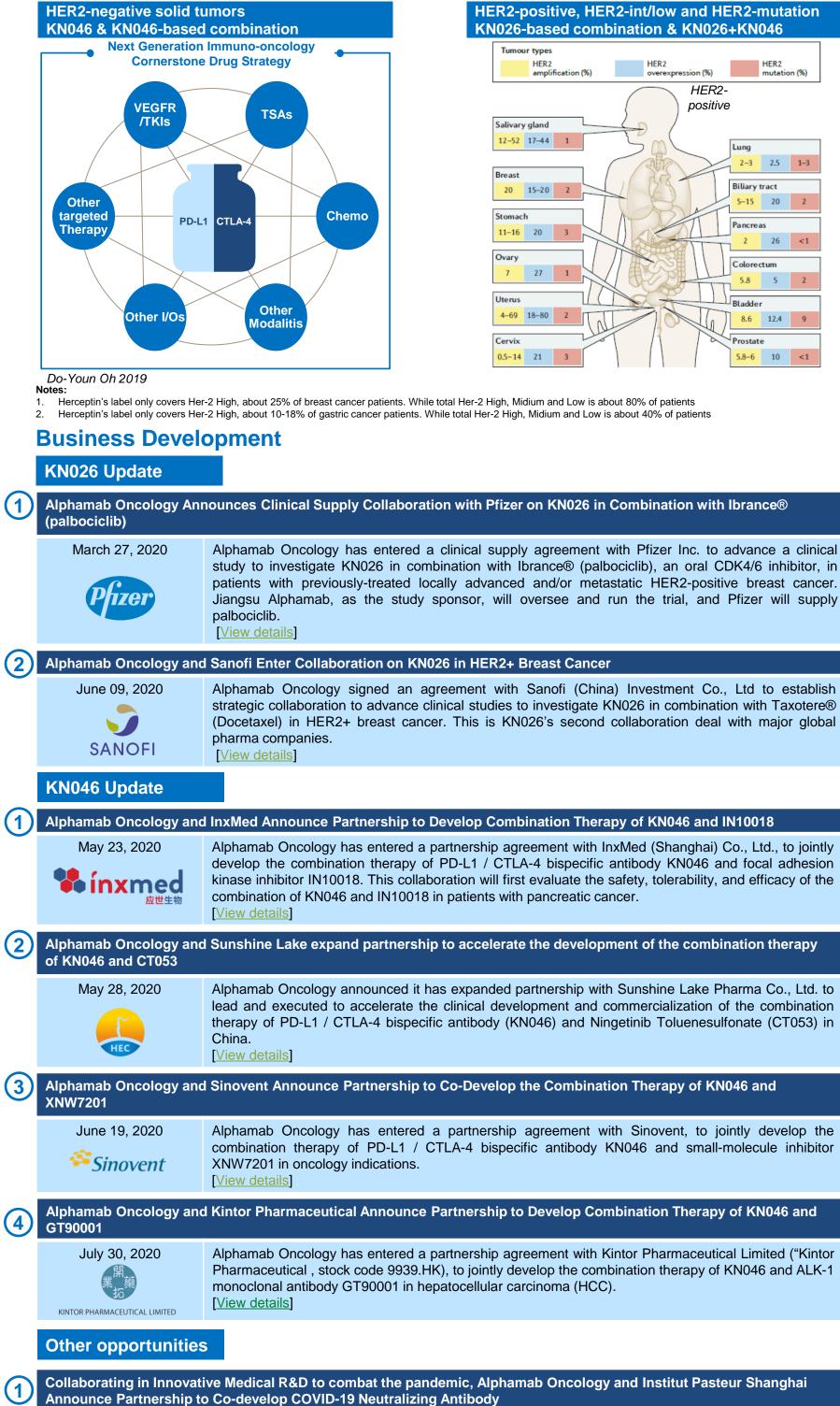
Preliminary Clinical Development Plan

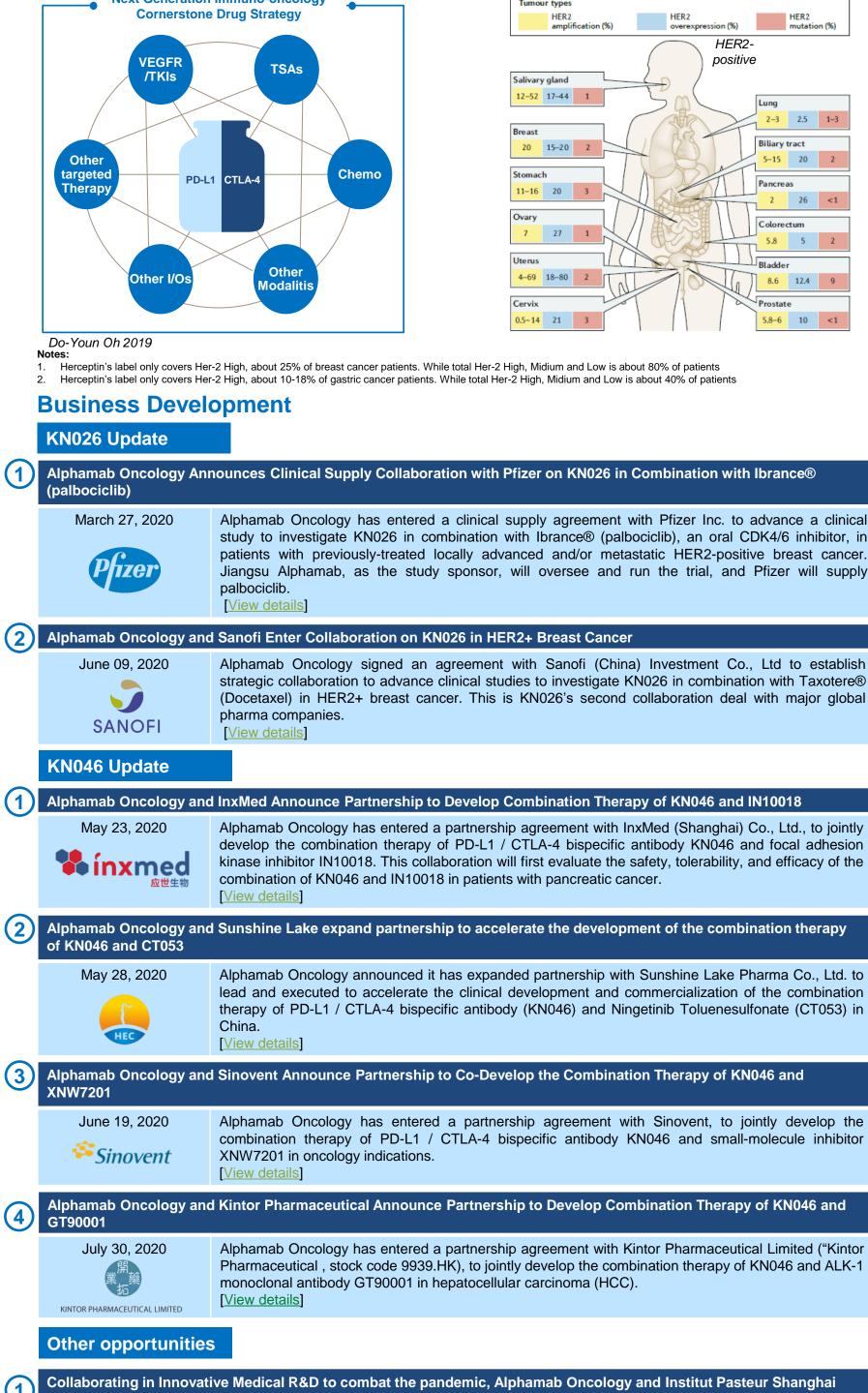
KN046 KN026

Program	Key indication	Preclinical	Phase I	Phase II	Phase III	BLA
	Thymic carcinoma		Registrat	ion trial (in p	eparation)	
	NPC		Registrat	ion trial (in p	eparation)	
-	NSCLC, 1L (<i>KN046+CT</i>)		Registrat	ion trial (in p	eparation)	
	NSCLC, PD1/PD-L1 ref/rel (KN046 or KN046+TKI)					۵
(N046	NSCLC, stage III (KN046+RT)					
PD-L1/CTLA-4)	TNBC, 1L (KN046+nab-paclitaxel)					
	TNBC, neoadjuvant					
	MSI-H/dMMR CRC, neoadjuvant) ک
	HCC, 1L (KN046+TKIs)					
	ESCC, 1L (KN046+CT, KN046+CRT)					
7	HER2-positive MBC, 1L (KN026+docetaxel)		Registrat	ion trial (in p	eparation)	
N026 HER2 bispecific)	HER2/HR-positive MBC, late line (KN026+CDK4/6+fulvestrant)					
. ,	HER2-low MBC & mGC/GEJ, late line (KN026)					
7	(HER2-positive mGC/GEJ (KN026+KN046)					۵ 🕒
KN026+KN046	HER2-positive solid tumors (KN026+KN046)) ک

Pivotal trail to be initiated in the near term

Business Development Strategy





June 10, 2020

Alphamab Oncology has entered a partnership agreement with Institut Pasteur of Shanghai, Chinese



Academy of Sciences on the co-development, manufacturing and commercialization of therapeutic antibody for Corona Virus Disease 2019 (COVID-19) worldwide. View details

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WuXi Biologics

Roche

Management Team Update



- Vice President, Regulatory Affairs Li Wan, Ph.D., RAC Over fifteen years of industry experience in global regulatory affairs and project management Served various positions in a number of pharmaceutical companies including Pfizer and
- Novartis in the US, Luye Pharma
- Led many global IND/CTA/NDA submissions and obtained approvals for small molecules and biologics products, with expert knowledge of the FDA, EMA, NMPA, PMDA, and ICH regulations
- Doctoral degree in Pharmaceutical Science from Rutgers University, MS/BS degrees in Biology from Nanjing University



Vice President, Quality Weidong Ma

- 25 years of extensive experience in Quality Management
- Served various positions in a number of pharmaceutical companies including WuXi Biologics, Amgen China and Roche Shanghai
- Led team to pass several audits from FDA, EMA and NMPA
- B.S in Chemistry from Shanghai Normal University

Manufacturing Update

Jiangsu Alphamab's New Manufacturing Facilities' Phase I production lines Have Received "Drug Production License"

Alphamab Oncology announced the Phase I 2x2,000L production lines of its new manufacturing July 06, 2020 facilities which has a designed total capacity over 30,000L and is located at No. 175 Fangzhou Road, Suzhou Industrial Park, Suzhou City, Jiangsu Province, has obtained "Drug Production License" by Jiangsu Provincial Drug Administration. [View details]





About Alphamab Oncology



We are a leading clinical-stage biopharmaceutical company in China with a fully-integrated

proprietary biologics platform in bispecifics and protein engineering, delivering world-class innovative therapeutic biologics to cancer patients globally.

Proven Team	Global Rights	Innovation	Integrated Platform		
 Founded by a visionary scientist who has made contributions to over 100 patents and patent applications since 2011 	All in-house developed candidatesGlobal rights (IP, Commercial)	All in-house developed proprietary sdAb, CRIB and CRAM	Fully-integrated platform consisting of drug discovery, development and manufacturing		
Strong in-house R&D contributed to the CMC processes of many biosimilar	 Ongoing Australia/China and imminent US trials for KN046 	 Robust first-in-class global next-generation product pipeline 			

- candidates including 4 out of 11 biosimilar BLAs filed in China since 2017
- Ongoing US/China trials for KN026
- Ongoing US/Japan/China trials for KN035

Product Overview

