

The background of the slide is a complex, abstract pattern of blue spheres and rods. The spheres are semi-transparent and have a glossy, reflective surface, showing highlights and shadows. They are connected by thin, cylindrical rods, creating a network-like structure that resembles a molecular model or a data network. The pattern is dense and fills the entire frame, with elements overlapping and receding into the background.

# Investor Relations **GENEXINE**

November . 2020

# 01 Genexine Overview



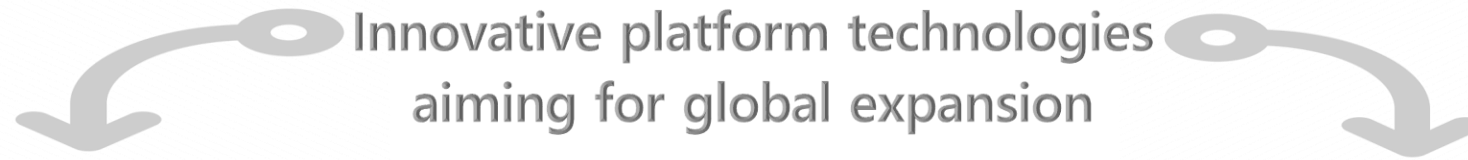
**Genexine**

*"Focused on the Development of  
Innovative Immunotherapeutics and  
Saving the lives of Patients."*

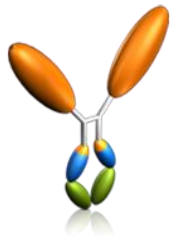
Chairman/CEO	<ul style="list-style-type: none"><li>• Young-Chul Sung Ph.D.</li></ul>
Key Milestones	<ul style="list-style-type: none"><li>• Established in June, 1999</li><li>• Listed on KOSDAQ since 2009</li></ul>
Core platform technologies	<ul style="list-style-type: none"><li>• hyFc antibody fusion technology</li><li>• DNA vaccine technology</li></ul>
Focus area of R&D	<ul style="list-style-type: none"><li>• Immuno-oncology</li><li>• Orphan drugs</li></ul>
Employees	<ul style="list-style-type: none"><li>• 155 (MD 1, Ph.D 20, MS 55)</li></ul>
Market Cap	<ul style="list-style-type: none"><li>• \$2.5 bn (October 2020)</li></ul>
Location	<ul style="list-style-type: none"><li>• Pangyo Korea Bio Park, Gyeonggi-do, Korea</li></ul>



## 02 Genexine's Platform Technologies



### hyFc™ (Long-acting protein drug)



Increased protein activity by combining IgD (flexible hinge) & IgG4 (stable long acting) for applying various APIs.

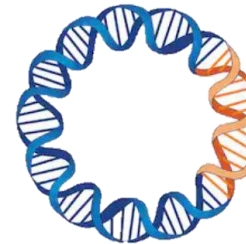
#### First-in-Class

- Immuno-oncology drug (GX-I7)
- Immunosuppressive drug (GX-P1, GX-P10)

#### Best-in-Class

- Growth hormone deficiency treatment drug (GX-H9)
- Chronic kidney disease-induced Anemia correction drug (GX-E4)
- Neutropenia correction drug (GX-G3)
- Type 2 Diabetes treatment drug (GX-G6)
- Short bowel syndrome treatment drug (GX-G8)

### DNA vaccine (cancer therapeutic/ infectious disease)



innovative gene therapy can provide preventive and therapeutic vaccines through strong immune response.

#### First-in-Class

##### Therapeutic DNA Vaccine

- Cervical cancer, Head and Neck cancer vaccine (GX-188E, GX-200 series)

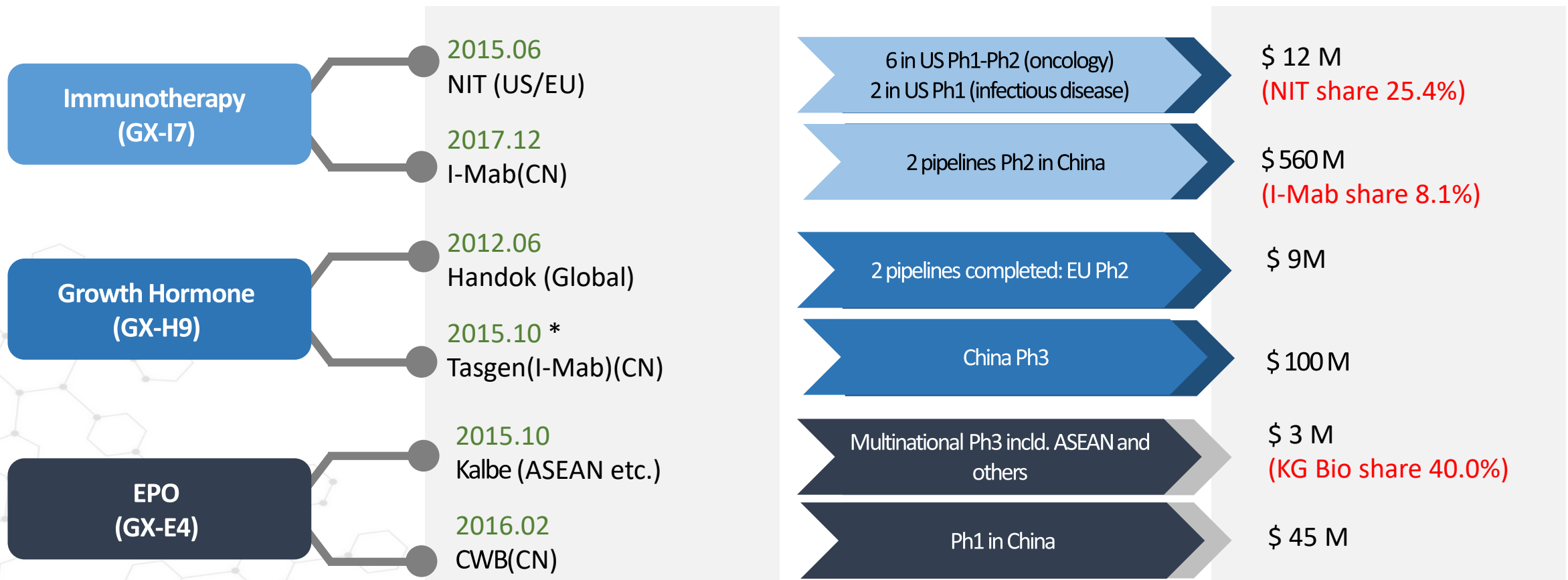
#### First-in-Class

##### DNA Vaccine for Prevention

- COVID-19 vaccine (GX-19)

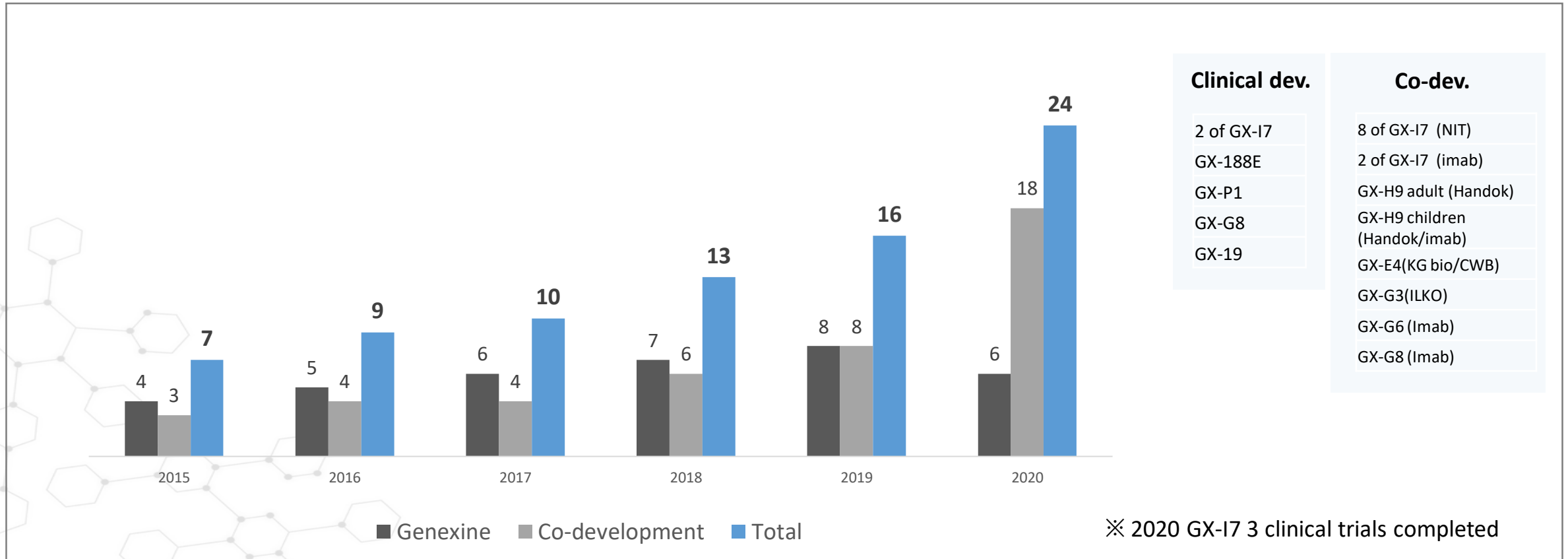
# 03 Genexine's Open Innovation - L/O and Strong Partnership

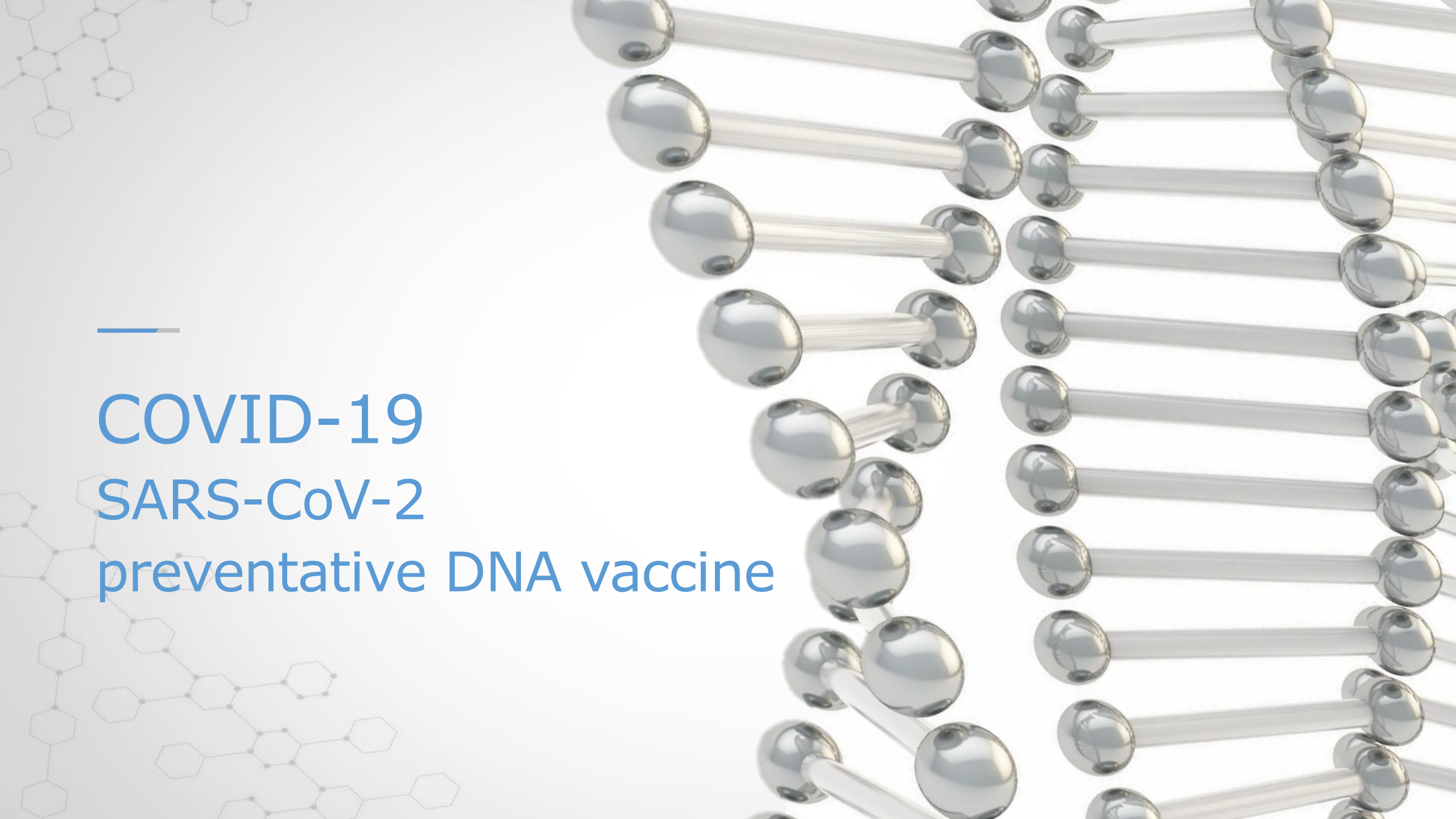
- Win-Win strategy with L/O partner company: share hold leads to strong partnership building process
- As clinical stage advances partners' company value increases + L/O value increases.



# 04 Genexine's Open Innovation : Co-development Strategy

- 6 (by GX alone) +18 (co-development trials) = **24 pipeline in clinical stage**
- Compare to 2015 number of clinical pipelines increased 3.5-folds
- R&D cost kept approx. \$ 40 M since 2017

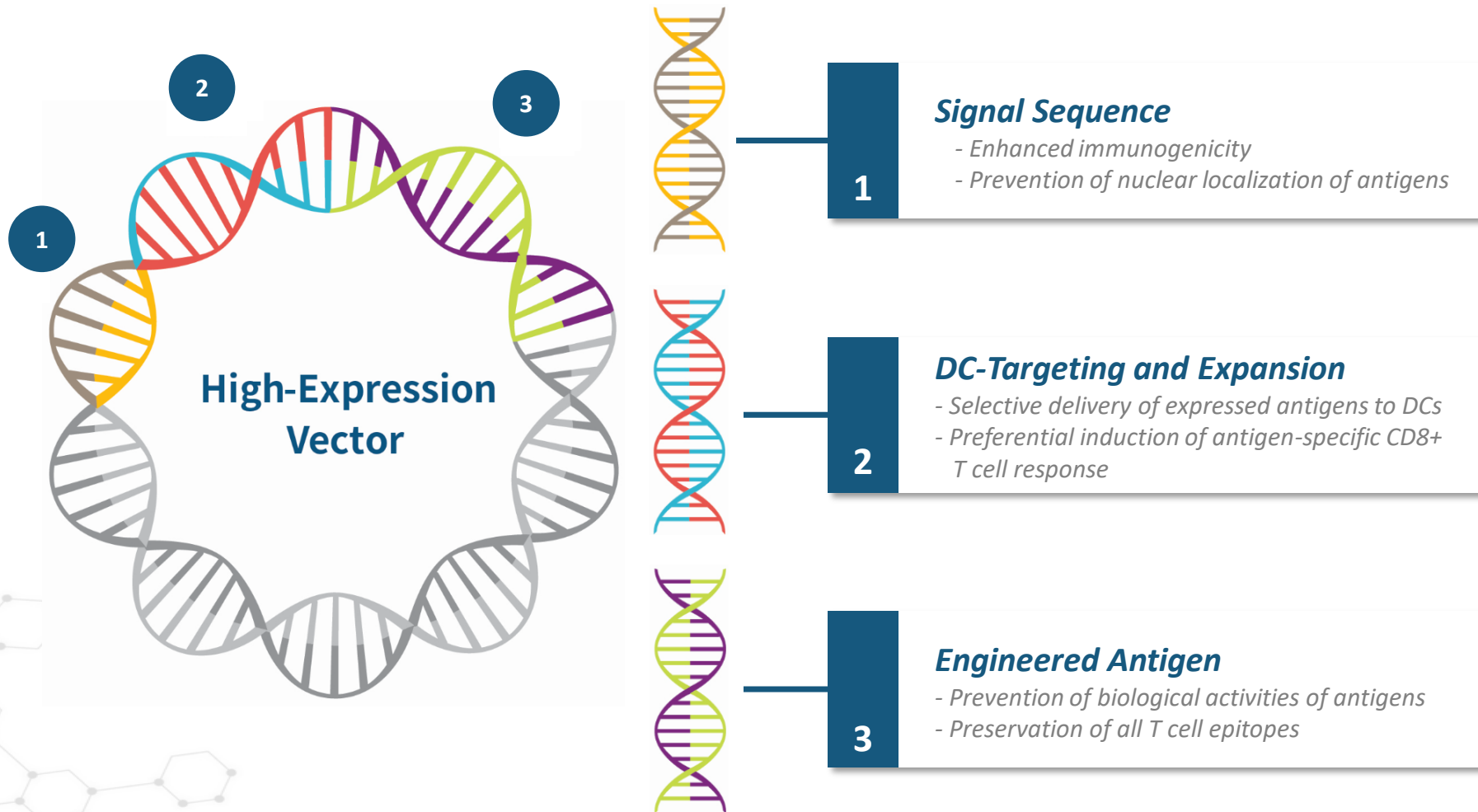




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# COVID-19 SARS-CoV-2 preventative DNA vaccine

# 05 Genexine's DNA vaccine Platform technology



✓ Clinically demonstrated safety and efficacy!

# 06 GX-188E : High efficacy and safety results (with Keytruda)

- **Interim analysis reported (KEYNOTE-567) at AACR in April 2020, Results from clinical trial phase 2 for combination with Keytruda**
  - Efficient HPV-specific immune responses induced in 78% of patient.
  - Excellent safety and tolerability (\*similar side effects observed in Keytruda mono. and combination therapy).

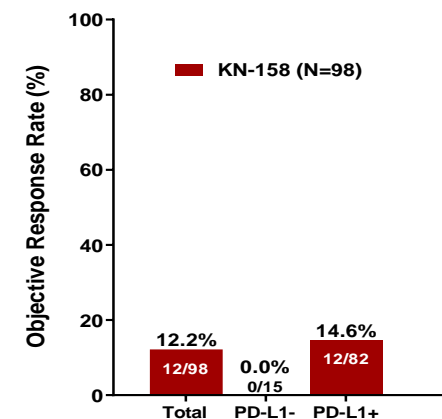
## Ph2 Interim Result

ORR (%)	Efficacy set <sup>a</sup> (N=26)	PD-L1 status <sup>b</sup>		HPV type	
		Positive (N=20)	Negative (N=6)	HPV16 (N=19)	HPV18or both (N=7)
CR	4 (15.4)	4 (20.0)	0 (0.0)	4 (21.1)	0 (0.0)
PR	7 (26.9)	6 (30.0)	1 (16.7)	5 (26.3)	2 (28.6)
SD	4 (15.4)	3 (15.0)	1 (16.7)	3 (15.8)	1 (14.3)
PD	11 (42.3)	7 (35.0)	4 (66.7)	7 (36.8)	4 (57.1)
<b>ORR</b>	<b>11 (42.4)</b>	<b>10 (50.0)</b>	<b>1 (16.7)</b>	<b>9 (47.4)</b>	<b>2 (28.6)</b>
DCR	15 (57.7)	13 (65.0)	2 (33.3)	12 (63.2)	3 (42.9)

AACR 2020 Poster Presentation

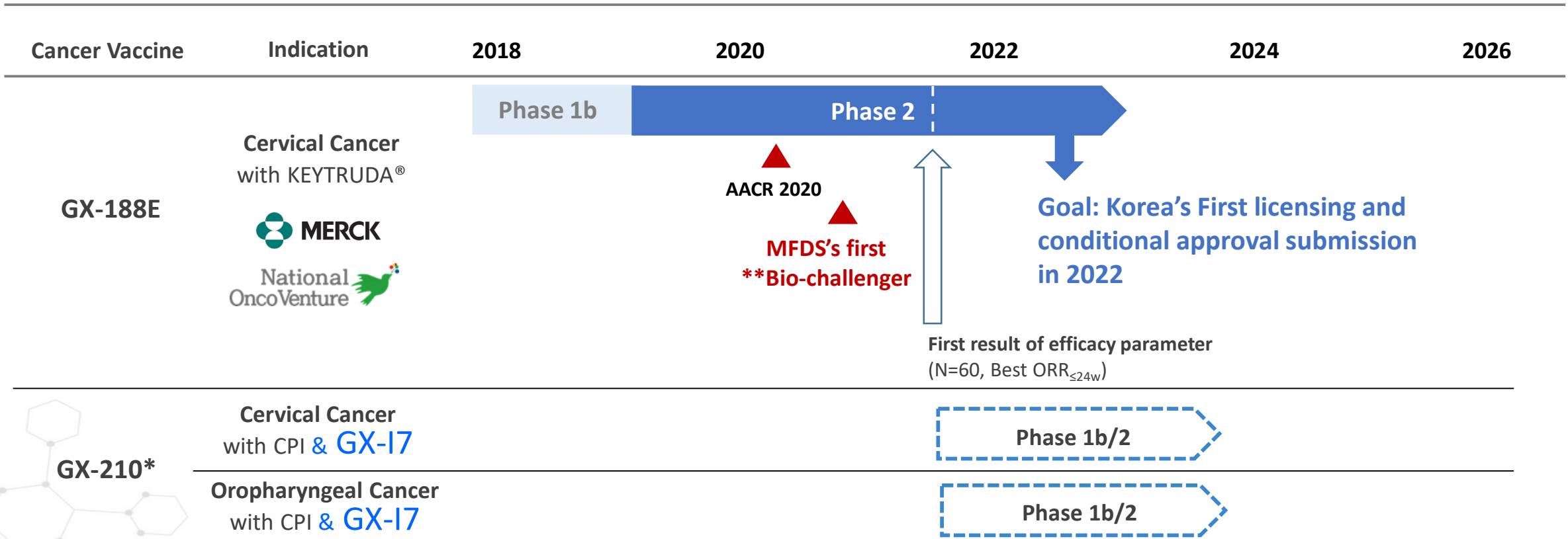
### Monotherapy of Keytruda (KEYNOTE-158, N=98)

- PD-L1-positive : ORR 14.6%
- PD-L1-negative: no ORR





# 07 GX-188E: Clinical Trial & Development Timeline

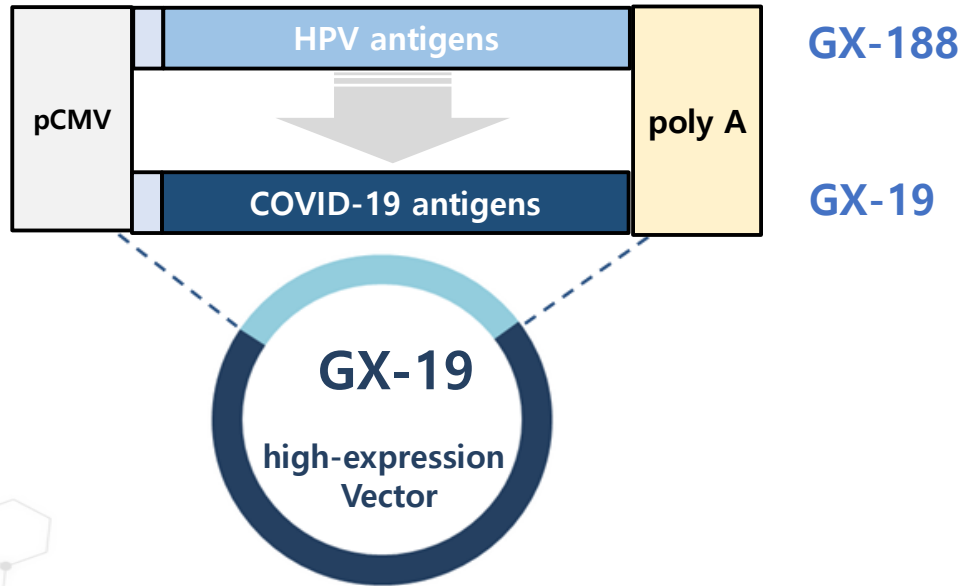


\*Next Generation of HPV DNA Vaccine: semi-personalized vaccine

- \*\*Bio Challenger program**
- MFDS selected Genexine's GX-188E as the first "Bio-Challenger" in June 2020.
  - MFDS provides overall specialized services by assigning dedicated personnel for accelerated process in registration, review, etc.

# 08 COVID-19 DNA vaccine

*"already acquired safety and efficacy from 300 patients"*



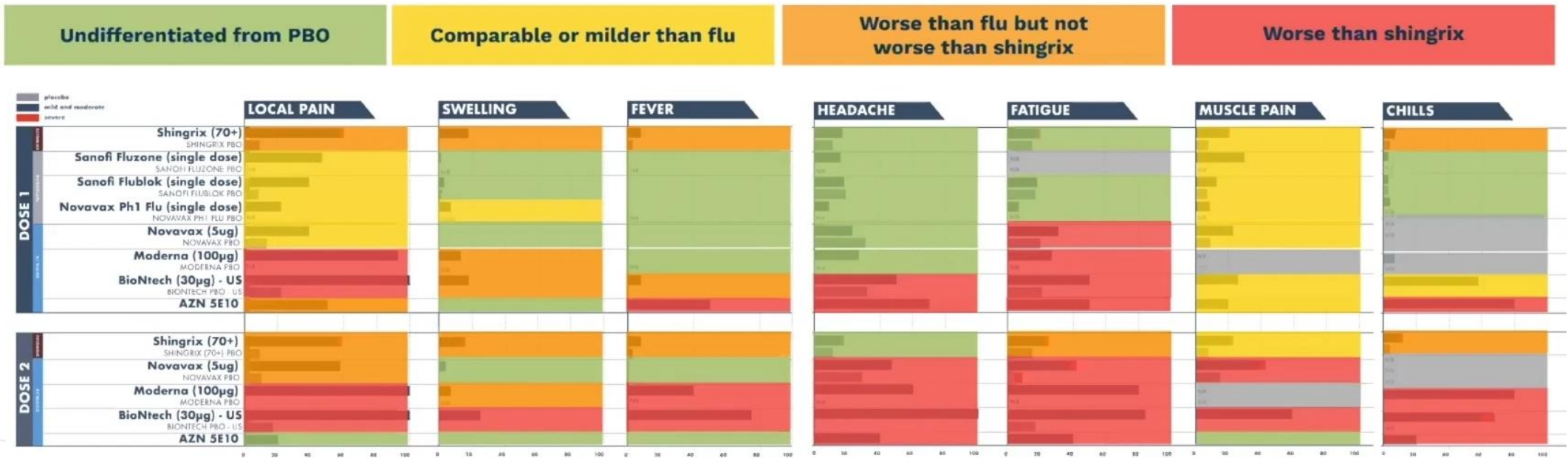
## GX-19 Development Outline/Overview

Type	• DNA vaccine
Code	• GX-19-HV- 001
Number of subjects	• Phase 1 : N=60 (20 per dose group) • Phase 2a : N=150 (100/placebo 50)
Study objectives	• Evaluate the safety, tolerability, and immune response of doses
Target subjects	• Healthy adults aged 19 ~ 50
Frequency & Method	• Intramuscular injection (2 injections/4 weeks)
Delivery devices	• Electroporator, EP • Needle free injection system
Clinical sites	• 6 institutions including Severance Hospital

## GX-19 Development Timeline

- Mar 2020 : Consortium formation among six institutions (Genexine, Binex, IVI, GenNBio, KAIST, POSTECH)
- June 2020 : Ph1/2a MFDS approved.
- 4Q 2020 : Ph1 completion and Ph2a start
- 3Q 2021 : Conditional approval submission

# 09 DNA vaccine shows good safety profile



"DOSE 2" of Novavax, Moderna, and BioNtech's vaccines induced more severe AE than "DOSE 1"

Source : RA Capital

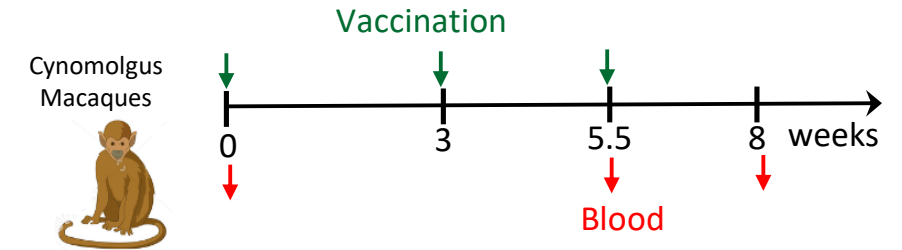
DNA Vaccine

(Multiple dose)

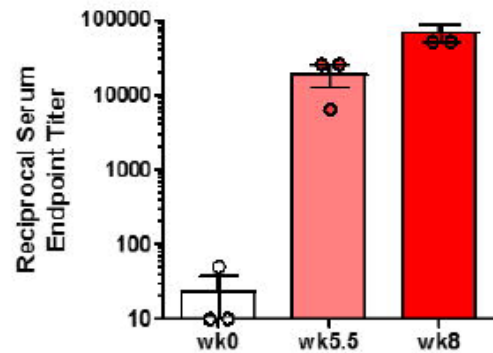
Pain by injection but transient

# 10 Immunogenicity of GX-19 in macaques

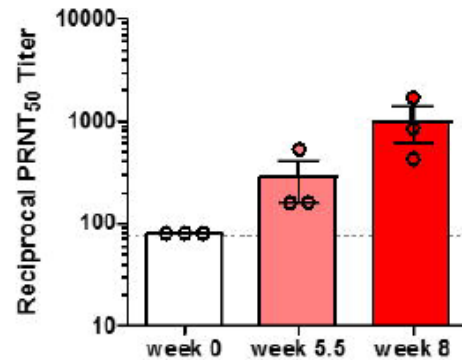
- S-specific Ab & neutralizing Ab were induced in macaques
- IFN- $\gamma$  ELISPOT & CD4 $^{+}$ /CD8 $^{+}$  T cell responses were induced



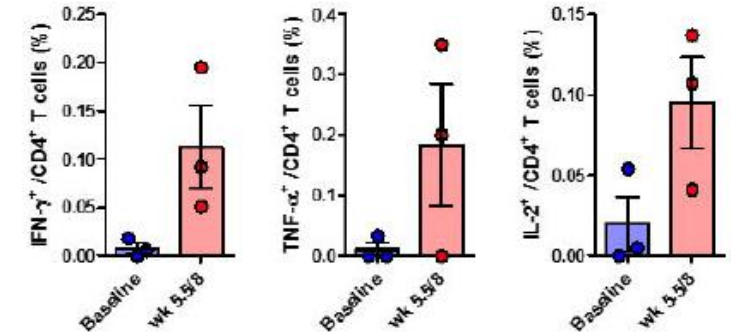
A. S-specific binding Ab



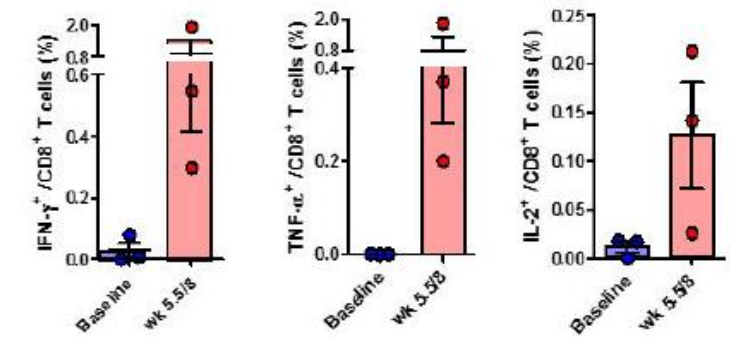
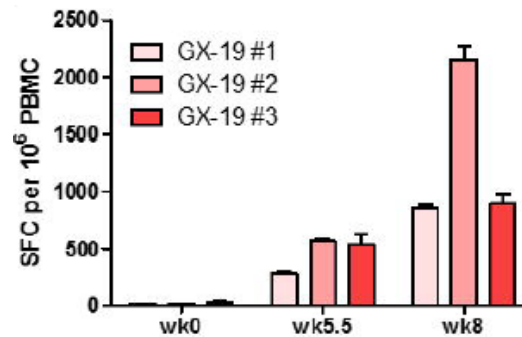
B. nAb to live SARS-CoV-2



D. Th1 cytokine-secreting CD4 $^{+}$ /CD8 $^{+}$  T cells



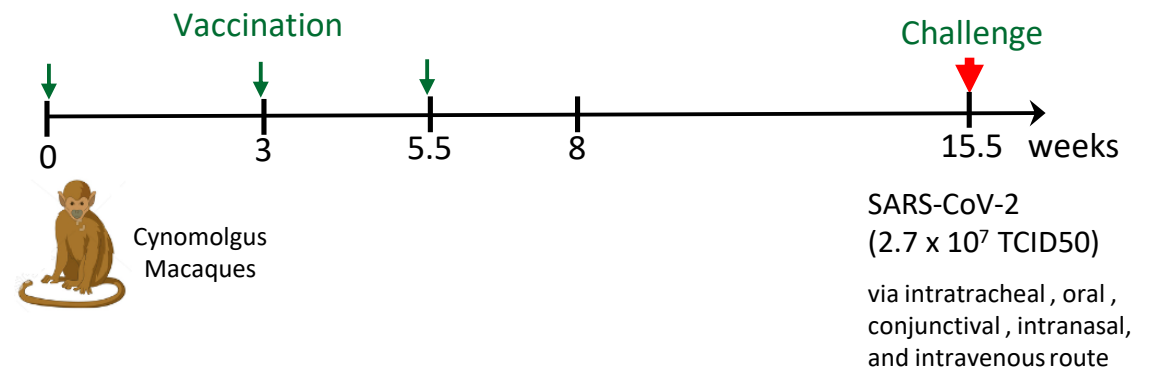
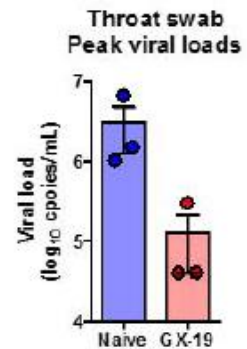
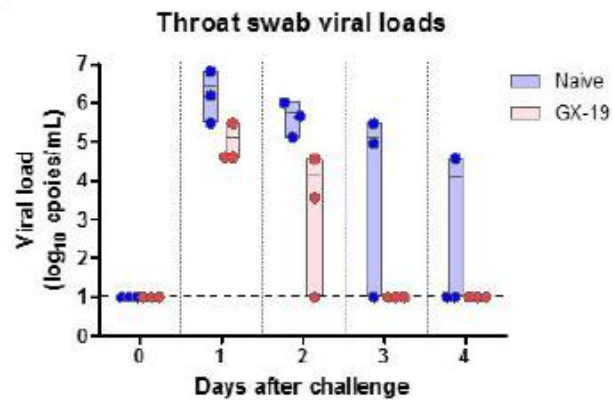
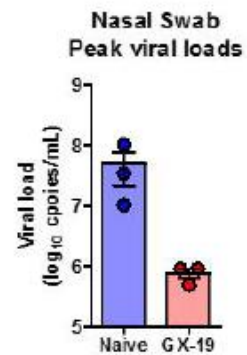
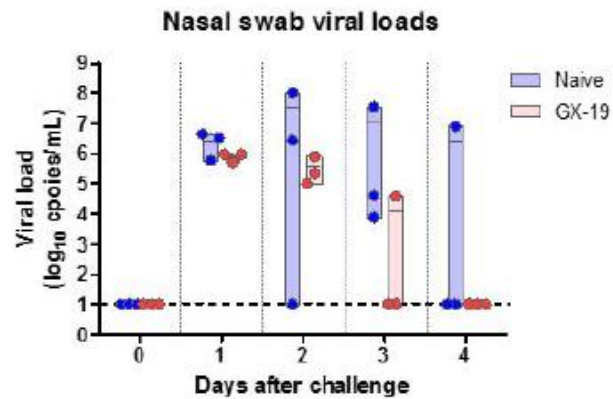
C. IFN- $\gamma$  ELISPOT responses





# 11 Protection against SARS-CoV-2 challenge : Viral loads

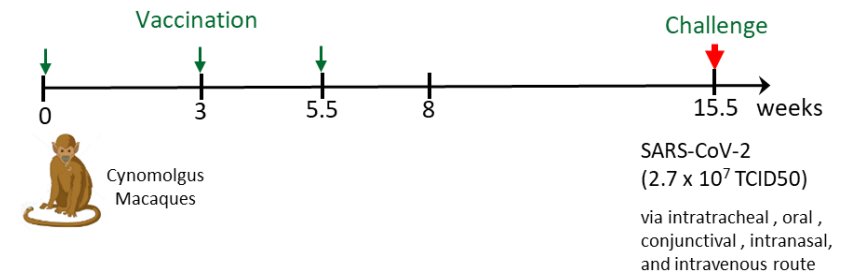
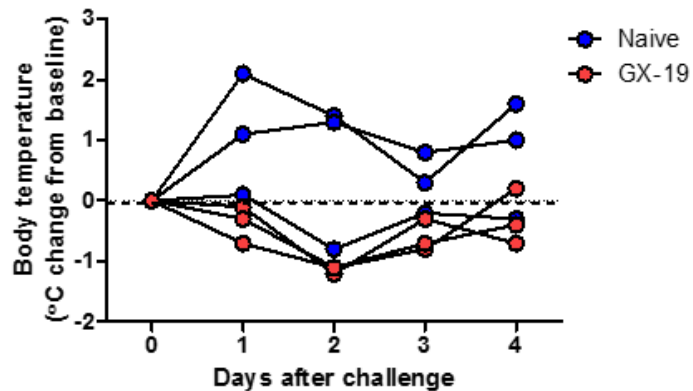
- Ten weeks after the final immunization, macaques were challenge with SARS-CoV-2 via combined route
- GX-19-immunized macaques showed reduced peak viral loads and early clearance of the virus



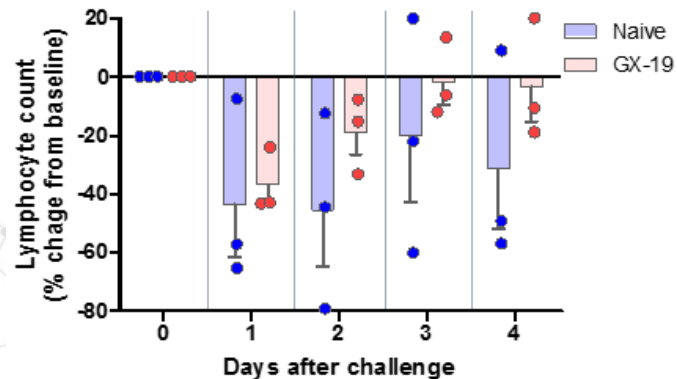
# 12 Protection against SARS-CoV-2 challenge : Symptoms & Infectious virus

- GX-19-immunized macaques did not have a fever after challenge
- Infectious SARS-CoV-2 was not detected at 2~4 days post challenge in vaccinated macaques

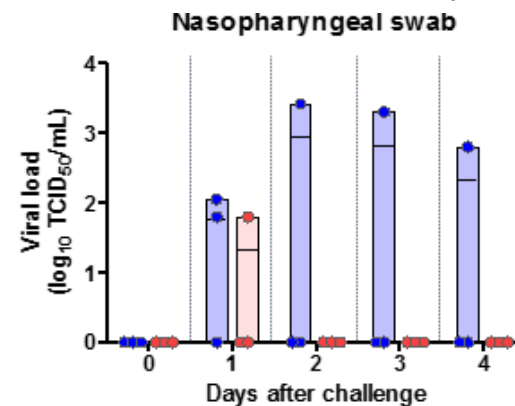
A. Body Temperature



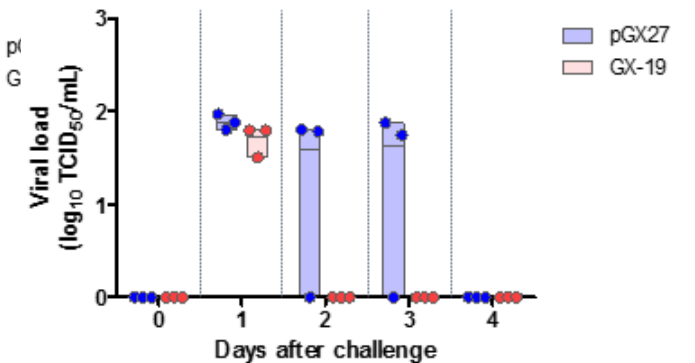
B. Blood Lymphocyte Counts



C. Infectious virus Titer (TCID<sub>50</sub>)

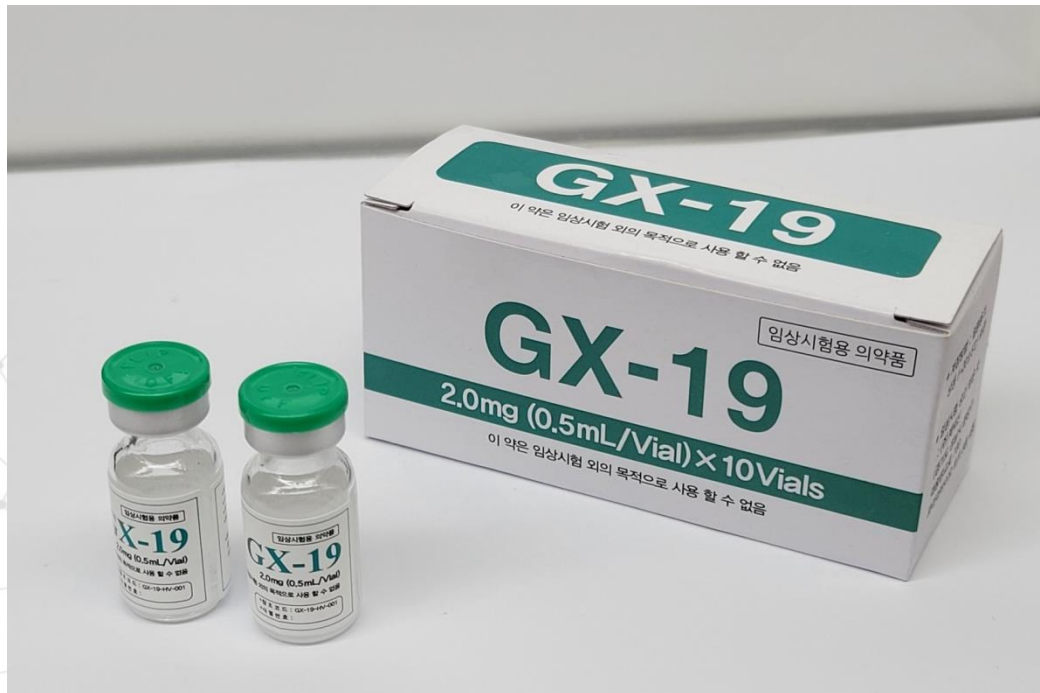


Oropharyngeal swab



# 13 GX-19, COVID-19 DNA vaccine

- **GX-19, 2 mg liquid vial containing plasmid DNA encoding SARS-CoV-2 Spike protein gene**
- **Route : Intramuscular injection using EP or needle-free jet injector**
- **Development stage : Ph1/2a approved by KFDA, currently Ph1 ongoing**



# 14 GX-19: Clinical Stage COVID-19 DNA Vaccine Candidate

Genexine, **Korea's 1<sup>st</sup> and global 15<sup>th</sup> approval** for clinical studies



## DNA Vaccine characteristics

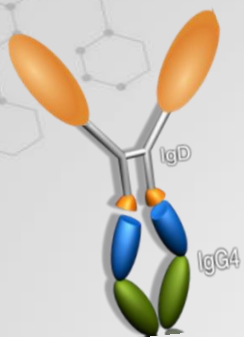
Fast development of the candidates – Manufacturing process is simple & fast

Over 460 clinical studies proved Safety, simultaneous responses of neutralizing antibody (Th1-biased) cellular immune responses

comparison		RNA vaccine	DNA vaccine
Manufacturing		in vitro (no host cell)	Cultivation of E.coli as host
Expression of antigen per nucleic acid molecule		High	In theory single DNA can produce more RNA, therefore it generates more antigens.
Risk in inserting into chromosome		None	Possible in theory but does not happen in real
Conditions in order to express antigen within a cell		Must exile from endosome	Needs to penetrate into nucleus
Optimization of deliveration		Need to be resolved (several methods are in trial)	Need to be resolved (several methods are developed)
Toxicology		Needs to proven from more studies	Safety confirmed from various clinical studies
Storage		Deep freeze ( -70 °C)	Room temp. or refrigeration(4°C ~ 25°C )

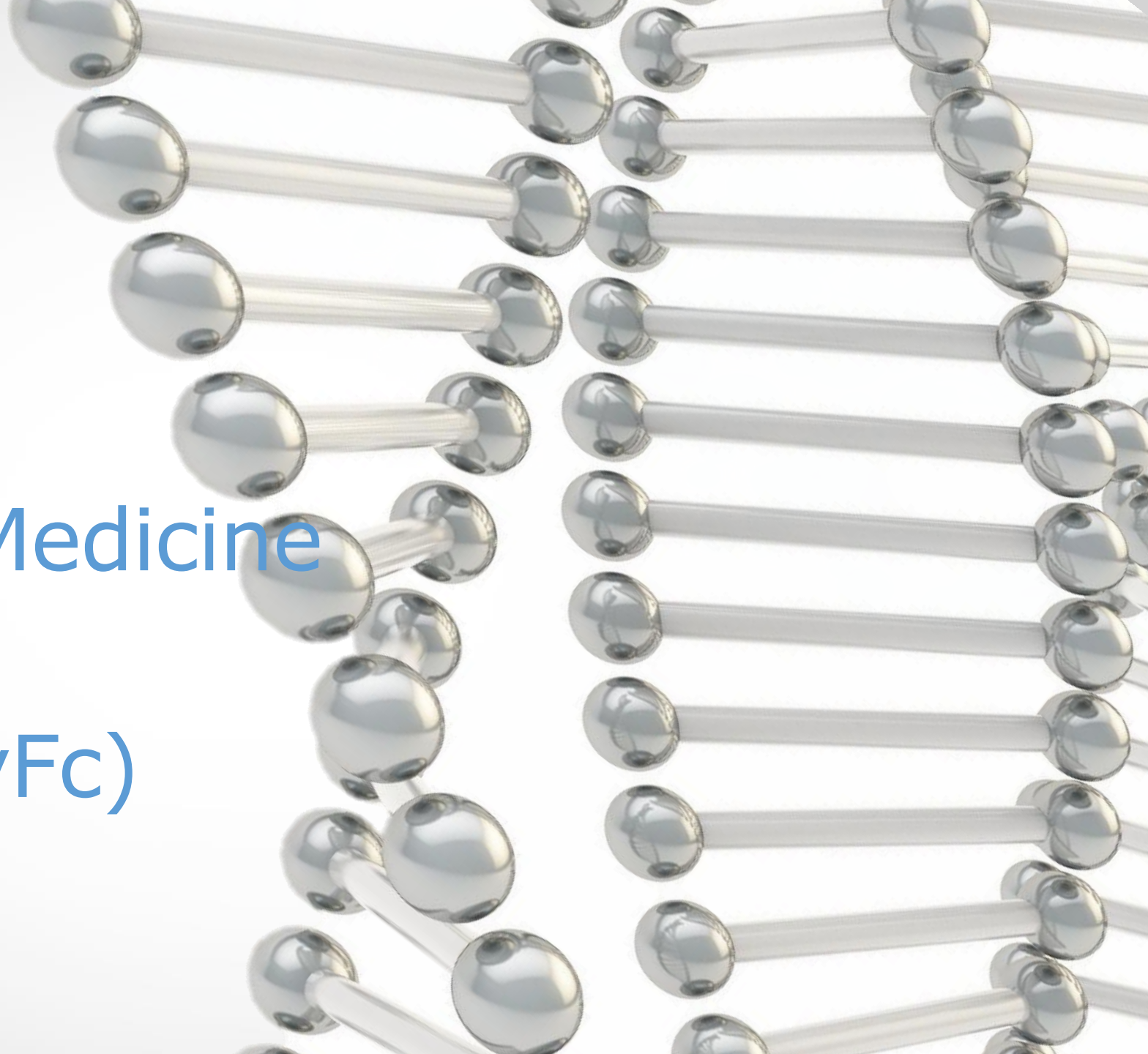
Others	Virus-vector Vaccine	<ul style="list-style-type: none"> <li>AstraZeneca(Oxford) : Ph3</li> <li>CanSino(Tianjin) : Ph3</li> </ul>	Subunit Vaccine	<ul style="list-style-type: none"> <li>Novavax Pfizer : Ph3</li> <li>SK Bioscience</li> </ul>	Inactivated Vaccine	<ul style="list-style-type: none"> <li>SinoPharm(Wuhan) : Ph3</li> <li>SinoVac(Beijing) : Ph3</li> </ul>

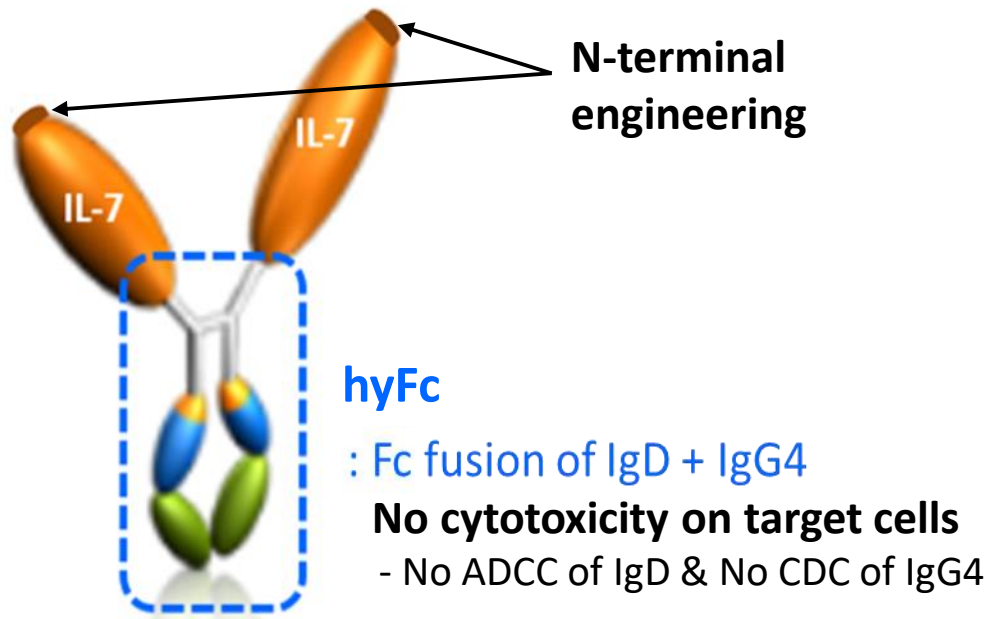




hyFc™

# Therapeutics Medicine For COVID-19 GX-17 (IL-7-hyFc)



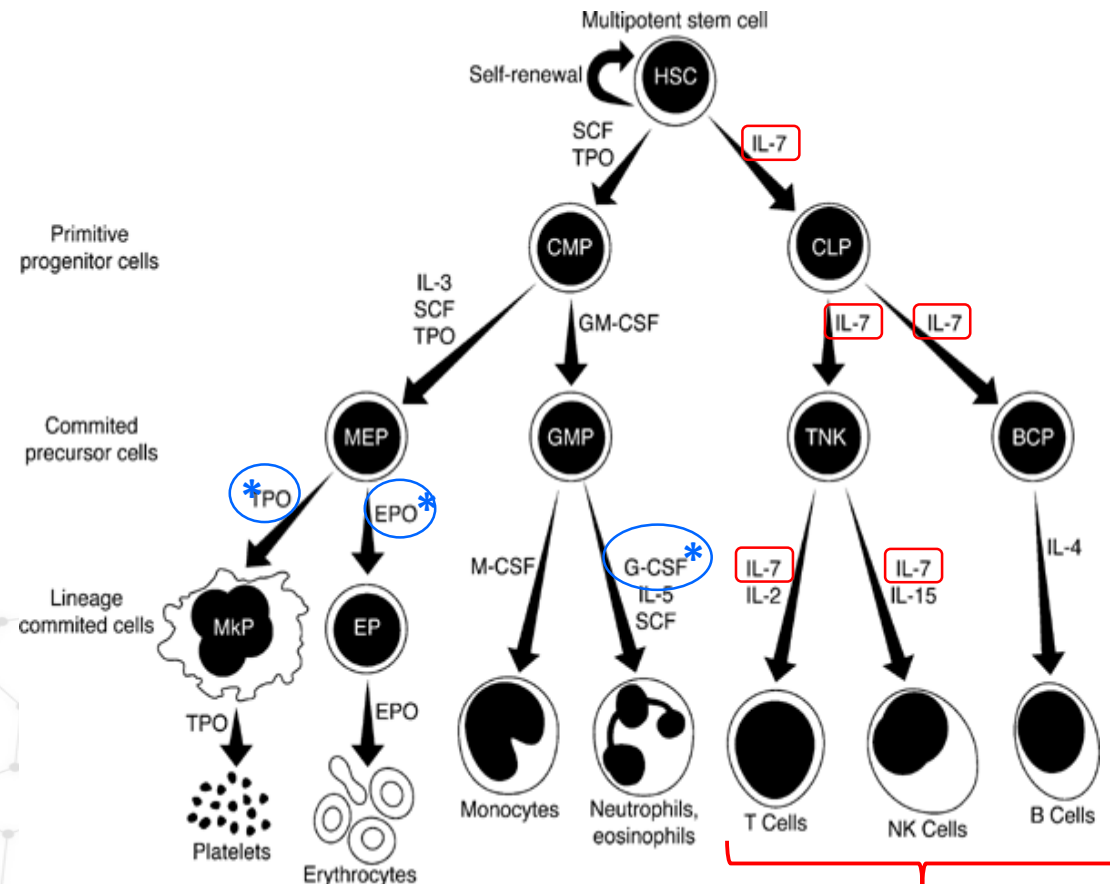


Hyleukin-7

## Comparison of Hyleukin-7 with rIL-7 protein

- ✓ **Higher protein stability** due to N-terminal engineering
- ✓ **Higher productivity<sup>+</sup>** than rhIL-7 protein by hyFc fusion
- ✓ **Longer in vivo half-life** than rhIL-7 protein due to FcRn-mediated recycling of IgG4 & reduced renal clearance.

## IL-7 Stimulates Differentiation of Multi-potent HSCs into CLP cells



\* blockbuster products

Lymphocytes

Baker SJ et al. Oncogene. 2007;15;26(47):6724-37

\*CLP; Common Lymphoid Progenitor

Anemia	Thrombocytopenia	Neutropenia	Lymphopenia
EPO	TPO	G-CSF	IL-7
ERYTHROCYTES	PLATELETS	NEUTROPHILS	LYMPHOCYTES
Amgen J&J Roche	Genentech Kirin Amgen	Amgen	Genexine/NIT
Global Market \$ 7.4 B. (2016) \$ 17.4 B*. (2025)	Global Market \$ 1.3 B. (2016) \$ 2.5 B*. (2025)	Global Market \$ 7.7 B (2016) \$ 12.6 B* (2025)	Global Market

# 17 GX-I7 : Developing as COVID-19 Therapeutics

**The only Korean biotech developing both vaccine and therapeutic medicine for Covid-19**

## Genexine COVID-19 therapeutic medicine

	MoA	Clinical Phase	Remark
IL-7-hyFc (GX-I7)	Immunotherapy (T cell amplifier)	KOREA: Phase 1b	Co-development with NIH
		US: Phase 1	

※ Collaboration with Y-biologics for developing antibody therapy (virus neutralization) nAb

## Development timeline

- 2020, 2Q, IND approval by US FDA (NeoImmuneTech)
- 2020, 3Q, IND approval by Korea MFDS (Genexine)
- 2020, 4Q, Patient injection start (Multi-national)
- 2021, 1Q, Clinical Ph1/2 Interim result
- 2021, 2Q, Ph3 IND submission

## Clinical development overview (Korea)

candidate	• GX-I7
Number of subjects	• 40 (32 + 8 placebo)
Study objectives	• safety, efficacy(increase lymphocytes %)
Target subjects	• Moderate patients
Frequency & Method	• Single dose within 7 days after infection



# 18 Lymphopenia in COVID-19: Worsening symptoms & mortality

JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

## Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected P

Dawei Wang, MD; Bo Hu, MD; Chang Hu, MD; Fangfang Zhu, MD; Xing Liu, MD; Jing Zhenshun Cheng, MD; Yong Xiong, MD; Yan Zhao, MD; Yirong Li, MD; Xinghuan War

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

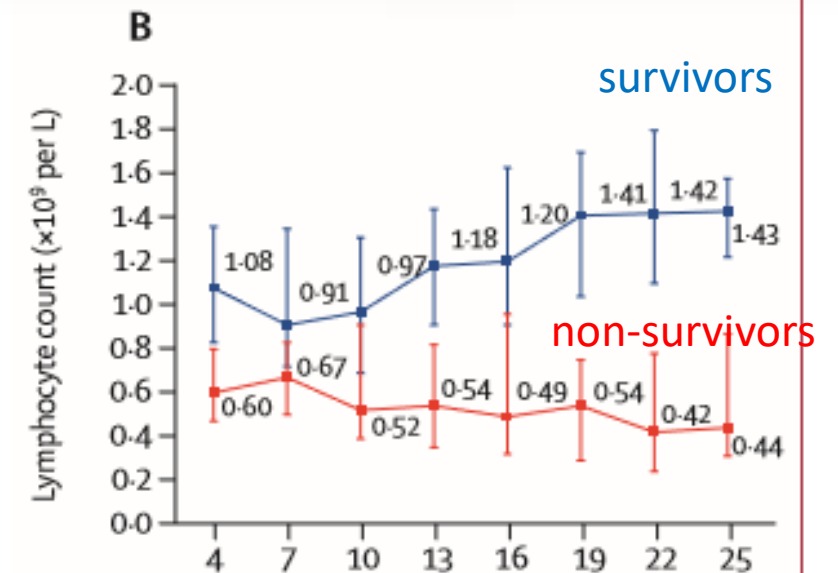
### Clinical Characteristics of Coronavirus Disease 2019 in China

## Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study

Fei Zhou\*, Ting Yu\*, Ronghui Du\*, Guohui Fan\*, Ying Liu\*, Zhibo Liu\*, Jie Xiang\*, Yeming Wang, Bin Song, Xiaoying Gu, Lulu Guan, Yuan Wei, Hui Li, Xudong Wu, Jiuyang Xu, Shengjin Tu, Yi Zhang, Hua Chen, Bin Cao

Lancet On line March 9<sup>th</sup> 2020

- **Moderate to severe COVID-19 patients develop severe lymphopenia** that is associated with **greatly increased mortality**.
- **Lymphopenia** may impair the ability of the patient to eradicate the virus and be more susceptible to **secondary bacterial infections**.
- **IL-7 is effective in reversing lymphopenia** in patients with bacterial sepsis and has also demonstrated efficacy in viral infections
- IL-7 has been used in >500 patients and has been well tolerated with a **minimal side effect** profile.
- **Elderly patients have highest mortality** and this is likely due to **immune senescence**; which is improved by IL-7.



“Theses abnormalities suggest that 2019-nCoV infection may be associated with cellular immune deficiency”

D.Wang *et al.*

# 19 Prevention and treatment of lymphopenia in COVID-19 by IL-7

- Patients infected with SARS-CoV-2 shows lymphopenia. Can be developed to fatal stage depending on severity of lymphopenia.
- Severe lymphopenia may significantly impair the ability of the patient to combat COVID-19 and contribute to increased (make him more) susceptibility to lethal secondary hospital-acquired infections.

- Secondary infections occurred in 58% who received IL-7, compared with 85% of those in the control group.
- IL-7 can be safely administered to critically ill patients with COVID-19 without exacerbating inflammation or pulmonary injury. P. Lattere *et al.* 2020 JAMA Network

Percent of patients critically ill with COVID-19 who developed a secondary infection by day 30:

Patients who received IL-7

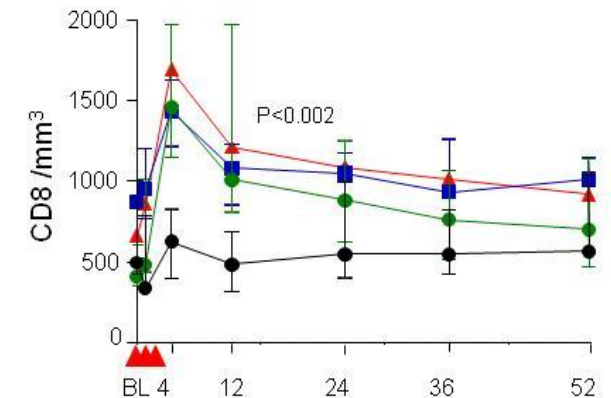
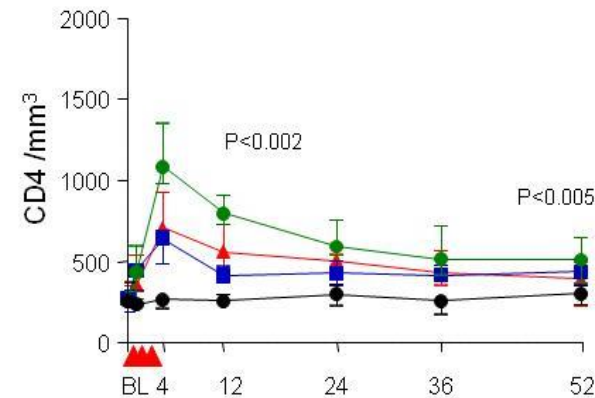


VS

Standard of care



- IL-7 prevents viral and bacterial pathogen induced lymphocyte apoptosis by increasing anti-apoptotic Bcl-2
- IL-7 increases CD4 and CD8 T cell numbers by stimulating cell proliferation

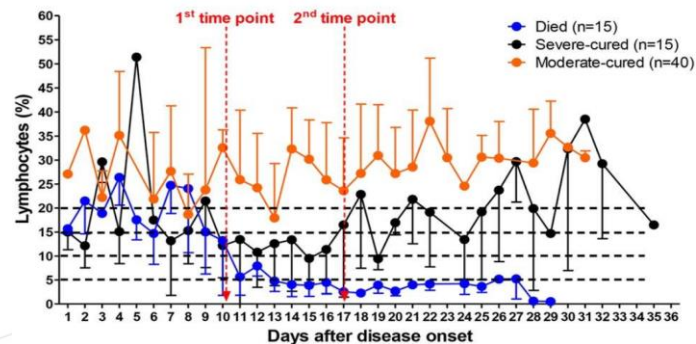


Cytheris' short acting IL-7  
**3 injections of IL-7 caused significant increase in CD4 and CD8 T cells** Levy *et al.* Clin. Infect. Dis. 55:291; 2012

# 20 Lymphopenia correction is key to the COVID-19 treatment

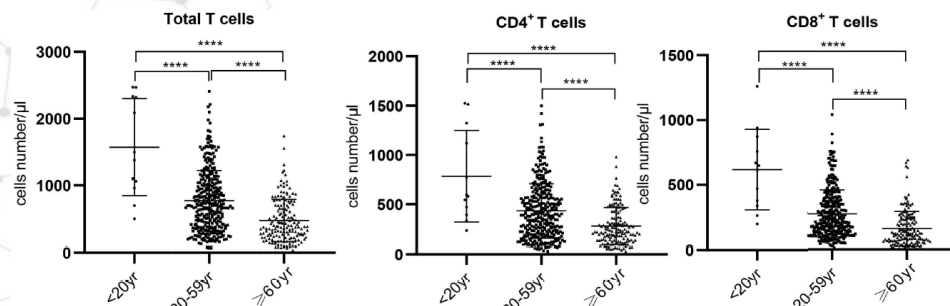
## Interleukin-7 restores lymphocytes from the lymphopenia induced by COVID-19 infection

### Level of T cell counts: survivors vs. non-survivors



Li Tan et al., Signal Transduct Target Ther. 2020 Apr 29;5:61.

### Lower T cell counts in elderly

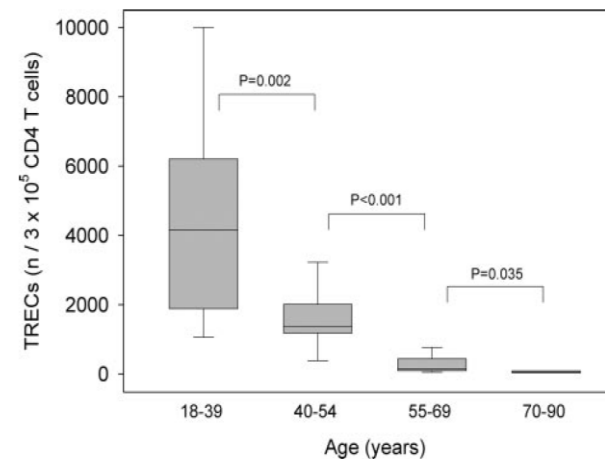


Diao B et al., Front Immunol. 2020 May 1;11:827.

### Age over 80 fatality rate (25.3%) due to immune senescence.

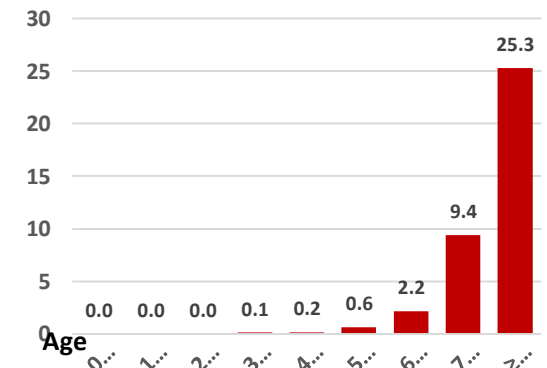
- **Elders have thymic involution** which will cause decrease in T cell's proliferation and diversity decrease.
- **Exposure to additional viral infection** due to compromised immune system which later can develop to viral sepsis

### T cell count by age



(Ref. Naylor K. et al, J Immunol, 2005, 174: 7446–7452.)

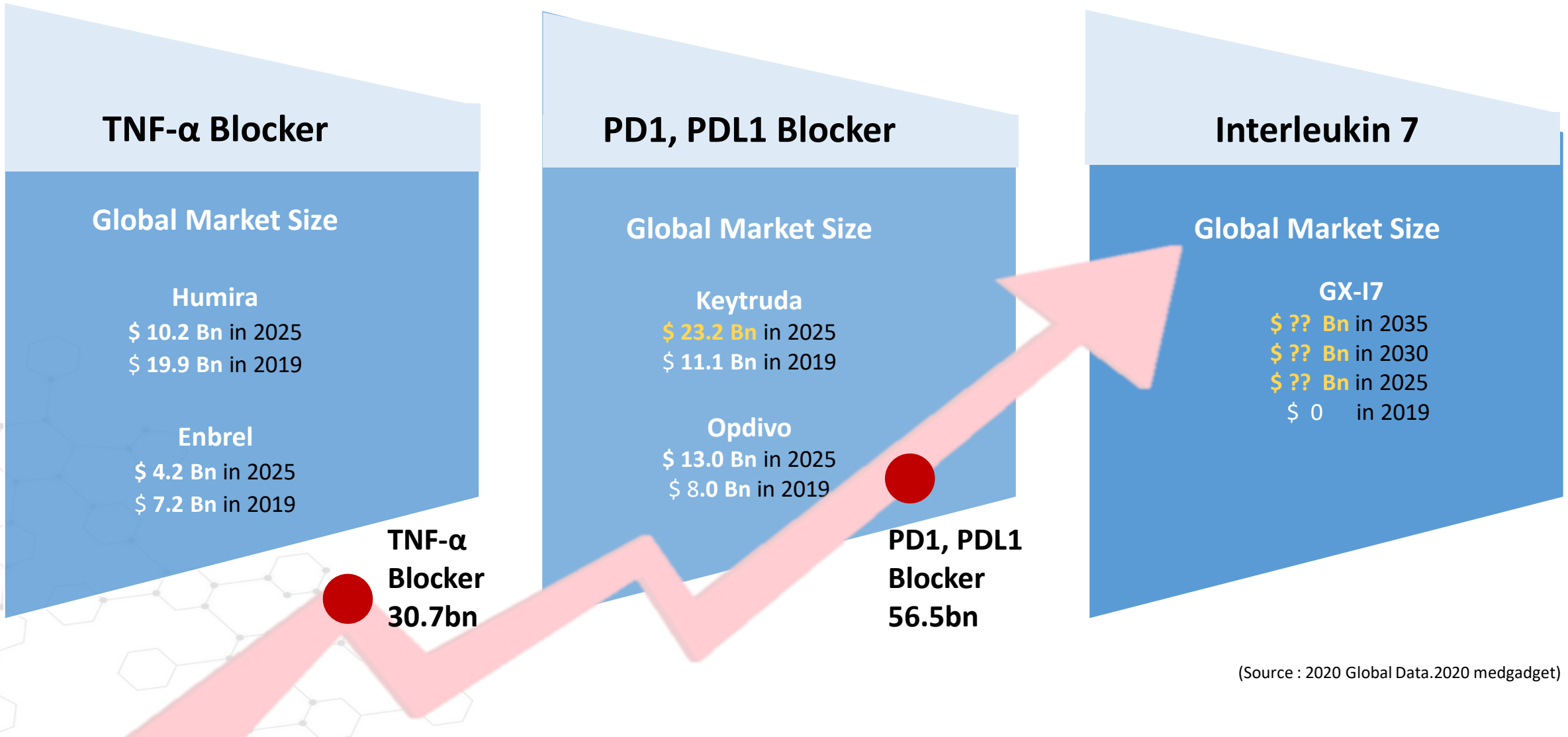
### fatality rate by age (%)



(Ref. <https://coronaboard.kr/en/> 8 August 2020)

# 21 What will be after Keytruda?

## Bio Blockbusters





## 22 GX-17: The only stable and long-acting IL-7 agent

### T-cell amplifier

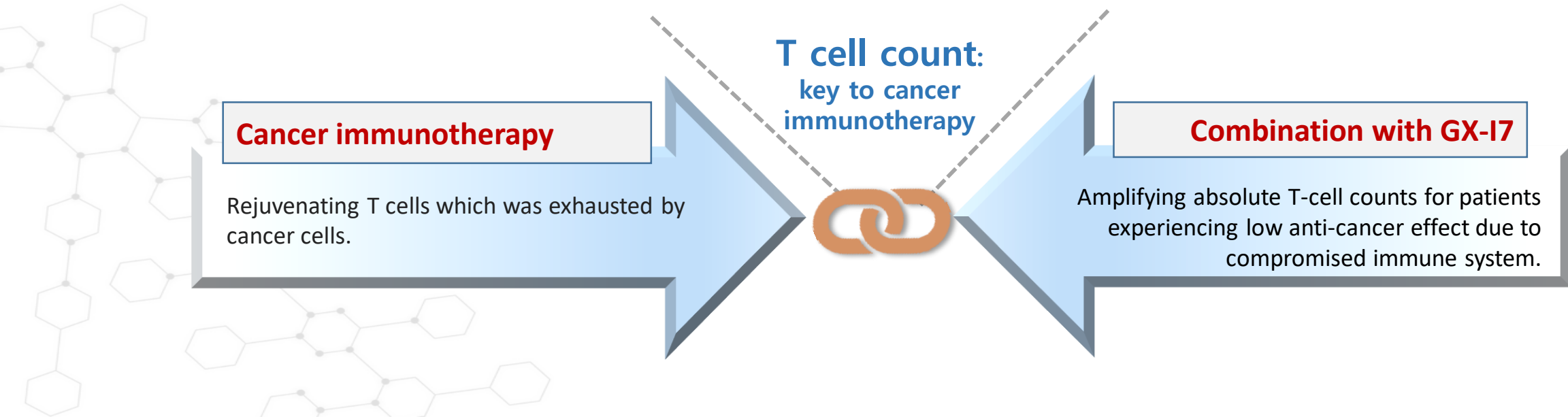
Increases # of T lymphocytes  
First-in-class drug ever developed  
for lymphopenia

### Universal use immuno- oncology therapeutic medicine

Combination therapy with radio/chemo,  
targeted, immunotherapy and cell therapy.

### Long-acting IL-7 agent

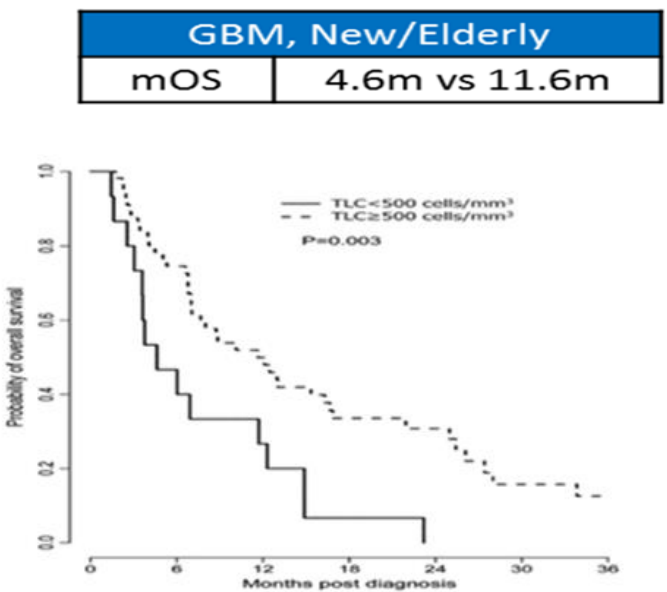
IL-7 + hyFc = Potential blockbuster  
long-acting protein drugs



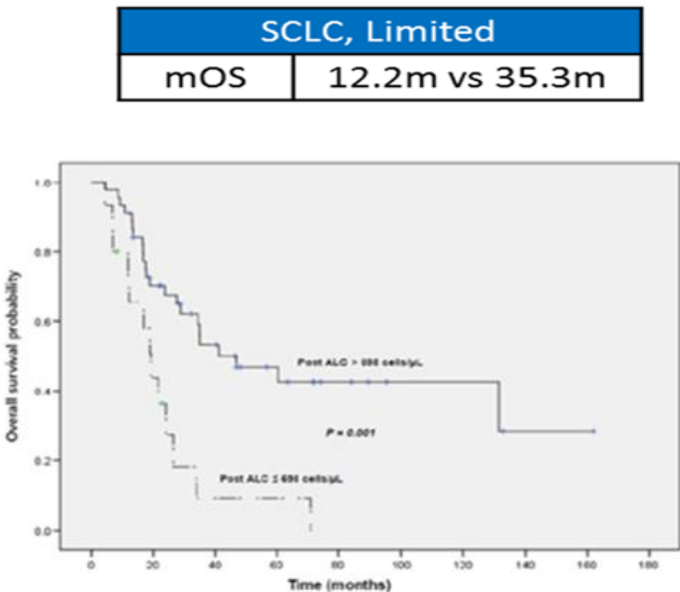
# 23 The Higher T cell # in Blood, The Better Overall Survival

- Low anticancer efficacy on low lymphocyte count patient
- Increased lymphocyte count will benefit higher anti-cancer effect

## Chemo/Radiotherapy



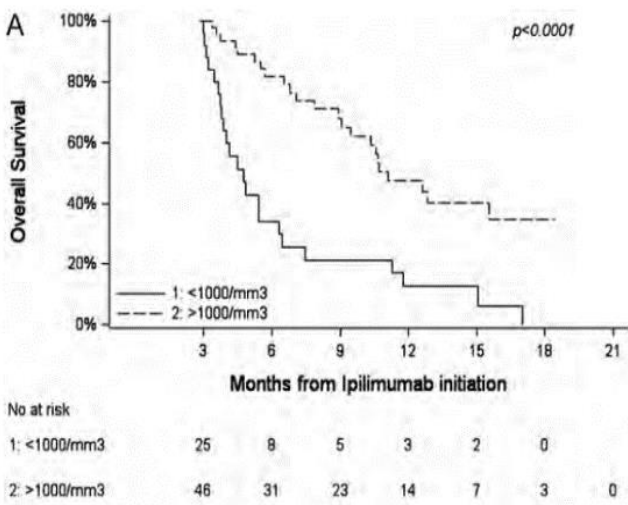
Mendez J. et. Al. *J Neurooncol.*  
2016 Apr;127(2):329-335.



Cho O et al.,  
*Tumour Biol.* 2016 Jan;37(1):971-8

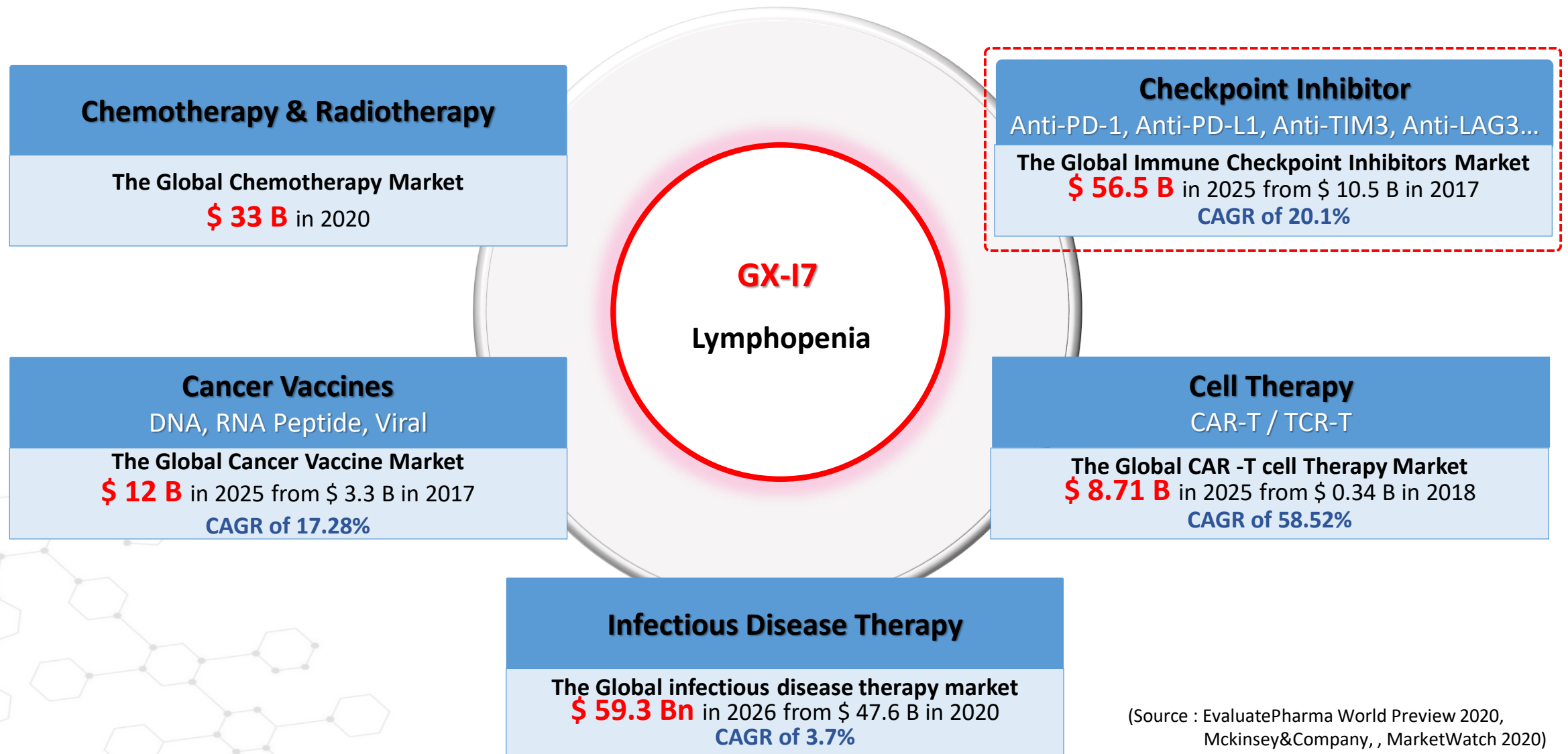
## anti-PD-1/PD-L1

**Melanoma (ALC < 1000/mm<sup>3</sup>)**  
Stage III and IV, receiving 4 courses of ipilimumab q3w














Delyon et al. *Annals of Oncology*, 2013

# 24 GX-I7: Unlimited potential with Combination Therapies



(Source : EvaluatePharma World Preview 2020,  
Mckinsey&Company, , MarketWatch 2020)

# 25 GX-17 (NT-17/ TJ-107): Clinical Trial & Development Timeline

Field	Type	Treatment	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Conducting company	Partner
Oncology	Co	KEYTRUDA®	TNBC 	Phase 1b/2				Genexine	 MERCK 
	Co	Avastin	Recurrent GBM	Preclinical				Genexine	
	Co	Temozolomide	GBM	Phase 2				I-MAB	
	Mono		Solid Tumor	Phase 2a				I-MAB	
	Mono	-	GBM	Phase 1/2				NeoImmuneTech	
	Co	Temozolomide	GBM	Phase 1/2				NeoImmuneTech	
	Co	Tecentriq®	High risk skin cancer	Phase 1b/2a				NeoImmuneTech	 
	Co	KEYTRUDA®	TNBC, Lung, Pancreatic, Colorectal cancer	Phase 1b/2a				NeoImmuneTech	
	Co	Opdivo®	Gastric, GEJ, and Esophageal Adenocarcinomas	Phase 2				NeoImmuneTech	
	Co	Kymriah®	Diffuse large B-cell lymphoma	Phase 1b				NeoImmuneTech	
Infectious Disease	Mono	-	Idiopathic CD4 <sup>+</sup> T Lymphopenia	Under IND submission				NeoImmuneTech	
	Co	Vaccine	Preventative vaccine (Elderly cancer survivors)	Phase 1/1b				NeoImmuneTech	
	Mono	Standard treatment	COVID-19 infected patients	Phase 1b				Genexine	
	Mono	Standard treatment	COVID-19 infected patients	Phase 1				NeoImmuneTech	




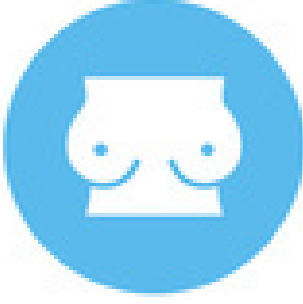





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# Business Strategy

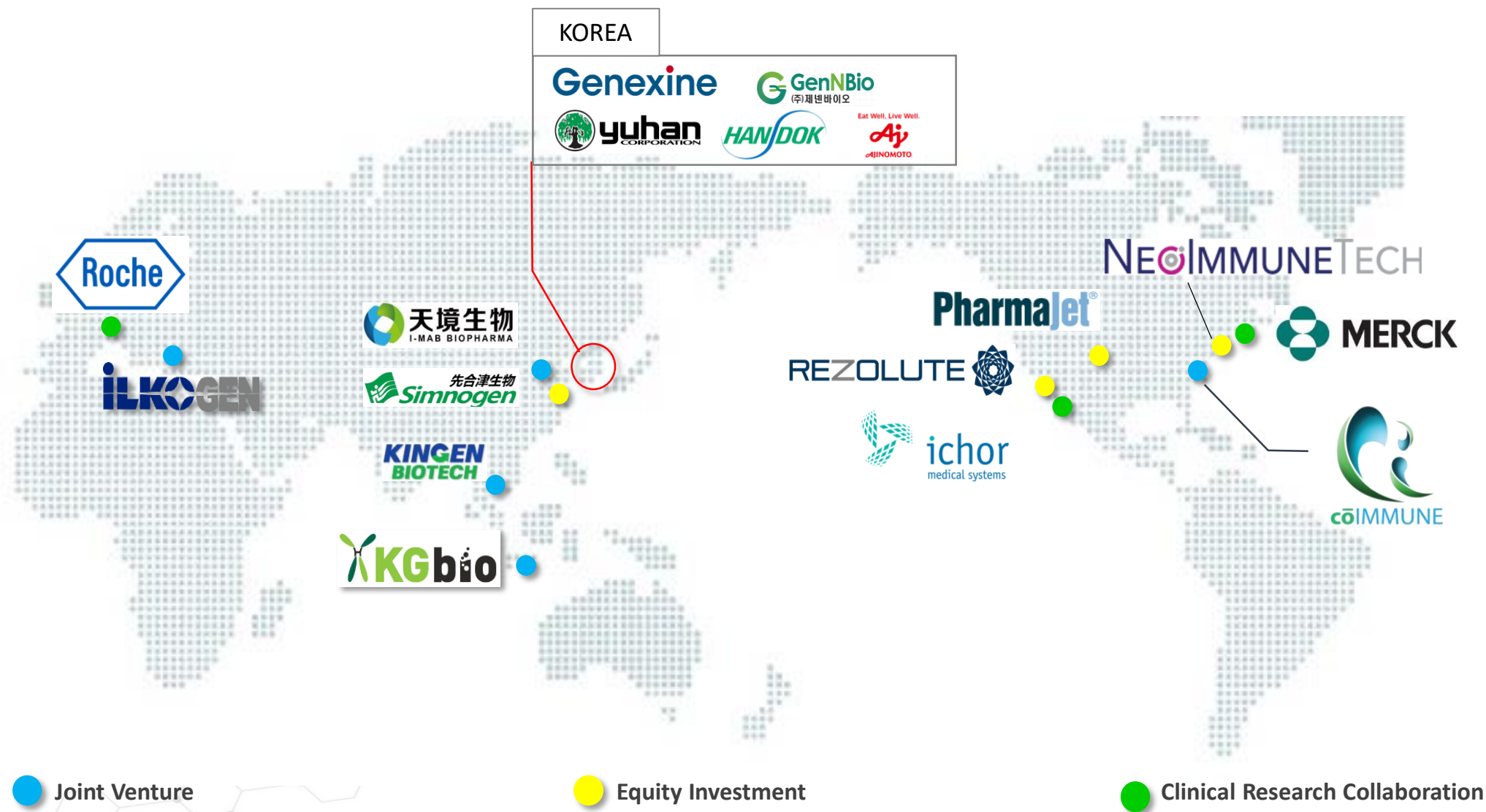


# 26 Commercialization Plan

Expected: 7 products' BLA submission within 5 years

2021/22	2022/23			2023/23		2024/25
<b>GX-19</b> (conditional approval)	<b>GX-I7 (NT-I7)</b> +Keytruda® (conditional approval)	<b>GX-188E</b> +Keytruda® (conditional approval)	<b>GX-I7</b> (conditional approval)	<b>GX-E4</b>	<b>GX-H9</b>	<b>GX-I7(NT-I7,TJ107)</b> +Temozolimide
						
Covid 19 DNA Vaccine	TNBC	Cervical cancer	Covid 19	CKD-induced Anemia	Growth Hormone Deficiency	GBM
Current clinical phase						
Phase I/IIa (Korea)	Phase Ib/II (Korea)	Phase II (Korea)	Phase Ib (Korea)	Phase III (SE Asia)	Phase III (China)	Phase II (China)

# 27 Global Partnership



# 28 Investment Highlights

## Corporate IPO Strategy & Status

Company Name	Listing Date (Predicted)	IPO Market (Country)	Share	Market cap.
I-MAB Biopharma (CN)	<b>Listed (2020. 01)</b>	Nasdaq (US)	7.4%	\$ 2.68 B
Rezolute (US)	<b>2020.11</b>	Nasdaq (US)	31.1%	
NeoImmuneTech (US)	<b>2021</b>	Kosdaq (KR)	25.4%	
ColImmune (US)	2023	Nasdaq (US)	33.0%	
KG BIO (Indonesia)	2024	Hong Kong (CN)	40.0%	

## 29 Investment Highlights: “It’s just beginning...”



### **Genexine, from K-Bio representative company to Global biotech leader**

- Successful L/O records and progress with First-in-Class pipelines based on innovative platform technologies to global partners.
- Global Open Innovation R&D strategies and Win-Win developments for expansion of pipelines.



### **The innovative immunotherapy anticancer GX-I7 with explosive potential**

- Clinical co-development with the three biggest immune checkpoint blockade companies (MSD, Roche, BMS).
- Continuous expansion of indications: mTNBC, High risk skin cancer, GBM etc,



### **The world’s first commercial DNA vaccine**

- Aim for commercialization of the first DNA vaccine for human in the world.
- Development of COVID-19 vaccine as the first from Korea, and the best from the world.



The background of the slide is a 3D rendering of numerous metallic, reflective spheres connected by thin, cylindrical rods. These elements are arranged in a complex, overlapping pattern that creates a sense of depth and movement, resembling a molecular structure or a network of interconnected nodes.

# THANK YOU

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