

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

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3. GX-188E
4. COVID19 Vaccine & Therapeutic Medicine

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1. Global Partnership
2. Development timeline for Commercialization



# 01 Overview



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 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>• \$2.3bn (November 2020)</li></ul>
Location	<ul style="list-style-type: none"><li>• Pangyo Korea Bio Park, Gyeonggi-do, Korea</li></ul>



## 02 Philosophy and Principle

### Management Philosophy

Saving the lives of patients  
by developing innovative biologics.

### Management Principle

Transparency  
Innovation  
Professional  
Speed

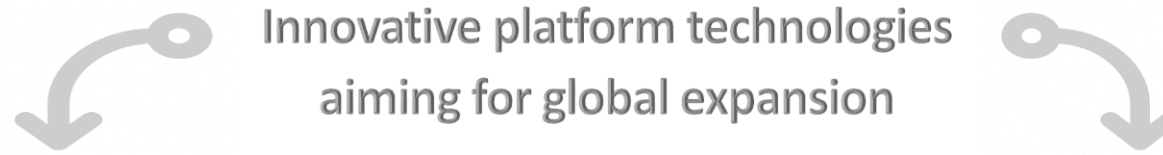
**Genexine**

### Genexian

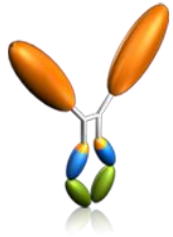
Dream  
Passion  
Credibility  
Positivity

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

# 03 Platform Technologies



## hyFc™ (Long-acting protein drug)



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

### First-in-Class

- GX-I7: Immuno-oncology drug
- GX-P1/GX-P10: Immunosuppressive drug

### Best-in-Class

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

## DNA vaccine (Cancer therapeutic/ Infectious disease)



Innovative gene therapy providing preventive and therapeutic vaccines through strong immune responses

### First-in-Class

#### Therapeutic DNA Vaccine





- GX-188E/GX-210: Cervical cancer, Head and Neck cancer vaccine

### First-in-Class

#### Preventive DNA Vaccine

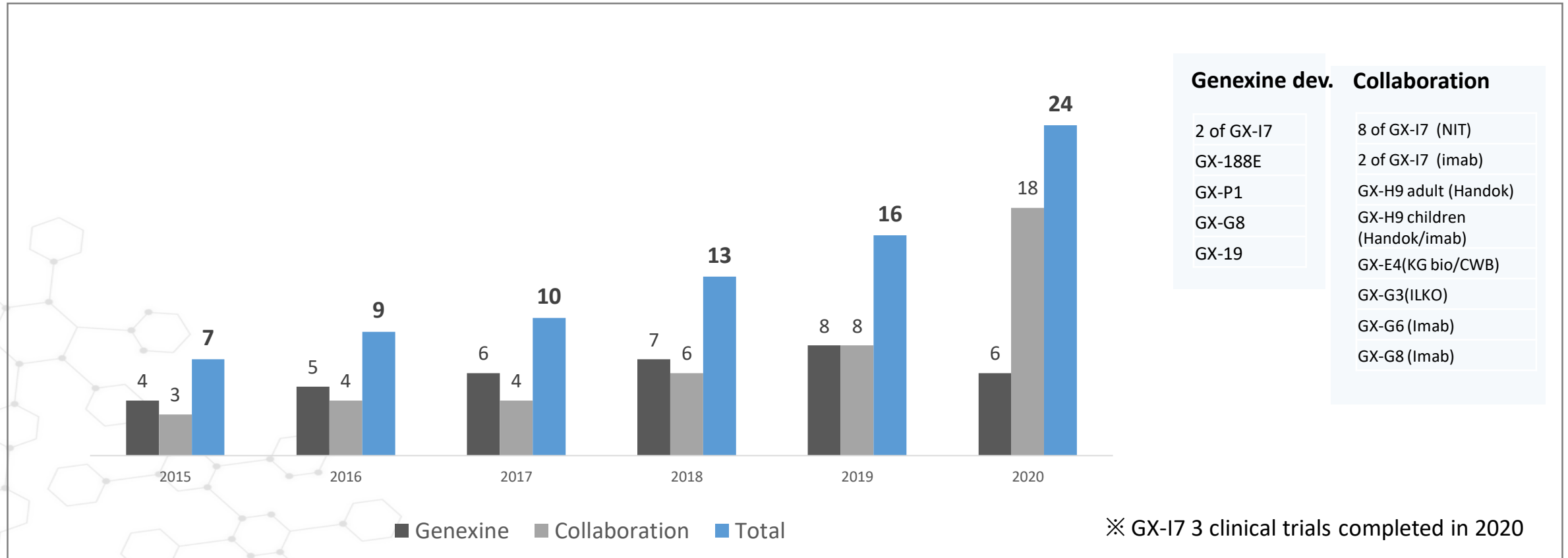
- COVID-19 vaccine

# 04 Clinical Development Status

Pipeline	Indication	Clinical Stage			Developer	Collaborator
		Phase 1	Phase 2	Phase 3		
GX-E4	CKD-induced Anemia	Phase 2 in Korea		Phase 3 in SE Asia	Genexine KG Bio	
GX-H9	Growth Hormone Deficiency (PGHD)	Phase 2 in Korea/EU		Phase 3 in China	Genexine/Handok I-MAB	
	Growth Hormone Deficiency (AGHD)	Phase 2 in Korea/EU			Genexine/Handok	
GX-I7	TNBC, GBM, Skin cancer etc	Phase 1~2 in Korea/US/China			Genexine NeoImmuneTech I-MAB	 <b>MERCK</b>  <b>Roche</b>  <b>Bristol Myers Squibb™</b>
GX--188E	Cervical cancer	Phase 2 in Korea			Genexine	 <b>MERCK</b>
GX-P1	Transplantation	Phase1 in Korea			Genexine	
COVID Vaccine	Preventive	Phase1 in Korea			Genexine	

# 05 Genexine's Open Innovation: Collaboration Strategy

- 6 independent + 18 collaboration = **total 24 clinical studies currently in clinical development**
- Compared to 2015, # of clinical studies increased 3.5-folds
- R&D expenses kept approx. \$ 40mn since 2017



## 06 Open Innovation - L/O and Strong Partnership

- Win-Win strategy with L/O partner companies: shareholding leads to strong partnership building processes
- As clinical stage advances, partners' company value increases + L/O value increases.







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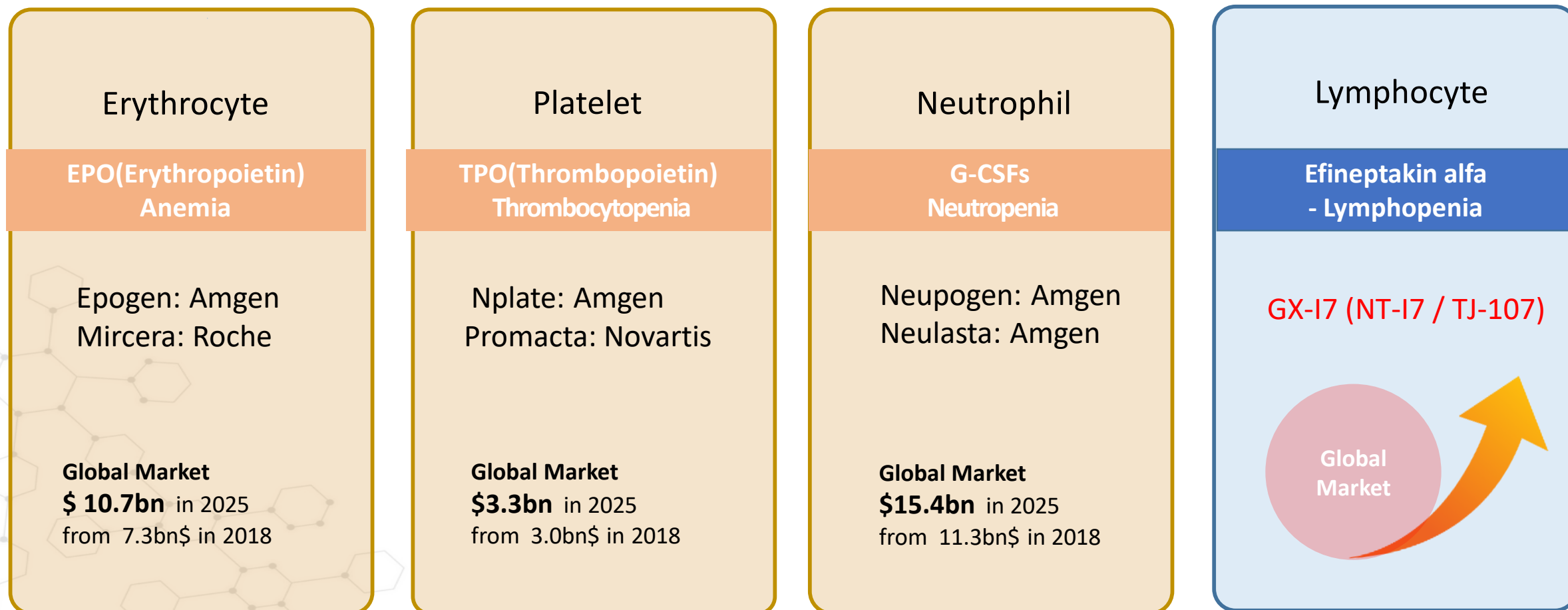
# GX-I7

Long acting interleukin-7  
(IL-7-hyFc)

Cancer & Lymphopenia

# 07 GX-17: The only solution for Lymphopenia

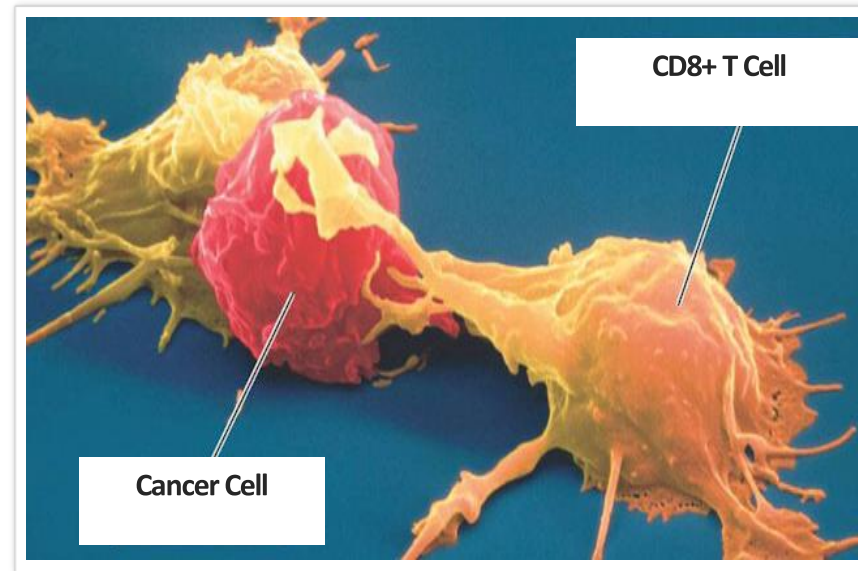
Multi-billion market for major blood cell targeting drugs,  
however **no lymphopenia correction drugs have been developed so far.**



# 08 GX-I7 in Cancer Immunotherapy

## T cell Amplifier

- IL-7, Hyleukin-7 (GX-I7)
- Under clinical trials actively



## T cell Activator

- Cancer vaccine
- IL-2, IL-15, IFN-alpha
- CD137 L, OX40 L, ICOSL
- TLR agonists, etc

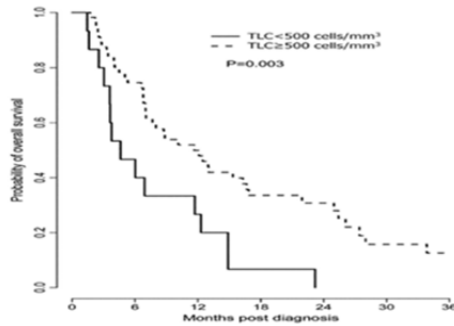
## Blockade of T cell Suppressor

- anti-PD-1, anti-PD-L1
- anti-CTLA4
- anti-TIM-3, anti-TIGIT
- anti-TGF-beta

# 09 The Lower # of T cells are, the lower Overall Survival is.

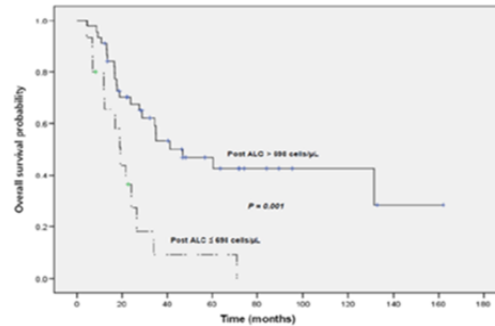
## Chemo/Radiotherapy

**GBM, New/Elderly**  
mOS 4.6m vs 11.6m



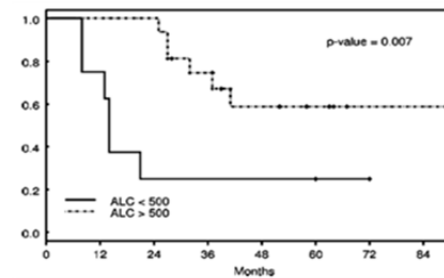
Mendez J. et. Al. *J Neurooncol.* 2016 Apr;127(2):329-335.

**SCLC, Limited**  
mOS 12.2m vs 35.3m



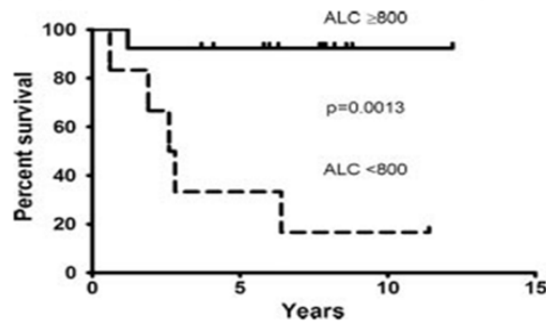
Cho O et al.,  
*Tumour Biol.* 2016 Jan;37(1):971-8

**Ewing Sarcoma**  
5y OS 25% vs 58.7%



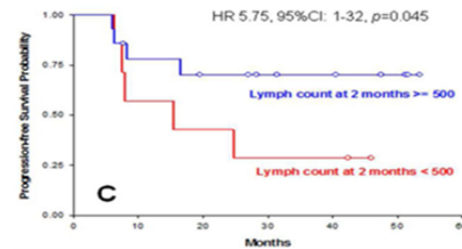
De Angelo G. et al., *J Pediatr Hematol Oncol.* 2007

**Pediatric Osteosarcoma**  
5y OS 33.3% vs 92.3%



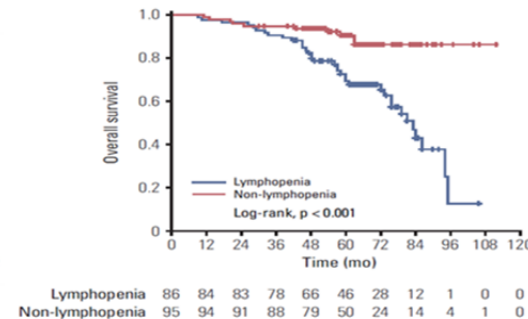
Moore C. et al., *Pediatr Blood Cancer.* 2010

**Squamous Cell H&N, New**  
mPFS Hazard Ratio 5.75



Campian J. et al., *Head Neck.* 2014; 36(12): 1747-1753

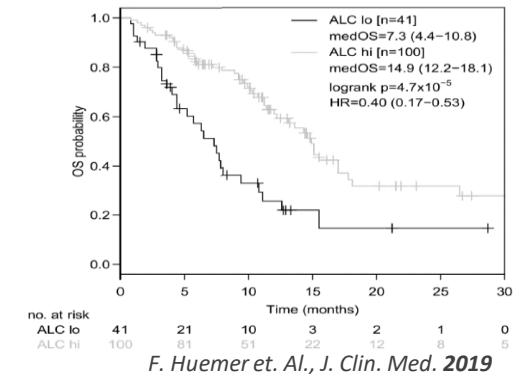
**Nasopharyngeal Carcinoma**  
mOS HR 1.76 post3m ALC



Liu LT et. al. *Cancer Res Treat.* 2018;50(1):19-29

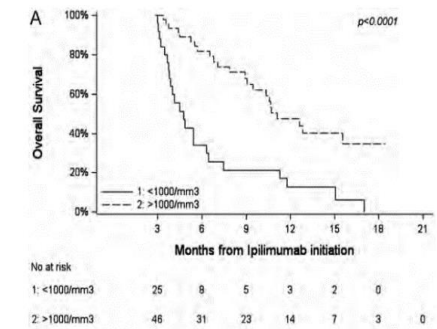
## anti-PD-1/PD-L1

**Adv. NSCLC (ALC < 930/mm³)**  
anti-PD-1/PD-L1 treatment (nivolumab, pembrolizumab, or atezolizumab)



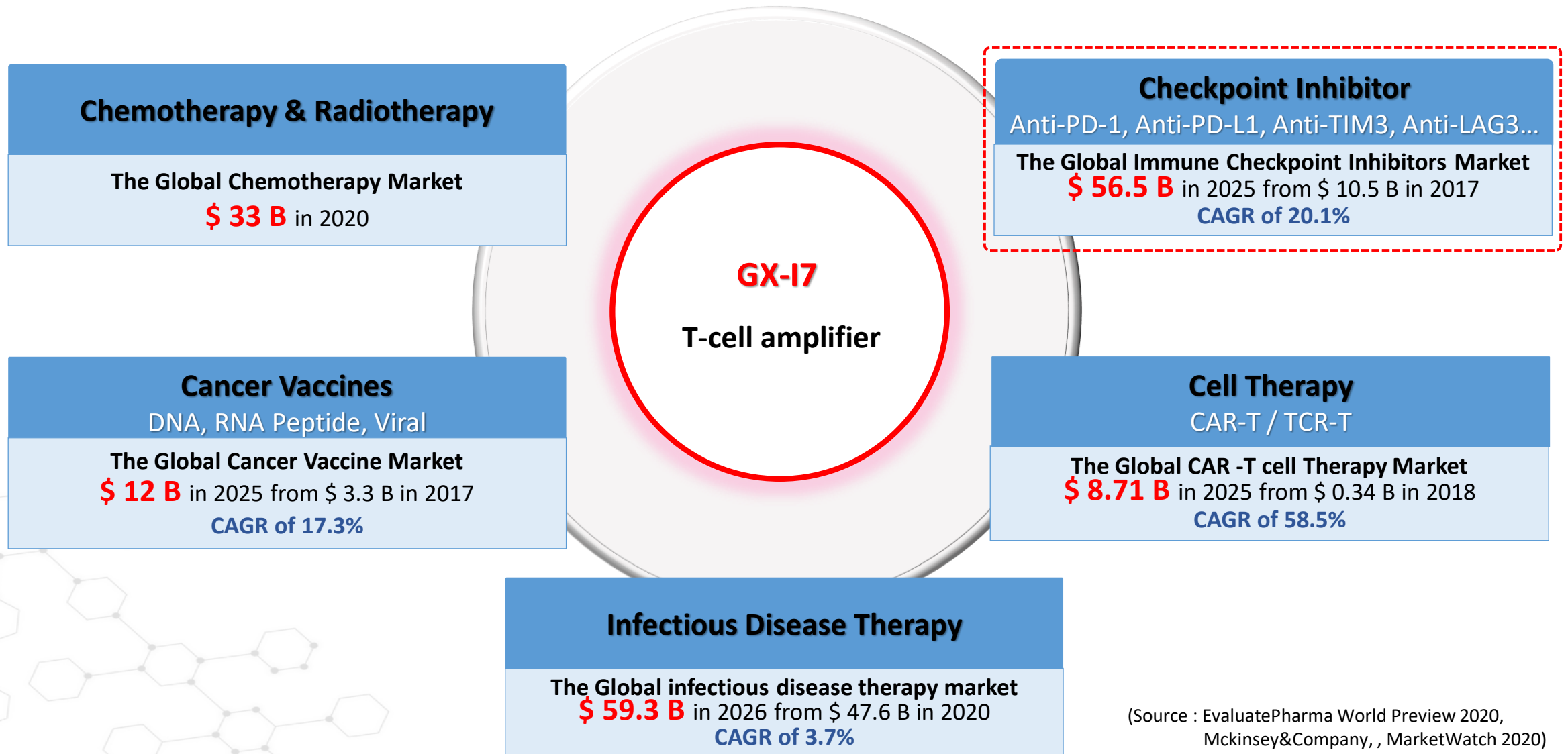
F. Huemer et. Al., *J. Clin. Med.* 2019

**Melanoma (ALC < 1000/mm³)**  
Stage III and IV, receiving four courses of ipilimumab q3w



Delyon et al. *Annals of Oncology*, 2013











# 10 GX-I7: Unlimited potential with Combination Therapies



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



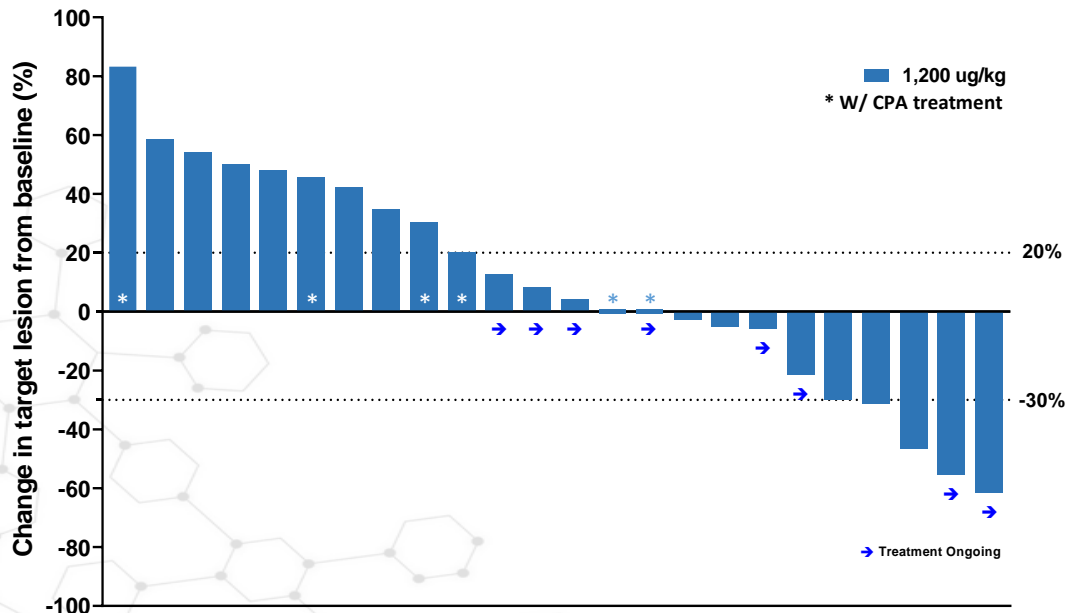
# 11 GX-I7(NT-I7/ TJ-107): clinical development in immuno-oncology

Field	Type	Treatment	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Developer	Partner / Remark
Oncology	Mono	-	Advanced solid cancers	Phase 1b				Genexine	2019 SITC Poster Presentation
	Co	KEYTRUDA®	TNBC 	Phase 1b/2				Genexine	 <b>MERCK</b>  2020 SITC Poster Presentation
	Co	Avastin	Recurrent GBM	Preclinical				Genexine	
	Co	Temozolomide	GBM	Phase 2 (IND approved)				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	Tecentriq®	NSCLC, Non-Small Cell Lung Cancer	Phase 2(Prepare IND submission)				NeoImmuneTech	
	Co	Kymriah®	Diffuse large B-cell lymphoma	Phase 1b				NeoImmuneTech	

# 12 GX-I7: Efficacy Results in mTNBC

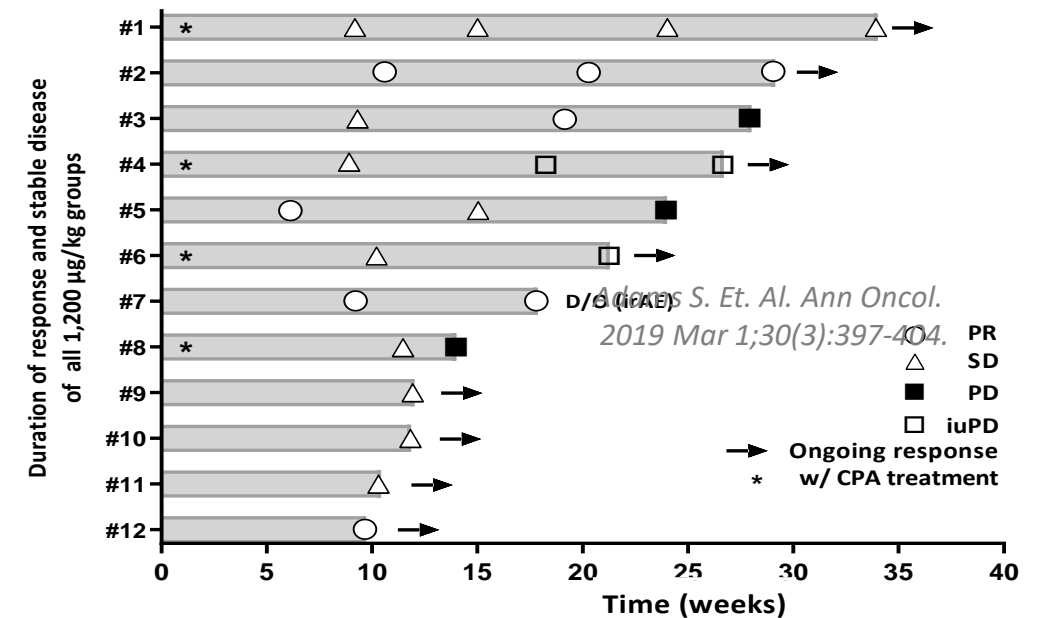
- Interim analysis report of the Combination GX-I7 and Keytruda(KEYNOTE-899) at SITC in November 2020
  - Dose levels ranging from 360 µg/kg to 1,440 µg/kg, with or without CPA
  - Simultaneous treatment(n=18) of GX-I7 and pembrolizumab induced higher ORR(28%) than sequential treatment (n=6) of GX-I7 and Pembrolizumab with CPA in 1,200 µg/kg groups.
  - Pembrolizumab monotherapy showed 5.3% ORR (KEYNOTE-086) in a phase 2 study (*Adams S et al. Annals of Oncology. 2019*)

## Tumor response



SITC 2020 Poster

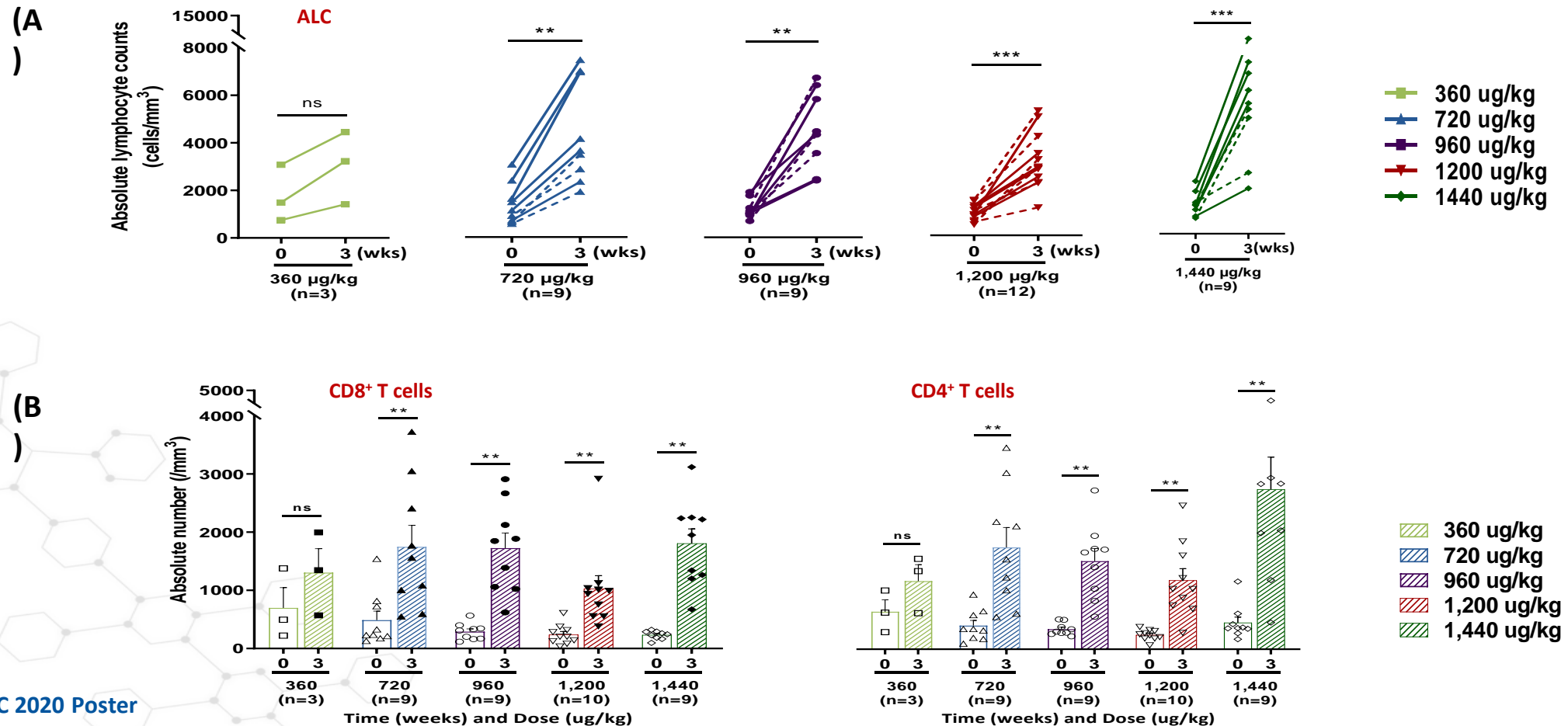
## Duration of response and stable disease of all 1,200 µg/kg groups.



# 13 GX-I7: T cell increase in patients with mTNBC

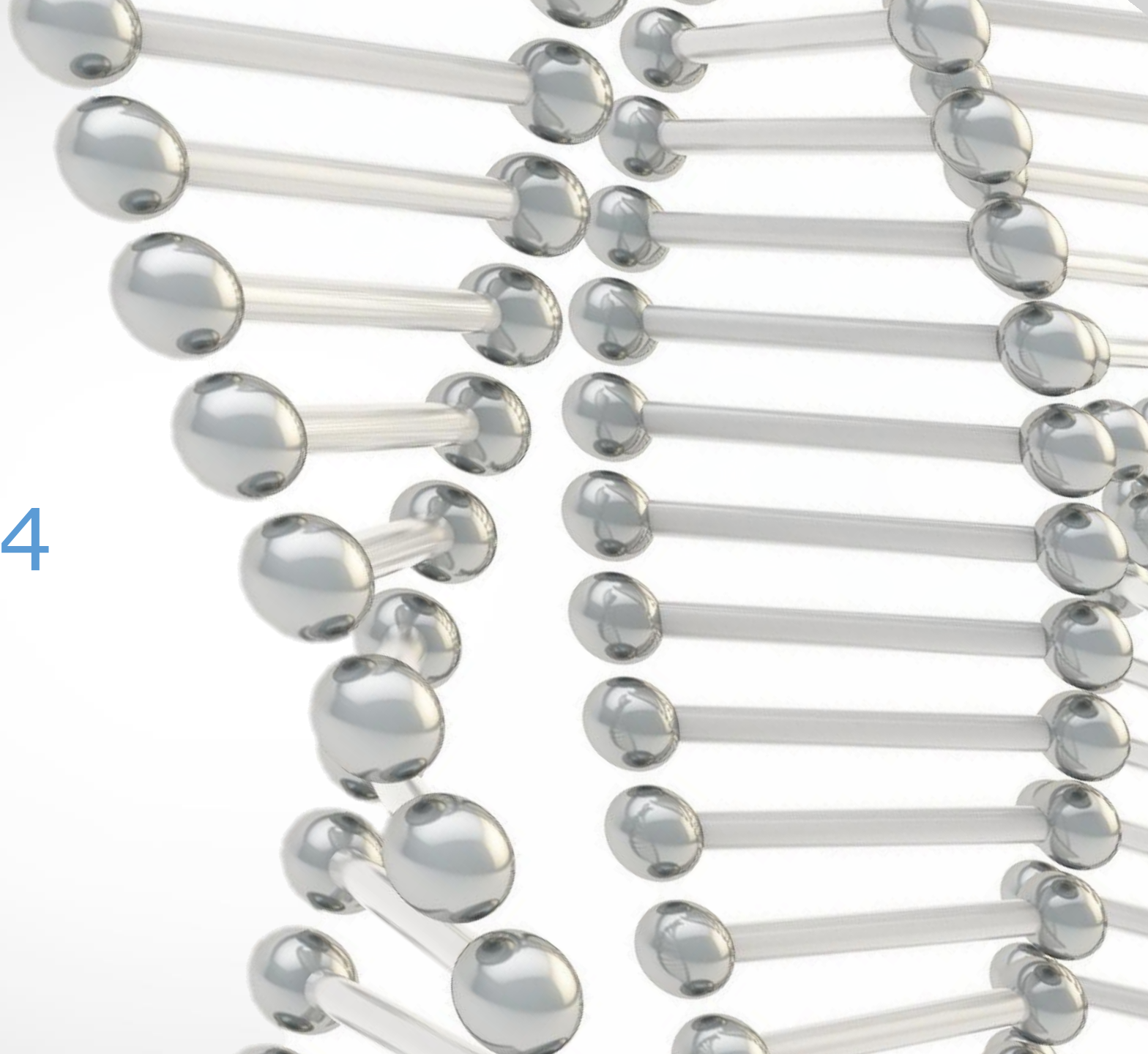
- Change from baseline in ALC, CD4+ T cells, CD8+ T cells and Treg in PB

- T cell increase in the peripheral blood (PB) by GX-I7 (360 µg/kg to 1,440 µg/kg with or without CPA).



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# GX-H9 & GX-E4



# 14 GX-H9 : Long-acting Growth Hormone

## Daily injections

➤ 365 injections/year

### Daily

- Failure to comply with the dosing
- Pain of daily injections every day
- Treatment effect reduction

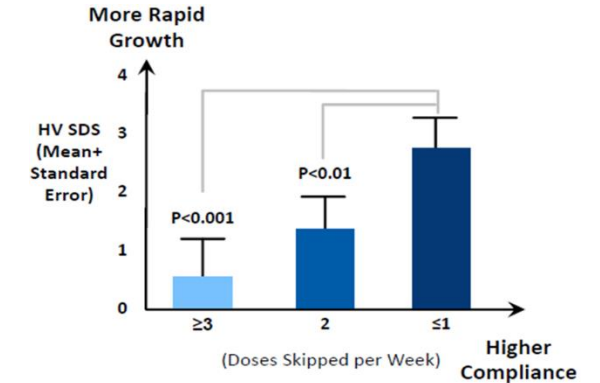
VS

## Weekly/Twice monthly injections

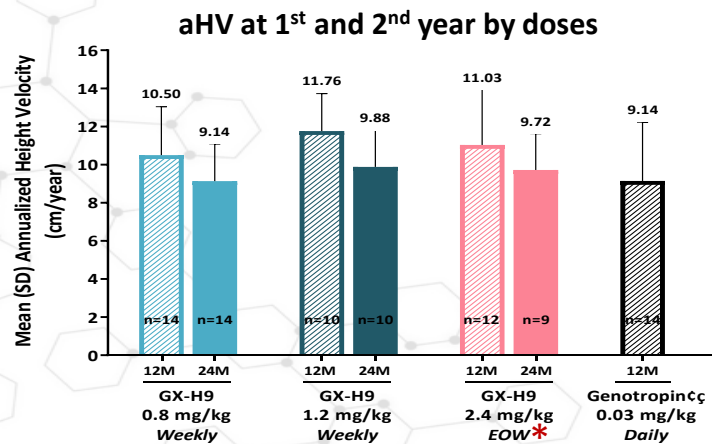
➤ 52/26 injections/year

### Weekly/ Twice-Monthly

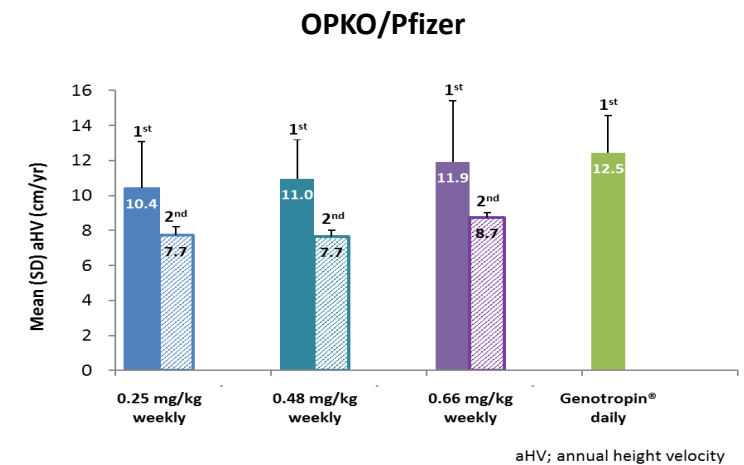
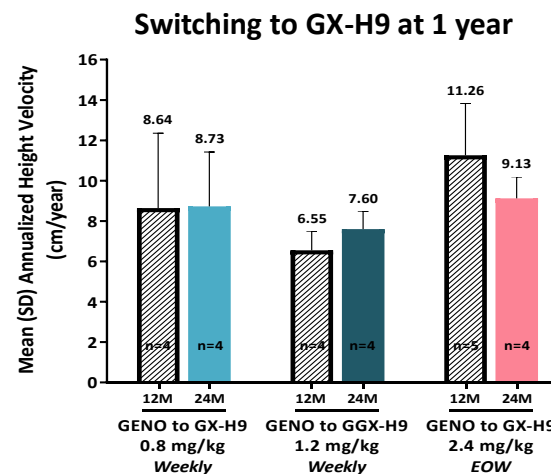
- To relieve the pressure of daily injections
- Convenient and improve QoL
- Improvement of treatment effectiveness



## Average annual growth data



\* EOW : Every Other Week





# 15 GX-H9 : Phase 3 Clinical Trial Status

## License-out Status

- Co-development with Handok(2012) targeting Worldwide (except Greater China)
- To IMAB (2015) targeting Greater China

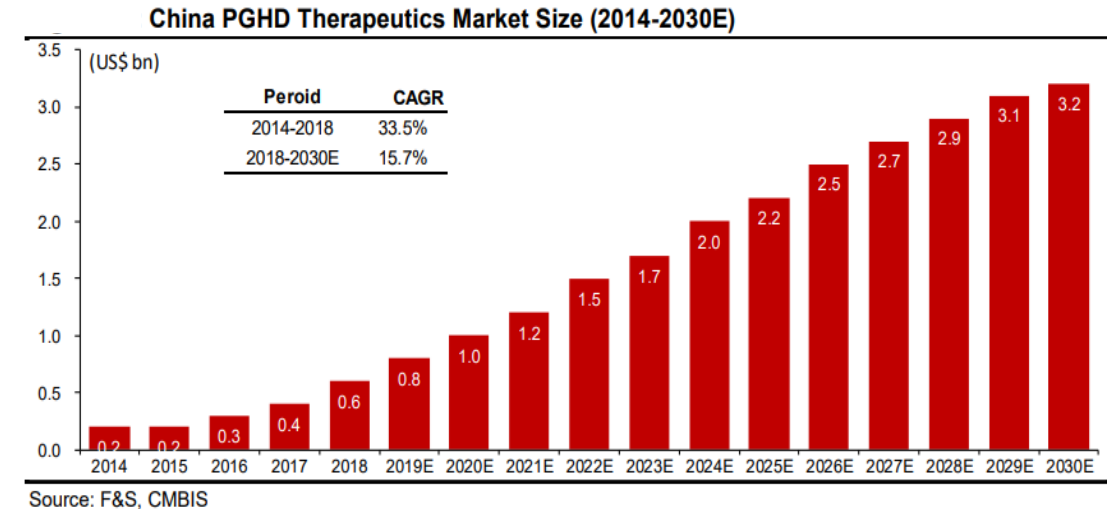
## Clinical Trial & Development Timeline

- IMAB: **China Ph3 IND approved in PGHD (Sept. 2020)**
  - clinical trial (N=224)

## Large unmet need in PGHD market in China

- PGHD affected approximately 3.4mn patients in 2018 in Greater China
- Only 3.7% of all PGHD patients in China were receiving growth hormone replacement therapy in 2018
- Short-acting rhGH is commonly used for the long-term treatment of PGHD and AGHD

## China PGHD Therapeutics Market Size



(Source : F&S, CMBIS)

# 16 GX-E4: Long-acting Erythropoietin (EPO-hyFc)



KALBE



- Biweekly & monthly injection EPO product: long acting anemia treatment induced by chronic renal failure

## License-out Status

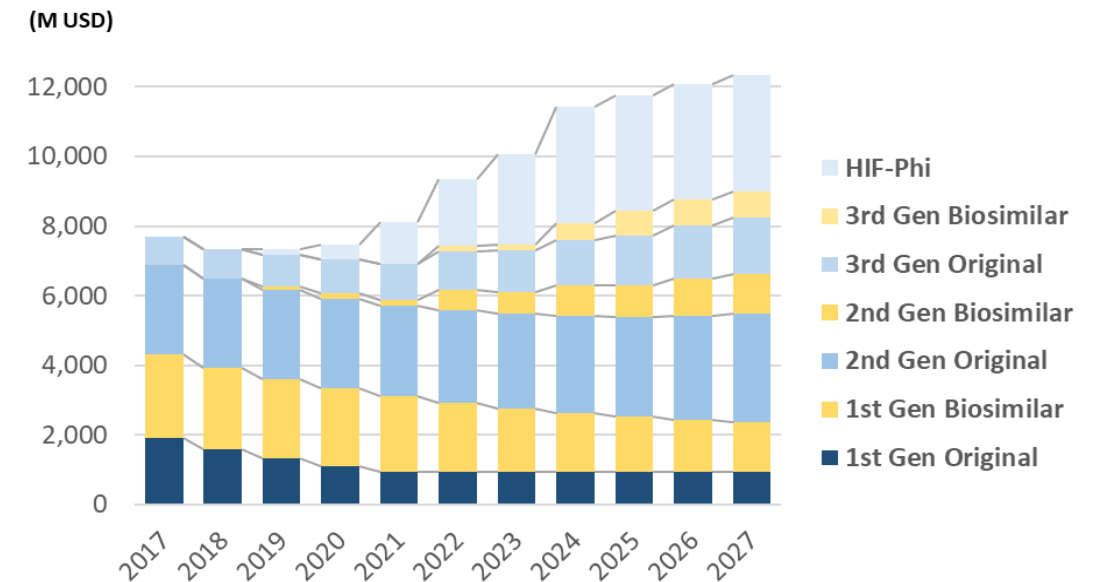
- To KG bio(2015) targeting ASEAN 10 countries, Australia, NZ, and MENA
- To CWB (2016) targeting China

## Clinical Trial & Development Timeline

- **KG bio : Started Phase 3 clinical trials in multiple countries in 2020**
  - Australia, Taiwan & Indonesia, Malaysia, Thailand Philippines (6 countries)
  - Target date from FPI to LPO: June 2020- Q4 2021
  - Estimated Enrollment: 386 pts

## Global EPO Market Size

- Forecast of global EPO market size in 2027 USD 12.3 B (average growth rate of 4.4%)
- Biosimilar/Biobetter Market Size USB 3.3 B Forecast (27% market share)



( Reference: IMS + Global Data(HIF-PHI) + Roche Data Base + VIFOR Annual Report + Amgen Annual Report)



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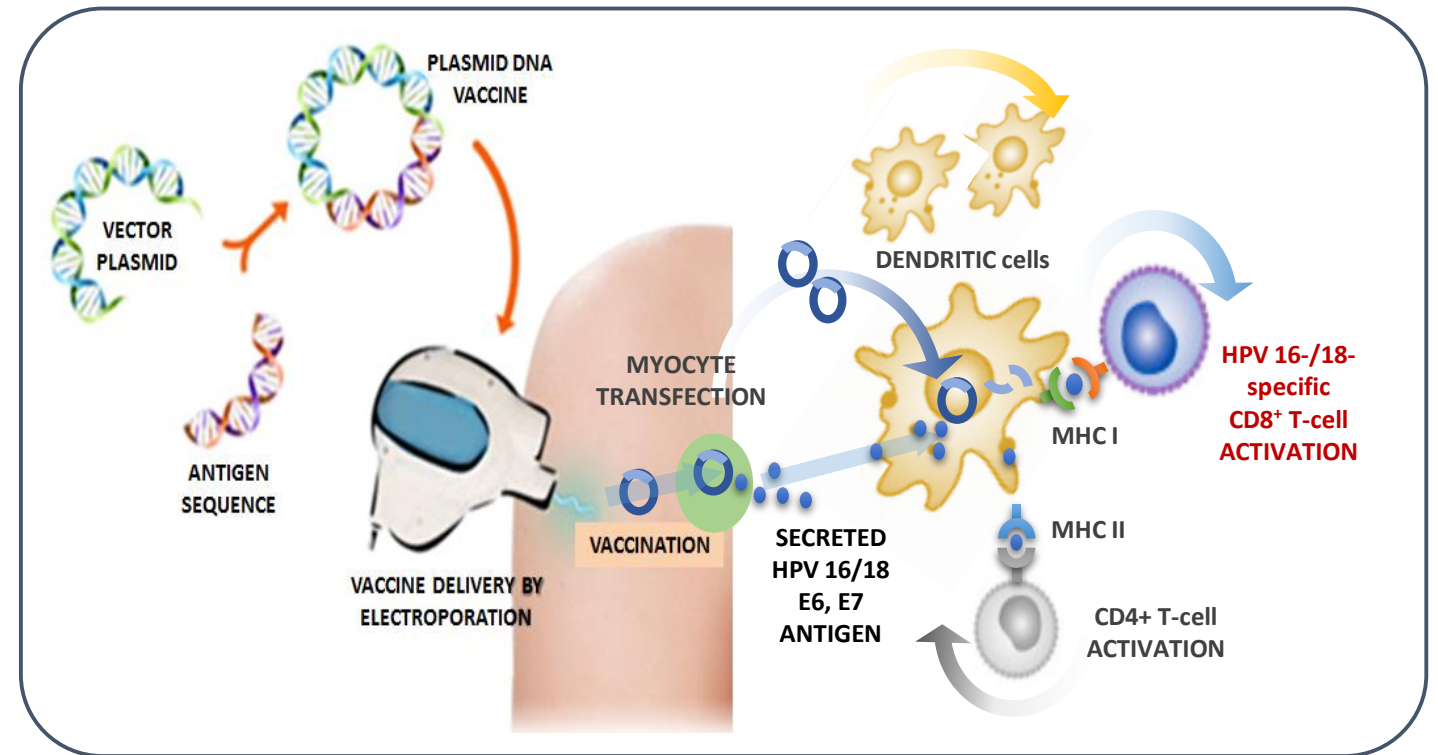
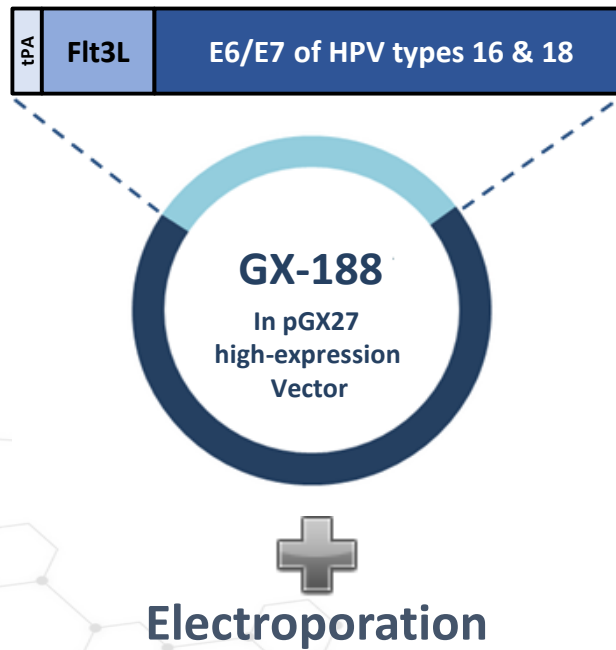
GX-188E

Papitrol-188

HPV Therapeutic DNA vaccine

# 17 GX-188E : The first Therapeutic DNA Vaccine

- Therapeutic DNA Vaccine for HLP 16/18-caused Diseases
- Rationally designed DNA vaccine to enhance HPV 16/18, E6- and E7-specific CD8+ T cell responses



# 18 GX-188E : Market Potential

- Globally greater than 300 million HPV infected cases.
- Cervical cancer patients: globally greater than 500,000 new cases/yr; Head and neck cancer patients: greater than 100,000 new cases/yr

## HPV-induced/caused cancer

### Cervical cancer

Globally  
601,000  
new cases/yr  
  
270,000  
Deaths/yr  
  
HPV 16/18  
Related 70%

### Head and neck cancer

Globally  
142,387  
new cases/yr  
  
97,940  
Death/yr  
  
HPV 16  
Related 63%

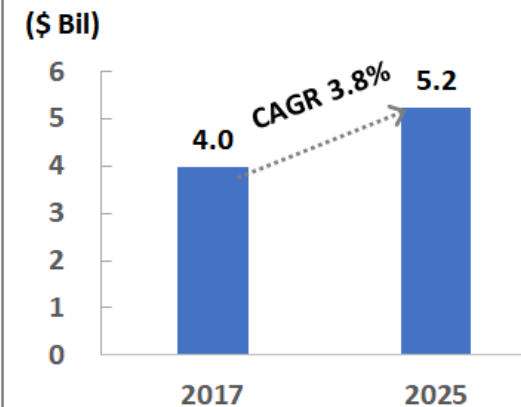
### Anogenital cancer

Globally  
44,480  
new cases/yr  
  
6,000  
Deaths/yr  
  
HPV 16  
Related 72%

(Source: CDC, hpvcentre.net, WHO IARC)

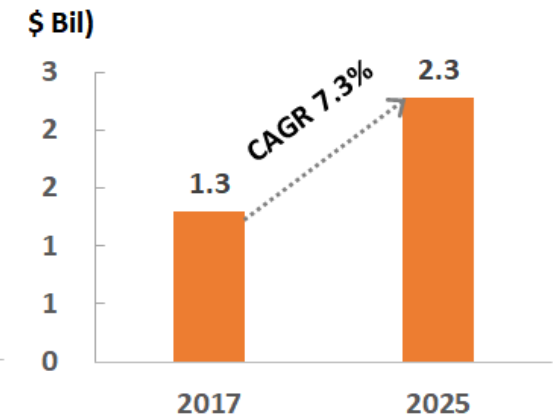
## Potential Market

### Cervical Cancer Treatment Market



Source: Grand View Research\*(2019), Coherent Market Insights\*\*(2019)

### Head & Neck Cancer Treatment Market



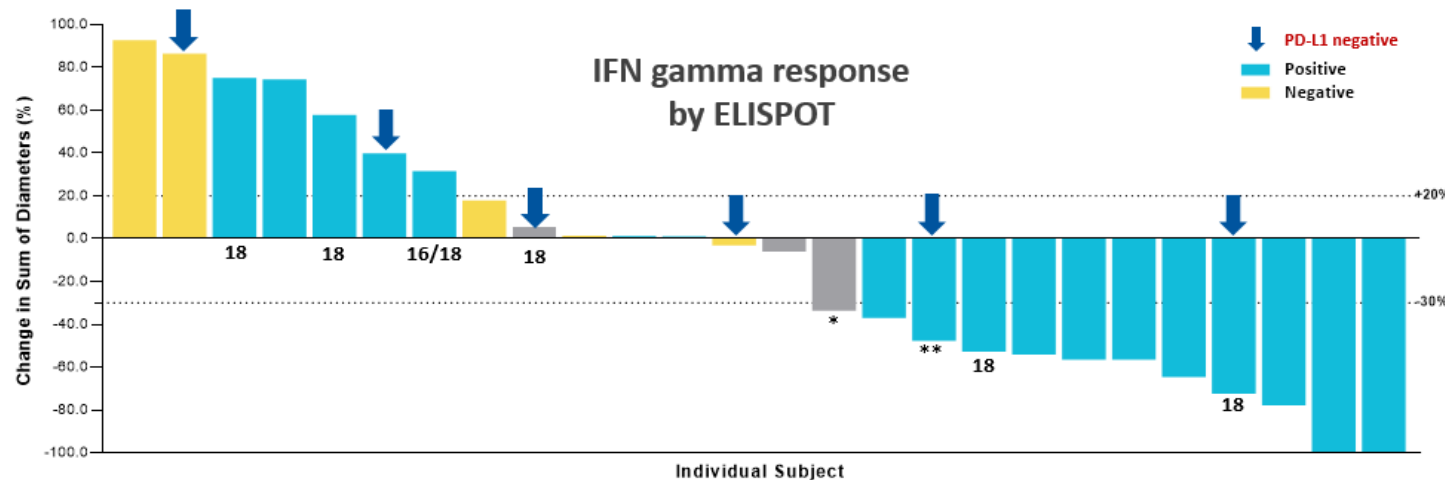
Source: Allied Market Research (2019)



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

- Interim analysis report of the Combination GX-188E and Keytruda(KEYNOTE-467) at AACR in April 2020
  - ORR: PD-L1-positive: 50% HPV16: 47%, Squamous cell carcinoma: Treatment response rate of 45%
  - PD-L1-negative also showed 12.2% of ORR
  - HPV-specific immune responses were observed in 78% of patients.
  - Safe and well-tolerated

## Tumor Regression from Baseline for PD-L1 +/-and HPV 16/18



\*: 3 patients could not be tested for immune responses due to unavailability of PBMCs this time

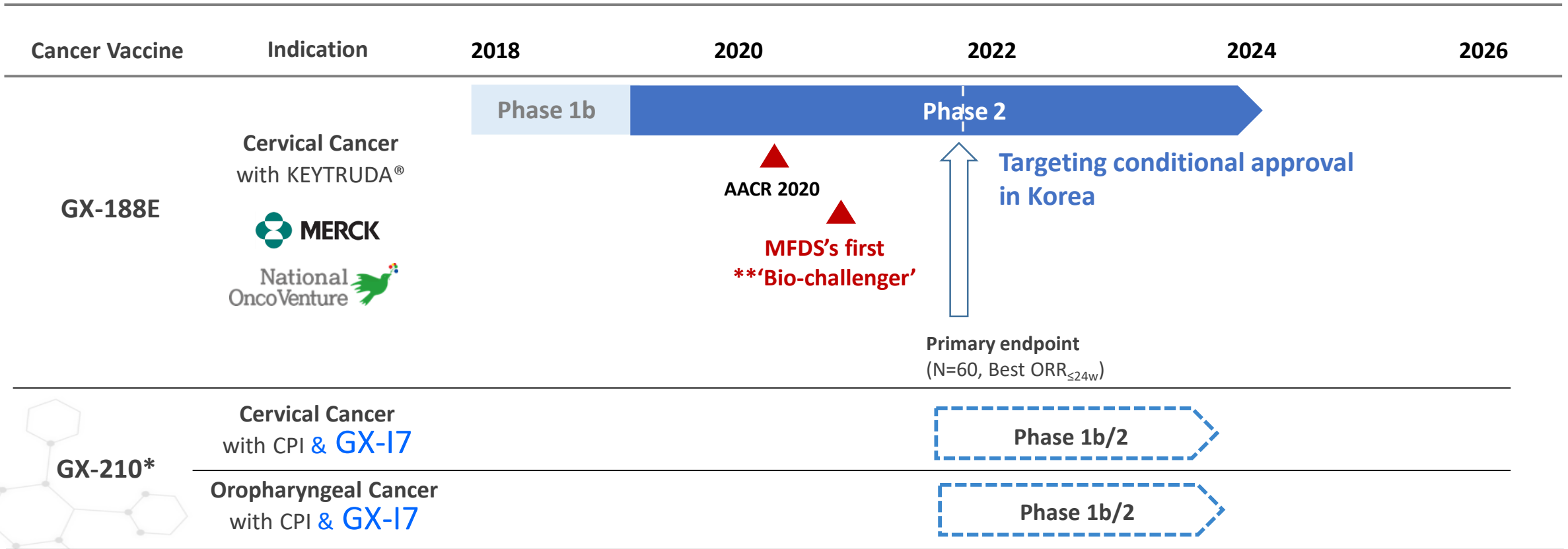
\*\*: The patient showed PR (- 48%) in target region at 10w but new lesion was also found.

## ● Monotherapy of Keytruda

(KEYNOTE-158, N=98)

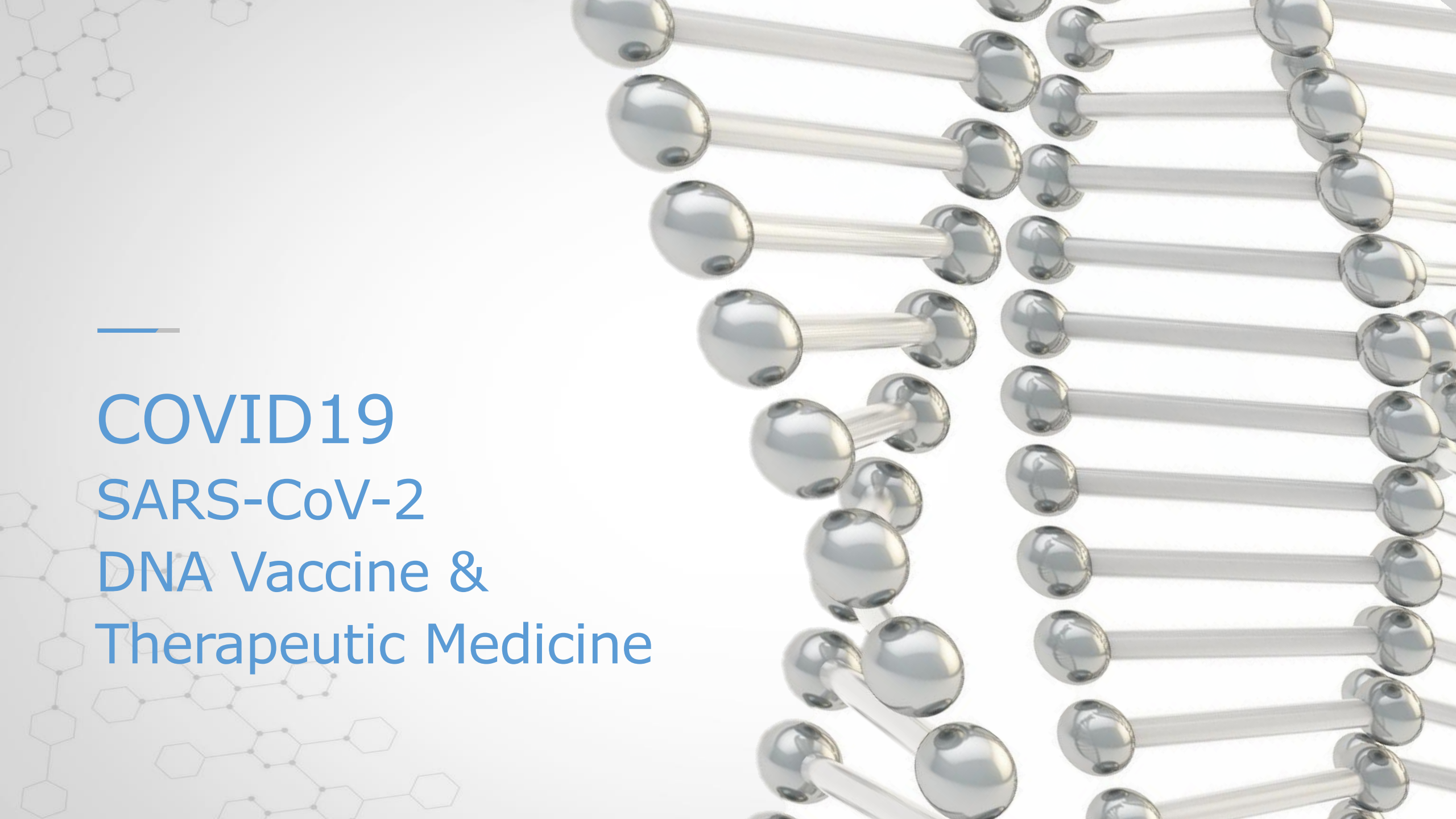
- PD-L1-positive : **ORR 14.6%**
- PD-L1-negative: no ORR

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



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

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

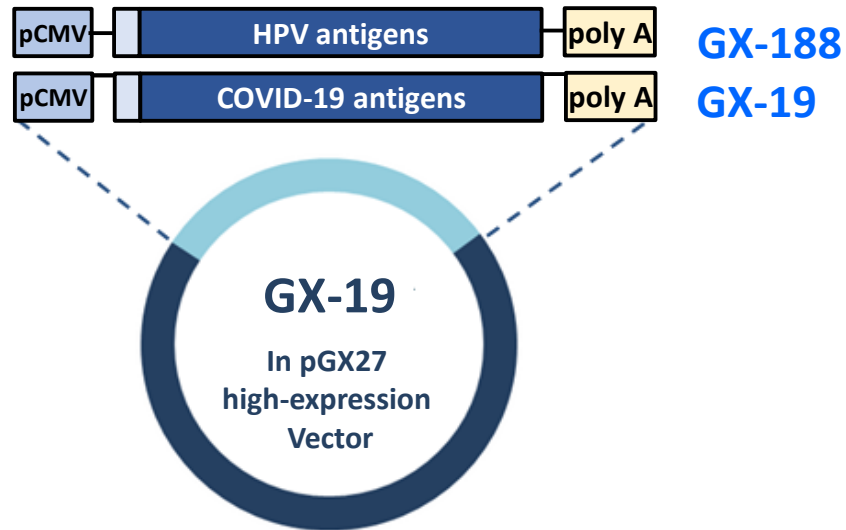


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# COVID19 SARS-CoV-2 DNA Vaccine & Therapeutic Medicine

# 21 COVID-19 DNA vaccine

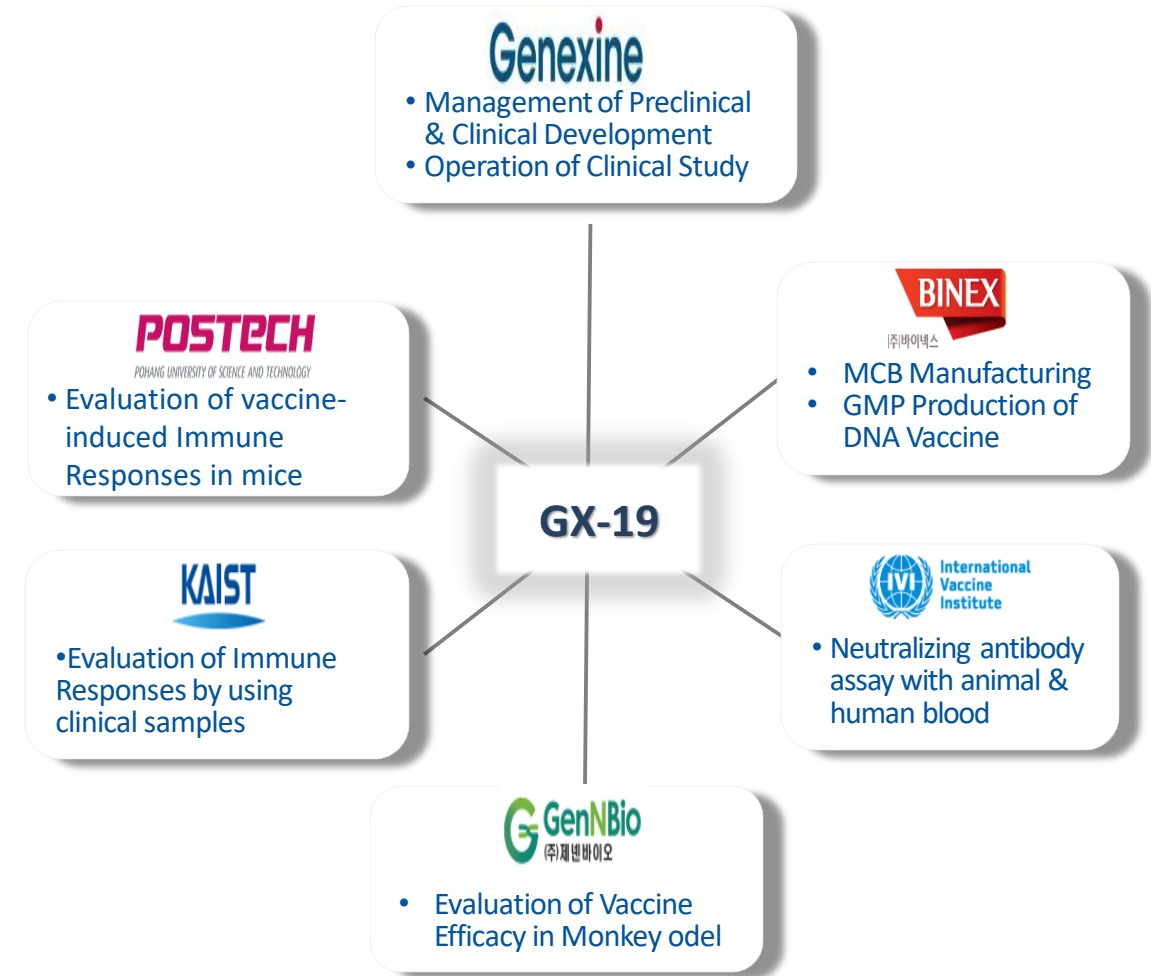
1<sup>st</sup> in Korea and global 15<sup>th</sup> approval for clinical studies



## GX-19 Development Timeline

- **Mar 2020 : Consortium formation among six institutions**  
(Genexine, Binex, IVI, GenNBio, KAIST, POSTECH)
- **June 2020 : Ph1/2a MFDS approved**  
(Ph1 : N=60, Ph2a : N=150)
- **4Q 2020 : Ph1 completion and Ph2a start**

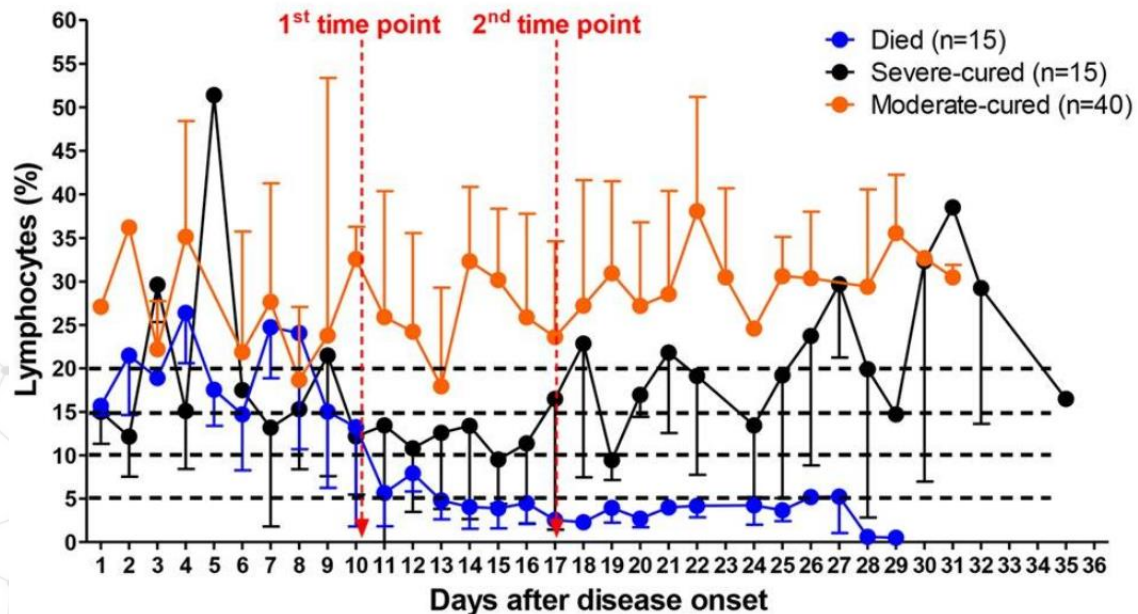
## Members of Consortium



# 22 COVID-19 Treatment: Lymphopenia Correction is Key

## COVID-19 Survival Depends on # of T cell

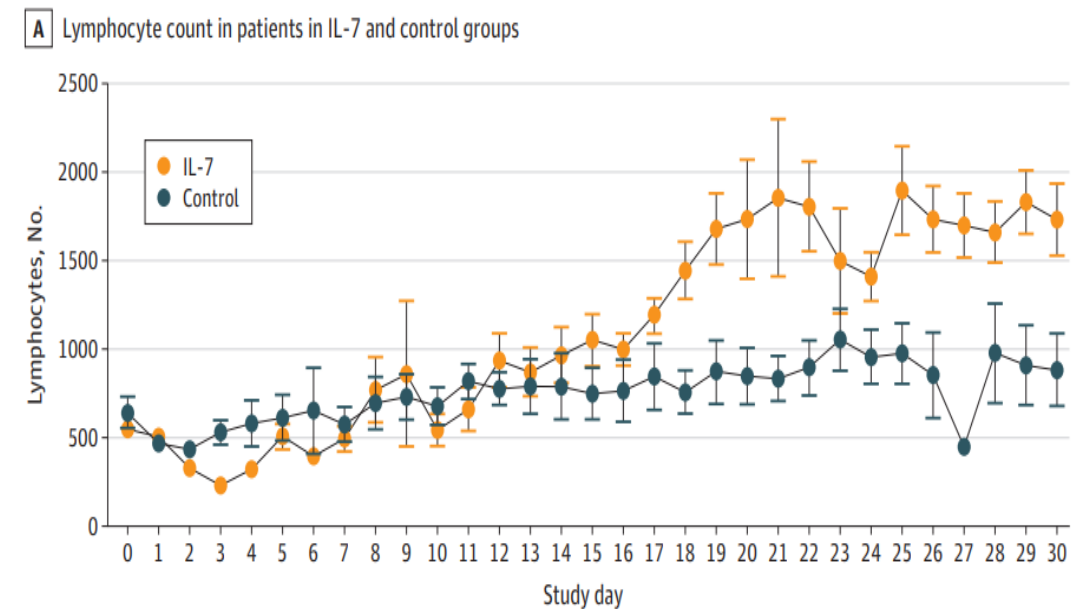
COVID19 patients show severe lymphopenia leading to high mortality



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

## IL-7 Injection Increases # of T cell with no CRS increase

Patients with IL-7 injection show strong lymphocyte count increase



Pierre Francois Laterre, MD1; Bruno François, MD2; Christine Collienne, MD1; et al July 22, 2020



## 23 COVID-19 Therapeutic Medicine, GX-I7

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

### Development Timeline

Indication	Pipeline	Clinical Trial (region)	Developer	Status
COVID-19 (Therapeutic)	GX-I7	<b>Phase 1b &amp; 2</b> - Korea (Ph1b)	GX	N=40, dose escalation scheme: 60~360 ug/kg, IM Target subjects : Asymptomatic and mild COVID-19
		- US (Ph1)	NIT	Expected to be enrolled on November
		- Indonesia(Ph2)	KALBE	Total n=210 - Part I n=90, 120, 240 ug/kg or Placebo, Single, IM - Part II n=120, RP2D, or Placebo, Single, IM 1. Protocol finalization (10/30) 2. Project setup - Preparation of ICF in Indonesian - EDC setup - Preparation of IMP labeling and packaging & delivery





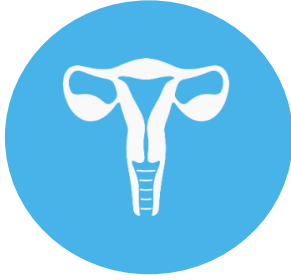
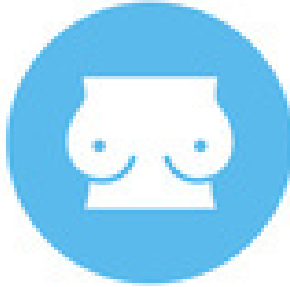



# Business Strategy

# 24 Global Partnership



# 25 Development timeline for Commercialization

- Expecting 7 products' **BLA submission** within 5 years

2021	2022/2023			2023/2024		2024/2025
<b>COVID-19 vaccine</b> (emergency use submission)	<b>GX-I7, COVID-19 therapeutic medicine</b> (conditional approval)	<b>GX-188E +Keytruda®</b> (conditional approval)	<b>GX-I7 (NT-I7) +Keytruda®</b> (conditional approval)	<b>GX-E4</b>	<b>GX-H9</b>	<b>GX-I7(NT-I7,TJ107) +Temozolimide</b>
						
COVID-19 DNA Vaccine	COVID-19	Cervical cancer	TNBC	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)



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

**Genexine, Inc.**

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+82-31-628-2274