

The background of the slide is a complex, abstract pattern of blue spheres and rods. The spheres are of varying sizes and are connected by thin, translucent rods, creating a network-like structure that resembles a molecular or biological model. The overall color scheme is a light blue, giving it a clean, scientific feel.

GENEXINE, Inc.

39th J.P. Morgan Healthcare Conference

Jung-Won Woo, Ph.D
President and Head of Research Institute

January 13th, 2021

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



Company

- Establishment : 1999 @POSTECH venture
- Chairman/CEO: Young-Chul Sung Ph.D.
- Employees : 155(MD 1, Ph.D 20, MS 55)

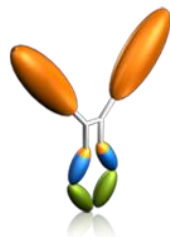
Technologies

- Proprietary platform technologies
 - hyFc[®] fusion technology
 - DNA vaccine technology

Stock

- Publicly Listed : KOSDAQ since 2009
- Ticker : 095700KS
- Market Cap : \$2.8bn (End of 2020)

hyFc® (Long-acting protein)



First-in-Class

- GX-I7: Immuno-oncology (Lymphopenia)
- GX-P1/GX-P10: Autoimmune Diseases

Best-in-Class

- GX-H9: Growth hormone deficiency
- GX-E4: CKD-induced anemia
- GX-G3: Neutropenia
- GX-G6: Type 2 Diabetes
- GX-G8: Short bowel syndrome

CKD; Chronic kidney disease

DNA Vaccine (Vaccines for Cancer/Infectious Disease)



First-in-Class

Therapeutic DNA Vaccine












- GX-188E/GX-210: HPV-induced cervical cancer & Head and Neck cancer

First-in-Class

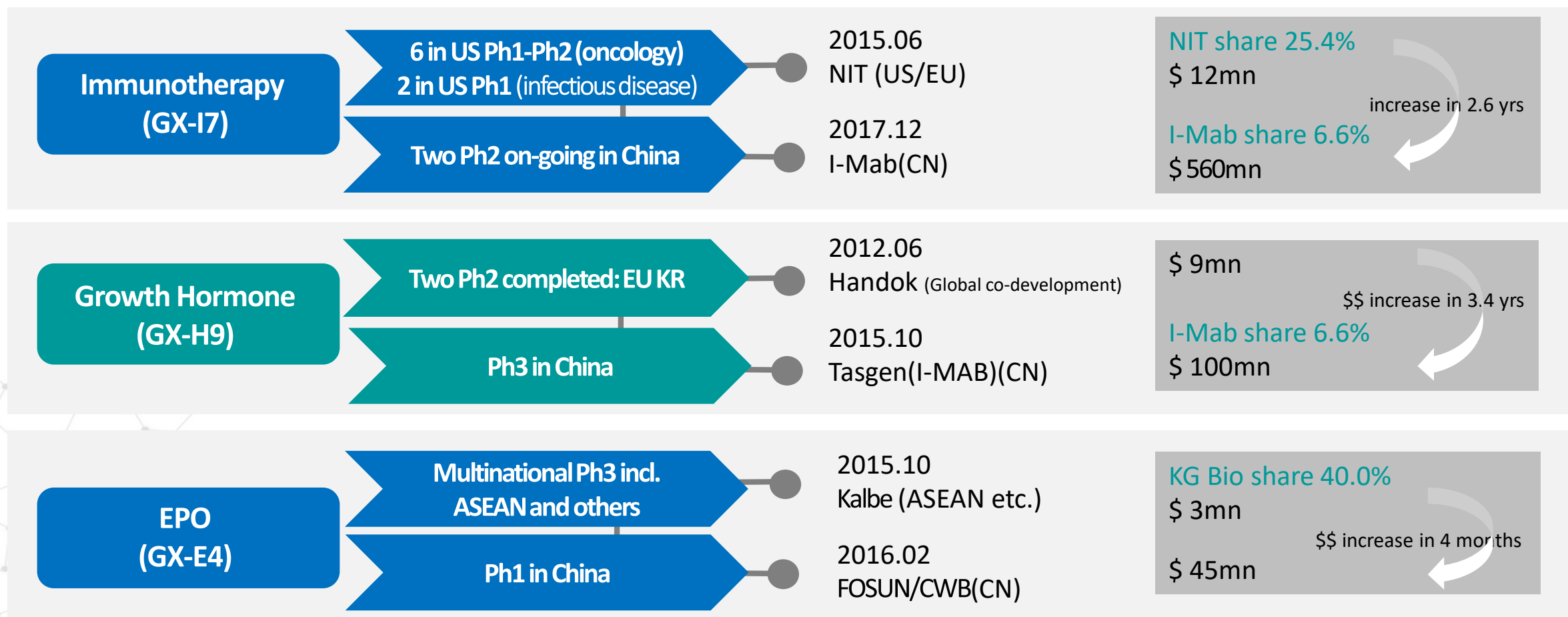
DNA Vaccine for Prevention

- GX-19N: COVID-19

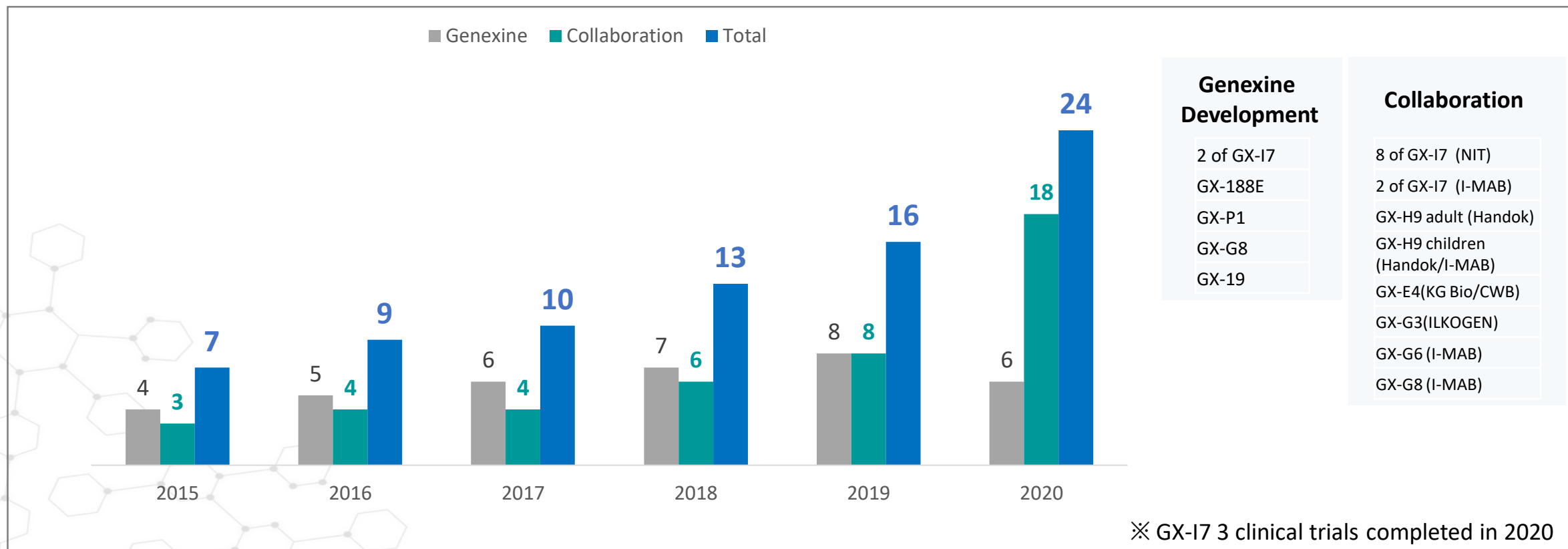
HPV; Human papillomavirus

Pipeline	Indication	Clinical Stage			Developer	Collaborator
		Phase 1	Phase 2	Phase 3		
First-in-class	 GX-I7 Immuno-oncology (Lymphopenia) COVID-19 (Treatment)	Phase 1 ~ 2 in KR/US/CN			Genexine, I-MAB NeoImmuneTech	   Bristol Myers Squibb™
		Phase 2 in Indonesia				
	 GX-188E HPV-induced Cervical Cancer	Phase 2 in KR			Genexine	
	 GX-19N COVID-19 (Preventive)	Phase 1 in KR			Genexine	
	 GX-P1 Autoimmune Diseases Organ transplantation	Phase 1 in KR				
Best-in-class	 GX-H9 Growth Hormone Deficiency (PGHD) Growth Hormone Deficiency (AGHD)	Phase 2 in KR/EU		Phase 3 in CN	Genexine, Handok I-MAB	
		Phase 2 in KR/EU				
	 GX-E4 CKD-induced Anemia	Phase 2 in KR		Phase 3 in SE Asia	Genexine, KG Bio	
	 GX-G3 Neutropenia	Phase 2 in EU				

- Win-Win strategy with L/O partner companies: shareholding leads to building of strong partnership
- As development stage advances, L/O deal size and company value of partners increase



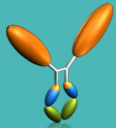

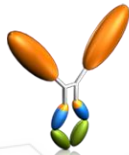
- 6 independent + 18 collaboration = **Total 24 trials currently in clinical development**
- Compared to 2015, # of clinical studies increased by 3.5-folds
- R&D expenses kept approximately \$ 40mn since 2017



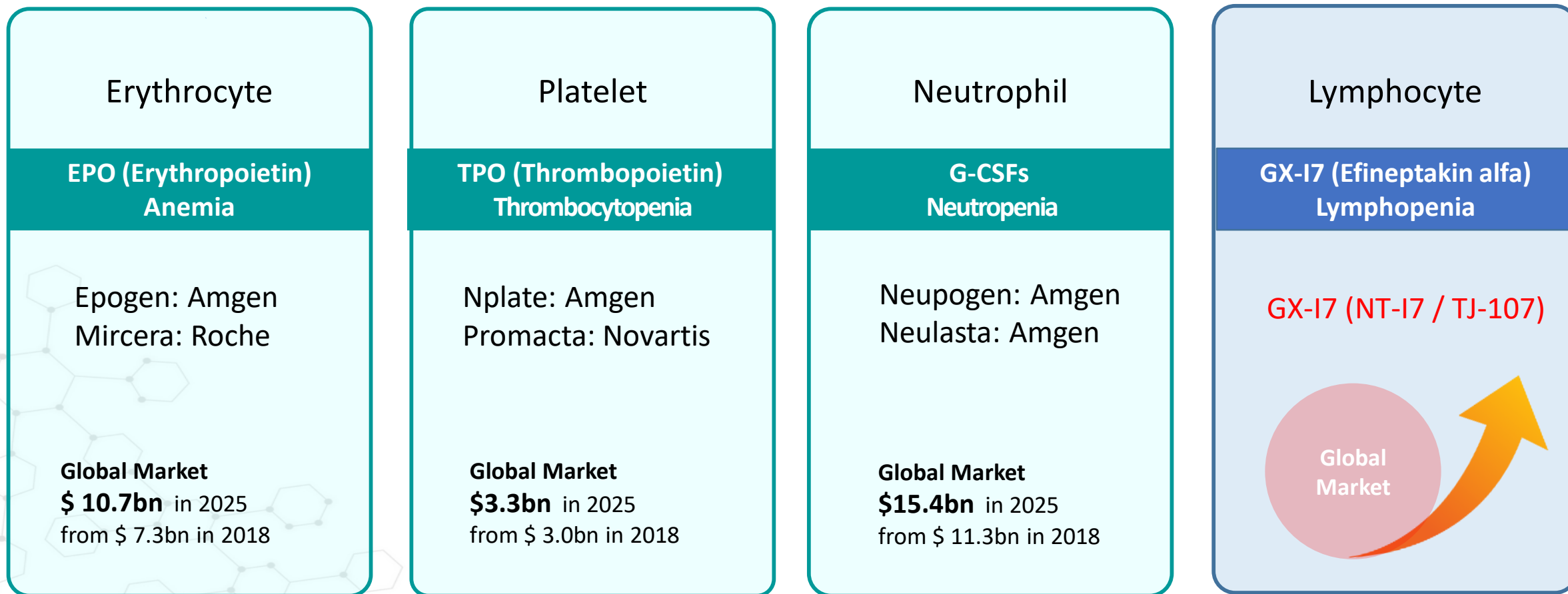
GENEXINE: Key Pipeline Events 2020-2021

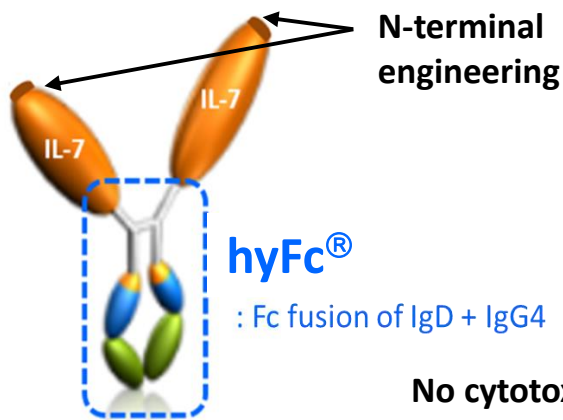
MAKE INCURABLES
CURABLE

Genexine is pioneering next generation biotherapeutics
to treat and save the lives of patients with serious diseases.

<p>hyFc® Long-acting protein drug</p> 	<p>GX-I7</p>	<p>The First Long-acting Lymphopenia Correction Drug in Cancer & COVID-19</p>
<p>DNA vaccine Cancer therapeutic & Infectious disease</p>  <hr/> <p>hyFc® Long-acting protein drug</p> 	<p>GX-188E</p> <p>GX-19N</p> <p>GX-H9</p> <p>GX-E4</p>	

- Multi-billion market for targeting blood cells/components
- No lymphopenia correction drugs have been approved, so far.



GX-I7 (IL-7-hyFc[®])

No cytotoxicity on target cells
via No ADCC of IgD & No CDC of IgG4



Higher protein stability



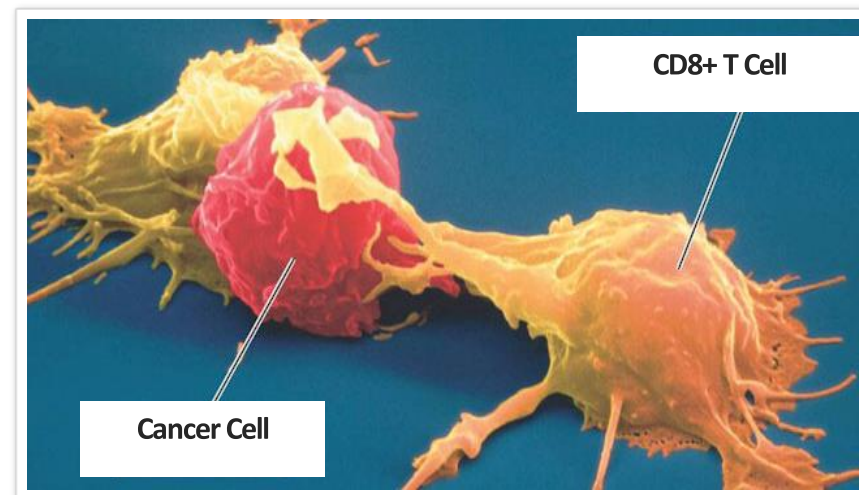
Higher productivity



Longer *in vivo* half-life

T cell Amplifier

Interleukin-7
Long-acting Interleukin-7



T cell Activator

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

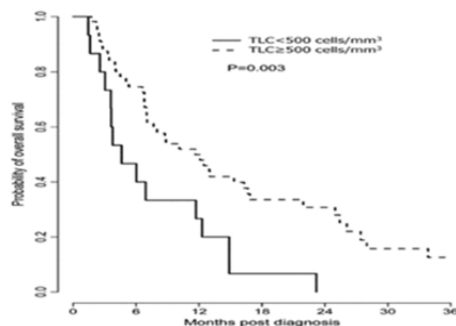
T cell Suppressor blockade

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

Chemo/Radiotherapy

GBM, New/Elderly

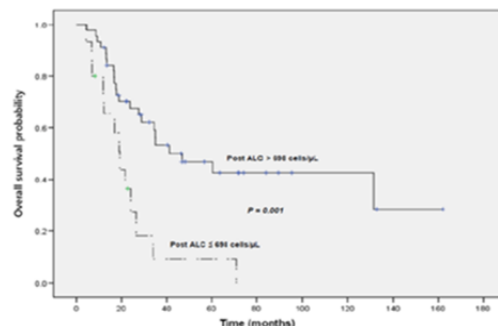
mOS 4.6m vs 11.6m



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

SCLC, Limited

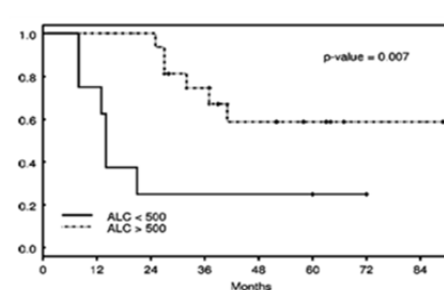
mOS 12.2m vs 35.3m



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

Ewing Sarcoma

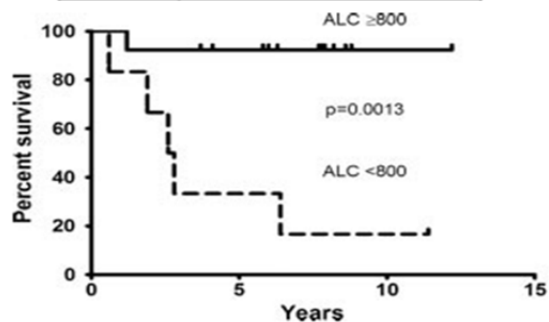
5y OS 25% vs 58.7%



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

Pediatric Osteosarcoma

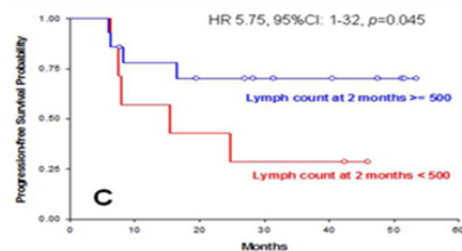
5y OS 33.3% vs 92.3%



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

Squamous Cell H&N, New

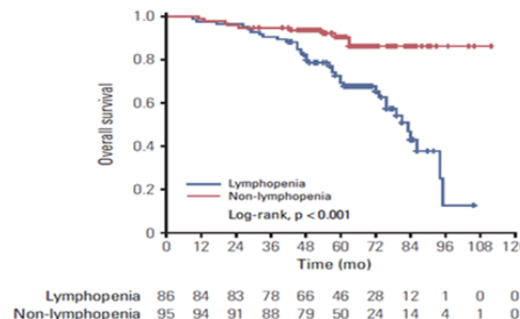
mPFS Hazard Ratio 5.75



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

Nasopharyngeal Carcinoma

mOS HR 1.76 post3m ALC

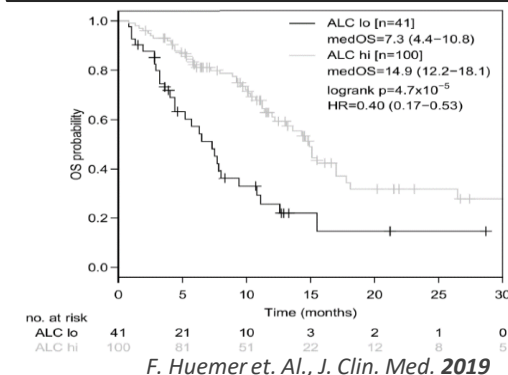


Liu LT et. al. *Cancer Res Treat.*
2018;50(1):19-29

Immunotherapy

Adv. NSCLC (ALC < 930/mm³)

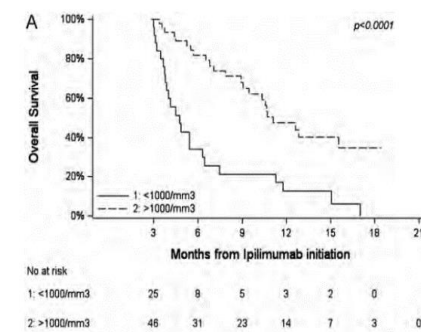
anti-PD-1/PD-L1 treatment (nivolumab, pembrolizumab, or atezolizumab)



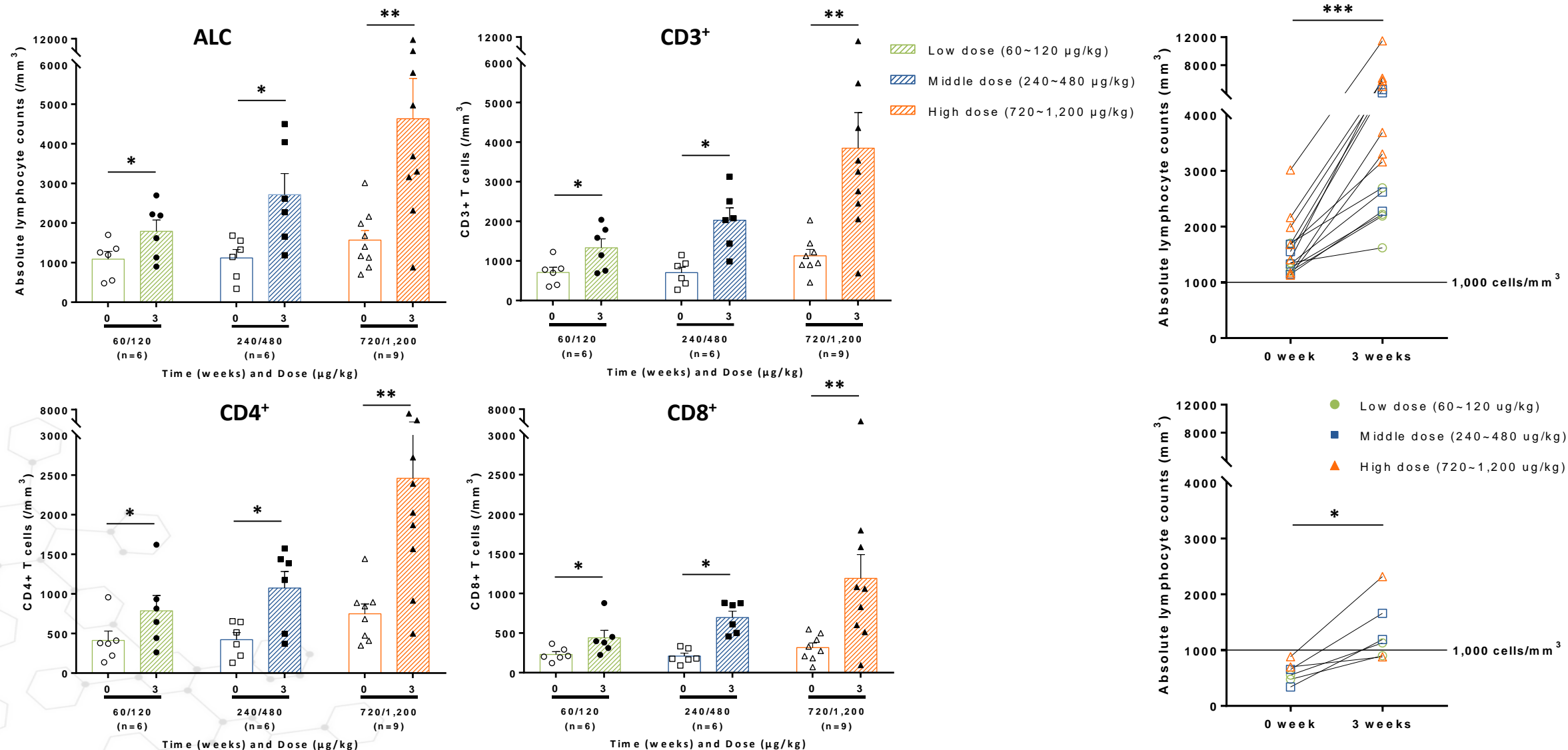
F. Huemer et. Al., *J. Clin. Med.* 2019

Melanoma (ALC < 1000/mm³)

Stage III and IV, receiving four courses of ipilimumab q3w



Delyon et al. *Annals of Oncology*, 2013

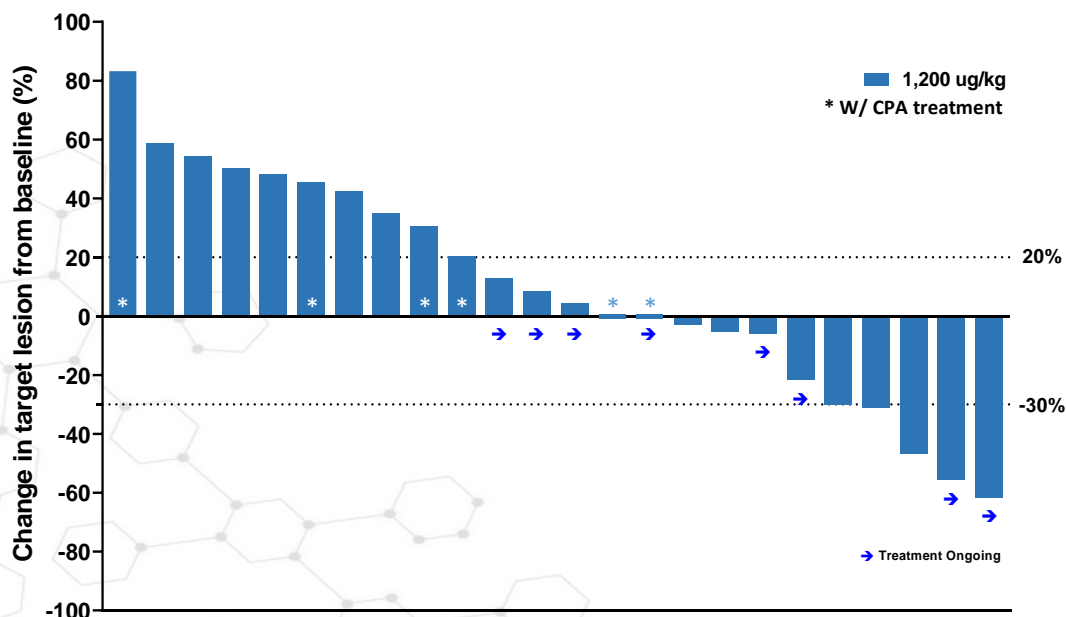


*p<0.05, **p<0.01, ***p<0.001 versus baseline (0 week) group by Wilcoxon matched-pairs signed rank test.

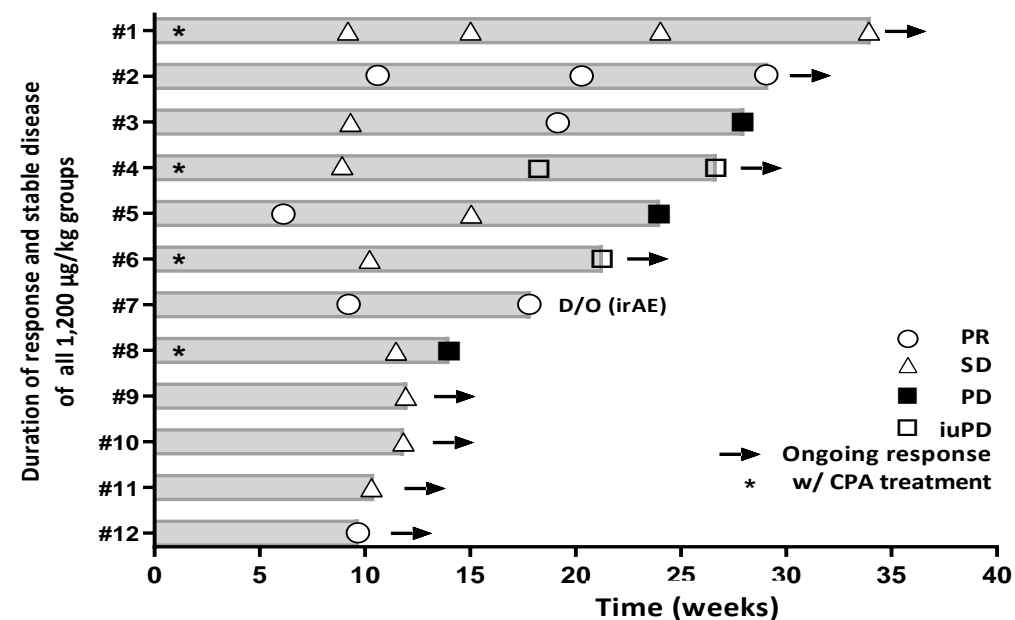
Source; MK Heo et. al, SITC 2019

- Interim analysis data of Combination Treatment of GX-I7 and Keytruda (KEYNOTE-899) presented at SITC, 2020
 - 1,200ug/kg dose of GX-I7 with Keytruda(Pembrolizumab) selected as RP2D for the Ph2 expansion study
 - Improved clinical outcome : **27.8 % ORR** (Keytruda alone: 5.3% ORR) *Source; Adams S et al. Annals of Oncology. 2019*

Tumor response



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



Source; JH Sohn et. al, SITC 2020

Chemotherapy & Radiotherapy

The Global Chemotherapy Market
\$ 33 B in 2020

Cancer Vaccines

DNA, RNA Peptide, Viral

The Global Cancer Vaccine Market
\$ 12 B in 2025 from \$ 3.3 B in 2017
CAGR of 17.3%

GX-17

T-cell amplifier

Checkpoint Inhibitor

Anti-PD-1, Anti-PD-L1, Anti-TIM3, Anti-LAG3...

The Global Immune Checkpoint Inhibitors Market
\$ 56.5 B in 2025 from \$ 10.5 B in 2017
CAGR of 20.1%

Cell Therapy

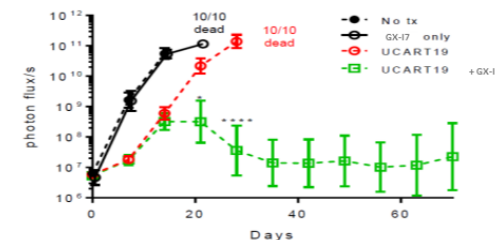
CAR-T / TCR-T

The Global CAR -T cell Therapy Market
\$ 8.71 B in 2025 from \$ 0.34 B in 2018
CAGR of 58.5%













Infectious Disease Therapy

The Global infectious disease therapy market
\$ 59.3 B in 2026 from \$ 47.6 B in 2020
CAGR of 3.7%

Source; EvaluatePharma World Preview 2020,
 Mckinsey&Company, , MarketWatch 2020



Source; DiPersio J. et . al. ASH 2018 (WASHU&NIT)

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 1/2a				I-MAB	
	Mono	-	GBM	Phase 1/2				NeolImmuneTech	
	Co	Temozolomide	GBM	Phase 1/2				NeolImmuneTech	
	Co	Tecentriq®	High risk skin cancer	Phase 1b/2a				NeolImmuneTech	 
	Co	KEYTRUDA®	TNBC, Lung, Pancreatic, Colorectal cancer	Phase 1b/2a				NeolImmuneTech	
	Co	Opdivo®	Gastric, GEJ, and Esophageal Adenocarcinomas	Phase 2				NeolImmuneTech	
	Co	Tecentriq®	NSCLC, Non-Small Cell Lung Cancer	Phase 2 (Prepare IND submission)				NeolImmuneTech	
	Co	Kymriah®	Diffuse large B-cell lymphoma	Phase 1b				NeolImmuneTech	
Infectious Disease	Mono	-	Idiopathic CD4 ⁺ T Lymphopenia	Under IND submission				NeolImmuneTech	
	Co	Vaccine	Preventative vaccine (Elderly cancer survivors)	Phase 1/1b				NeolImmuneTech	
	Mono	Standard treatment	COVID-19 infected patients	Phase 1b				Genexine	
	Mono	Standard treatment	COVID-19 infected patients	Phase 2				KGbio	
	Mono	Standard treatment	COVID-19 infected patients	Phase 1				NeolImmuneTech	

GENEXINE: Key Pipeline Events 2020-2021

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hyFc®
Long-acting
protein drug



GX-I7

DNA vaccine
Cancer therapeutic
& Infectious disease



GX-188E

Therapeutic HPV DNA Vaccine Achieving Synergy with ICB

GX-19N

GX-H9

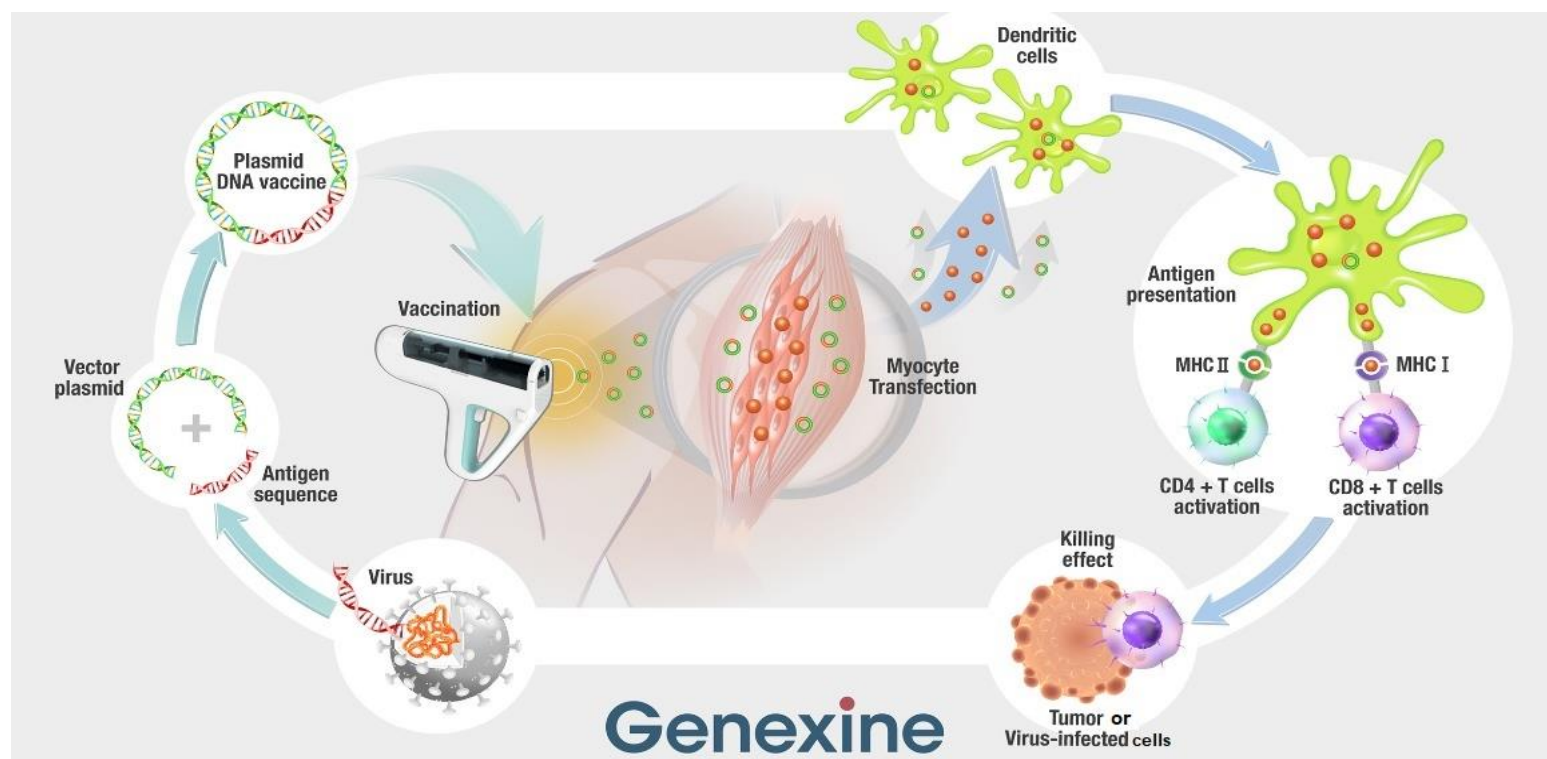
GX-E4



- Therapeutic DNA Vaccine for HPV Types 16/18-caused diseases
- Rationally designed DNA vaccine to enhance HPV 16/18, E6- and E7-specific CD8 + T cell responses
- Dramatic increase in efficacy as combination therapy with CPI

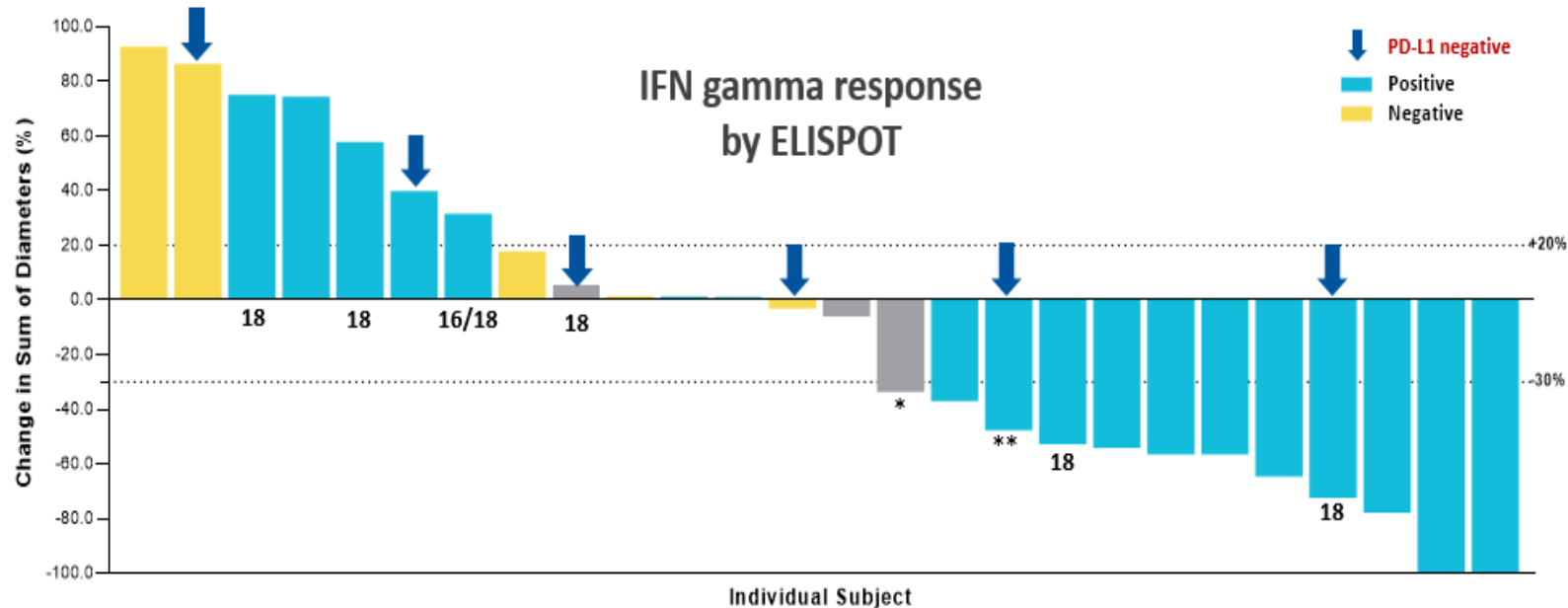


Electroporation



- Interim analysis report of combination GX-188E and KEYTRUDA® (KEYNOTE-467) at AACR, 2020

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.

Source; SY Hur, AACR 2020; JW Youn et. al, Lancet Oncol, 2020

Monotherapy of KEYTRUDA®

(KEYNOTE-158, N=98)

- PD-L1-positive : **14.6% ORR**
- PD-L1-negative: 0%
- Regardless of PD-L1: 12.2%

GX-188E + KEYTRUDA®

(KEYNOTE-567, N=26)

- PD-L1-positive : **50.0% ORR**
- PD-L1-negative: 16.7%
- Regardless of PD-L1: 42.4%

Market Potential

Facts in Cervical Cancer

601,000 new cases/year WW
270,000 deaths/year WW

~70%, HPV 16/18 related

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

Facts in Head and Neck Cancer

650,000 new cases/year WW
330,000 deaths/year WW

35~55% HPV 16 related

Clinical Trial Timeline

Pipeline	Indication	2018	2019	2020	2021	2022
GX-188E	Cervical cancer with KEYTRUDA®	Phase 1b		Phase 2		
				Selected for 1 st Bio-Challenger project by MFDS (Korea FDA)	Submission planned for conditional approval in Korea	

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**The Only Korean Biotech Developing
Both Vaccine and Therapeutic Medicine for COVID-19**

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Long-acting
protein drug



GX-I7

GX-188E

DNA vaccine
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GX-19N

hyFc®
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protein drug



GX-H9

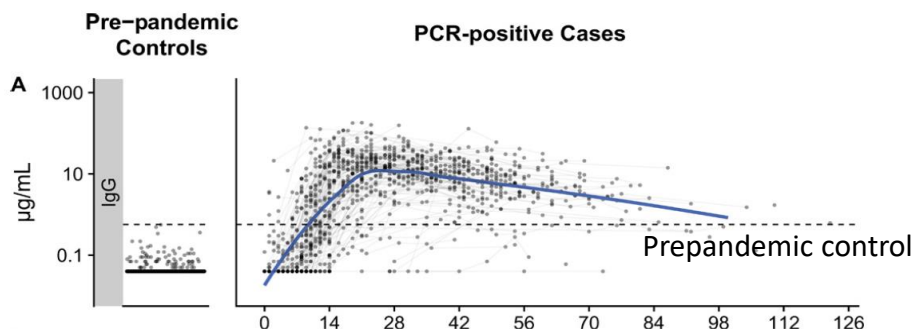
GX-E4

- **Ab response: Detectable for 3 to 5 months after COVID-19 infection**

Ref) Iyer AS (2020) *Sci Immunol*

- **T cell response: Lasting for longer than 6 months**

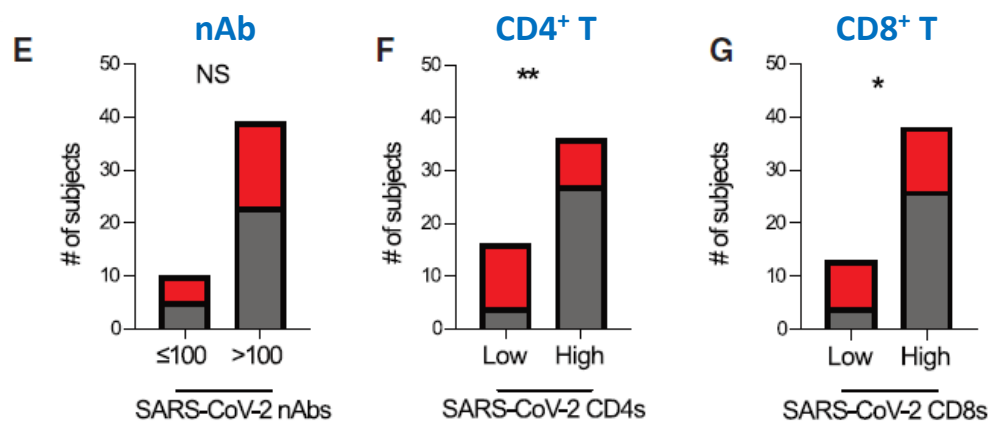
Ref) Adaptive biotechnology (2020), Zuo J (2020) *bioRxiv*, Nov 2



Iyer AS (2020) *Sci Immunol*, Oct 8

SARS-CoV-2 responsive T cell numbers are associated with protection from COVID-19 in a prospective cohort study

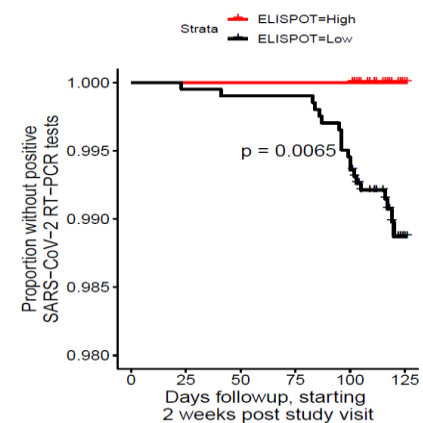
- Subjects with high T cell response although seronegative have been protected from SARS-CoV-2



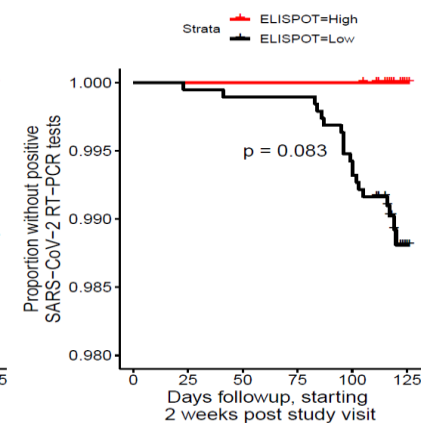
- Moderbacher CR (2020) *Cell*, Sep 11.

➤ nAb did not lessen disease severity.

Figure 5 A All individuals



B Seronegative individuals



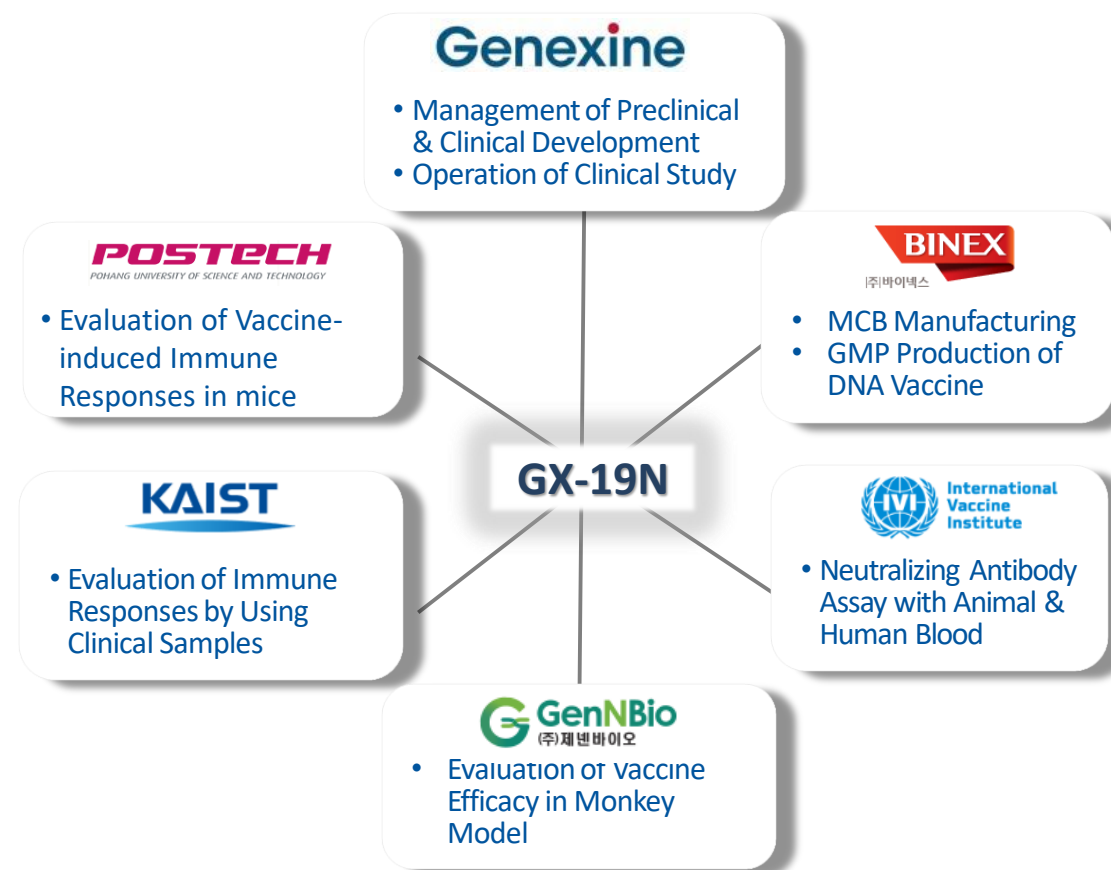
Ref) Wyllie D (2020) *medRxiv*, Nov 4

- GX-19N, the next generation COVID-19 DNA vaccine



Type	• DNA vaccine
Antigen	• Spike & Nucleocapsid Proteins
Number of Subjects	<ul style="list-style-type: none"> • Phase 1 : N = 20 (additional 30 for elderly) • Phase 2a : N = 150
Frequency & Method	• Intramuscular injection (2 injections with 4-week interval)
Delivery Devices	• Electroporator (EP)

Members of Consortium



- **Significant correlation between T cell responses and disease severity** of SARS-CoV-2 infection (*Moderbacher CR, Cell, 2020*).
 - COVID-19 fatalities observed in subjects even with high nAb levels, if no T cell responses are detected.

Genexine COVID-19 Preventative DNA Vaccine

- **Plasmid DNA encoding Spike + Nucleocapsid proteins of SARS-CoV-2**
- **Safe and Stable platform**
- **Strong and Broad T cell immunity**
: Nucleocapsid protein, more conserved and highly immunogenic (*J Virol, 94(13):e00647-20 (2020)*)

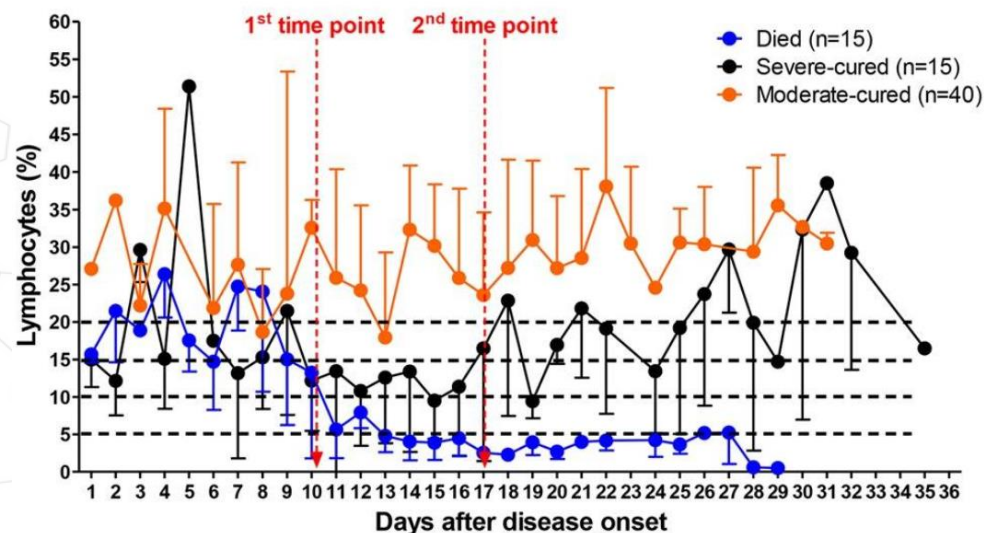
Development Timeline

Ph1/2a IND approval	• December 11 th , 2020
Ph1/2a	• December 2020 ~
Ph2b/3	• ~ December 2021 (Submission for Emergency Use)

- **GX-I7 has been repurposed to treat COVID-19 patients via lymphopenia correction.**
 - A single dose to be injected within the 7 days from the appearance of the first symptom.

COVID-19 Survival depends on number of T cells

Severe lymphopenia in COVID-19 patients associated with high mortality



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

Clinical Trials on-going

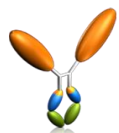
Region	Phase	Number of patients	Conducting company
KOREA	Phase 1b	40 patients ≥ 20 Aged	Genexine
US	Phase 1	30 patients ≥ 18 Aged (FPI in Nov. 2020)	NeolImmuneTech & NIH, NIAID, UNMC
Indonesia	Phase 2	210 patients Elderly participants 50 years	Genexine, KG Bio

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GX-I7

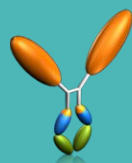
GX-188E

DNA vaccine
Cancer therapeutic
& Infectious disease



GX-19N

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GX-H9

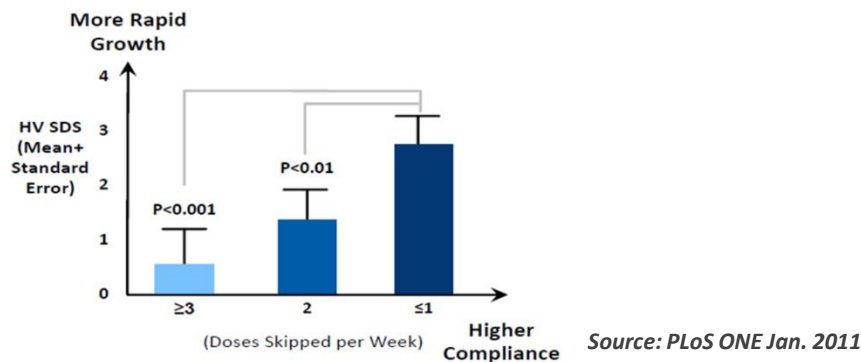
GX-E4

Competitive Long-acting Protein Drugs in Late-stage Clinical Trials

- Growth hormone deficiency, weekly and EOW injection

Daily injections
365 injections/year

Weekly / EOW injections
52/26 injections/year



License-out Status

- Co-development with Handok(2012) targeting worldwide
- To I-MAB (2015) targeting Greater China

Clinical Trial & Development Timeline

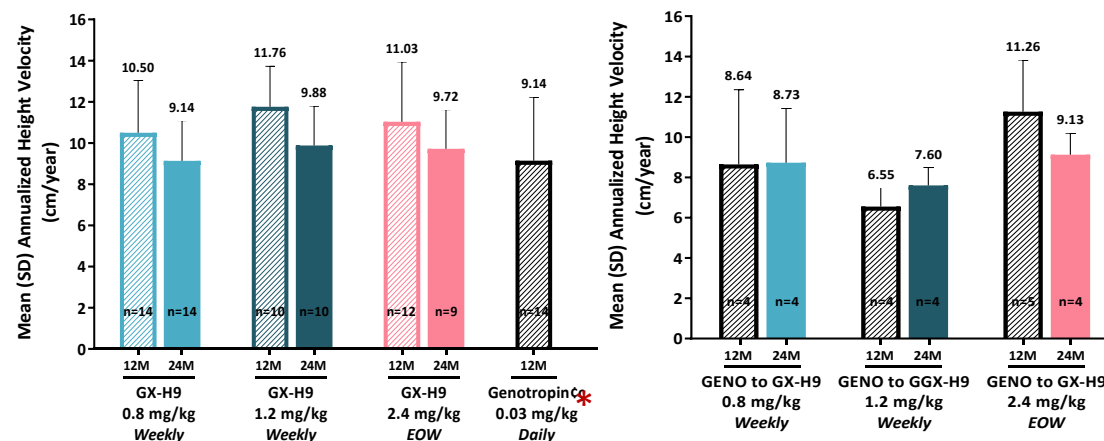
- I-MAB: China Ph3 IND approved (Sept. 2020)
- Ph3 clinical trial: N=224

Average Annual Growth Data

* EOW : Every Other Week

aHV at 1st and 2nd year

Switching to GX-H9 at 2nd year



Global PGHD Therapeutics Market Size

- Global : \$2.9bn in 2018 / \$6.0bn in 2030E
- China : \$0.6bn in 2018 / \$3.2bn in 2030E

33.5% of CAGR in 2014-2018 / 15.7% in 2018-2030E

- Biweekly & Monthly injection for correction and maintenance treatment of CKD-induced anemia

License-out Status

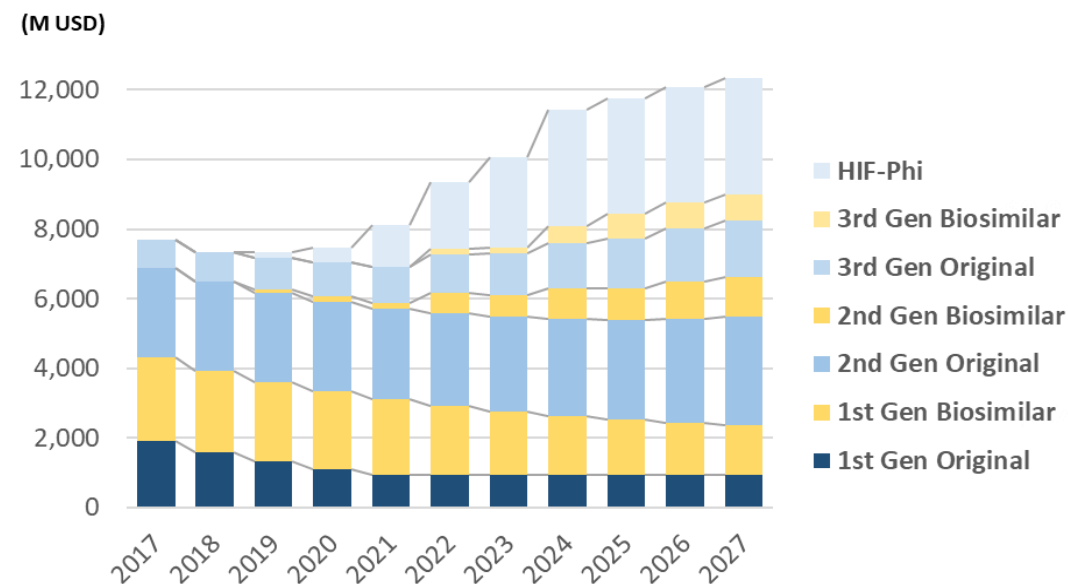
- To KG bio (JV with Kalbe, 2015) targeting ASEAN 10 countries, Australia, NZ, and MENA
- To CWB (2016) targeting China

Clinical Trial & Development Timeline

- KG bio : Started Phase 3 clinical trials in multiple countries (N=386)
 - Australia, Taiwan & Indonesia, Malaysia, Thailand Philippines (6 countries)
 - Recruitment completion by 2H, 2021

Global EPO Market Size


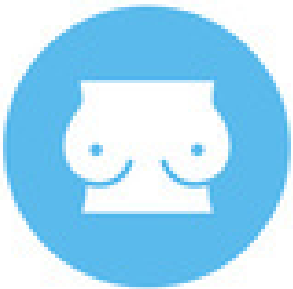


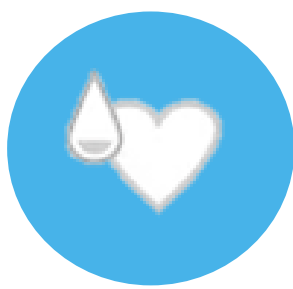


- Forecast of global EPO market size in 2027 USD 12.3 B (average growth rate of 4.4%)
- Biosimilar/Bio-better Market Size USB 3.3 B Forecast (27% market share)



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

Commercialization & Business Plan



2021	2022/2023			2023/2024		2024/2025
GX-19N, COVID-19 vaccine (emergency use submission)	GX-I7 (NT-I7) +KEYTRUDA® (conditional approval)	GX-188E +KEYTRUDA® (conditional approval)	GX-I7, COVID-19 therapeutic medicine (conditional approval)	GX-E4	GX-H9	GX-I7(NT-I7,TJ107) +Temozolomide (conditional approval)
						
COVID-19 DNA Vaccine	TNBC	Cervical cancer	COVID-19 Treatment	CKD-induced Anemia	Growth Hormone Deficiency	GBM
Current clinical phase						
Phase I/IIa (Korea)	Phase Ib/II (Korea)	Phase II (Korea)	Phase Ib, Phase II (Korea) (Indonesia)	Phase III (SE Asia)	Phase III (China)	Phase II (China)

KOREA

Genexine

GenNBio
(주)제넨바이오

ToolGen

HAN/DOK

Ajinomoto
AJINOMOTOyuhan
CORPORATION

NEOIMMUNETECH

PharmaJet

MERCK

REZOLUTE

ichor
medical systems

colIMMUNE

● Joint Venture

● Equity Investment

● Clinical Research
Collaboration

Company Name	Listing Date (Expected)	IPO Market (Country)	Share	Market cap.
I-MAB Biopharma (CN)	Listed (2020. 01)	Nasdaq (US)	6.1%	\$ 2,680mn
Rezolute (US)	Listed (2020. 11)	Nasdaq (US)	21.2%	\$ 160mn
NeoImmuneTech (US)	2021	Kosdaq (KR)	25.4%	To be listed in 1Q, 2021
ToolGen (KR)	2021~2022	Kosdaq (KR)	16.6%	KONEX / \$ 550mn
ColImmune (US)	2023	Nasdaq (US)	25.5%	-

1999 ~ 2010

- Innovative platform technologies
- hyFc[®], DNA Vaccine

2011 ~ 2020

- Immunotherapy & DNA vaccine
- Collaboration development with global big pharma
- L/O to global partners
- 24 clinical studies in 2020

2021 ~ 2025

- Potential for 7 launches of Mono-targeting antibody and DNA vaccine
- Dual-targeting antibody

2026 ~ 2030

- Potential for 15 launches of Genexine products
- Personalized cancer vaccine
- Gene therapy

1st hyFc[®] : Commercialization^I2nd hyFc[®] : Clinical Stage1st hyFc[®] : Commercialization^E2nd hyFc[®] : Commercialization^I

Gene Therapy : Clinical Stage

2009
Listed on
KOSDAQ

2010

2020

2030

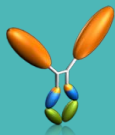

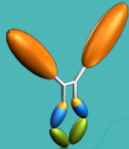
Market cap increased 36 folds (\$470mn→\$2.8bn)

I=Initiation E=Exponential growth

GENEXINE: Key Pipeline Events in 2021

MAKE INCURABLES
CURABLE

Genexine is pioneering next generation biotherapeutics to treat and save the lives of patients with serious diseases.

<p>hyFc® Long-acting protein drug</p> 	GX-I7	<ul style="list-style-type: none"> ● Expecting clinical results of COVID19 treatment from multiple countries ● Interim results of GX-I7/ICB combination treatment in multiple cancers ● Clinical data to be presented at International Conferences
<p>DNA vaccine Cancer therapeutic & Infectious disease</p> 	GX-188E	<ul style="list-style-type: none"> ● Interim results of GX-188E/Keytruda combination trial in adv. Cervical cancer ● Developed as the first “Bio Challenger” project with MFDS ● BLA submission planned for conditional approval in Korea
<p>hyFc® Long-acting protein drug</p> 	GX-19N	<ul style="list-style-type: none"> ● Ph1/2a completion ● Ph2/3 initiation ● Submission of Ph3 interim results for Emergency Use Approval
	GX-H9	<ul style="list-style-type: none"> ● Ph3 recruitment on-going in China (I-MAB Biopharma)
	GX-E4	<ul style="list-style-type: none"> ● Ph3 recruitment completion in 1H (6 countries)

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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