

# Genexine



*Clinical-Stage Biotherapeutics Company  
to Improve Patient's Quality of Life  
and Cure the Incurable*

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# Company Overview



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

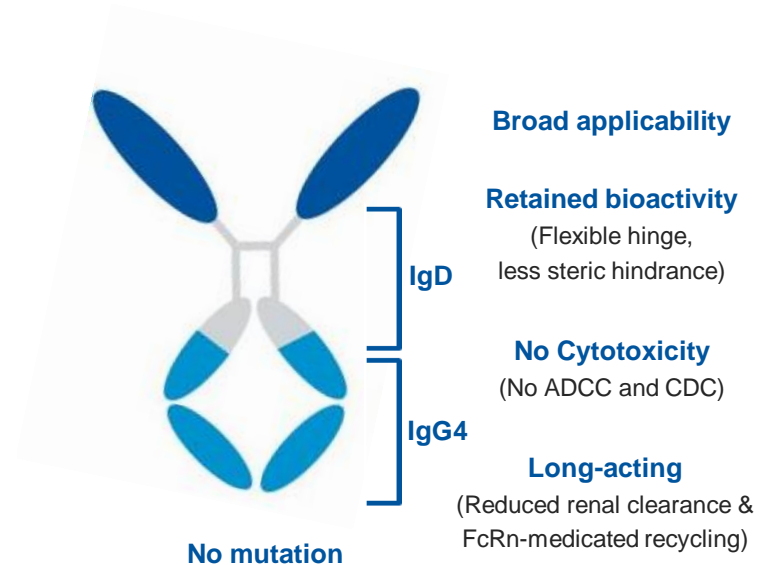
Chairman & Founder	<ul style="list-style-type: none"><li>Young Chul Sung, Ph.D.</li></ul>
CEO	<ul style="list-style-type: none"><li>You Suk Suh, Ph.D.</li></ul>
Key Milestones	<ul style="list-style-type: none"><li>Established in June 1999</li><li>Listed on KOSDAQ since 2009</li></ul>
Platform Technologies	<ul style="list-style-type: none"><li>Hybrid Fc Fusion Technology</li><li>DNA Therapeutic Vaccine</li></ul>
Developing Area	<ul style="list-style-type: none"><li><i>Immuno-oncology</i></li><li><i>Bio-better</i></li><li><i>Therapeutic DNA vaccine</i></li></ul>
Employees	<ul style="list-style-type: none"><li>~193 (MD 4, Ph.D 22, MS 78)</li></ul>
Location	<ul style="list-style-type: none"><li>Korea Bio Park in Techno Valley (Pangyo)</li></ul>

# GX Platform Technology: Hybrid Fc

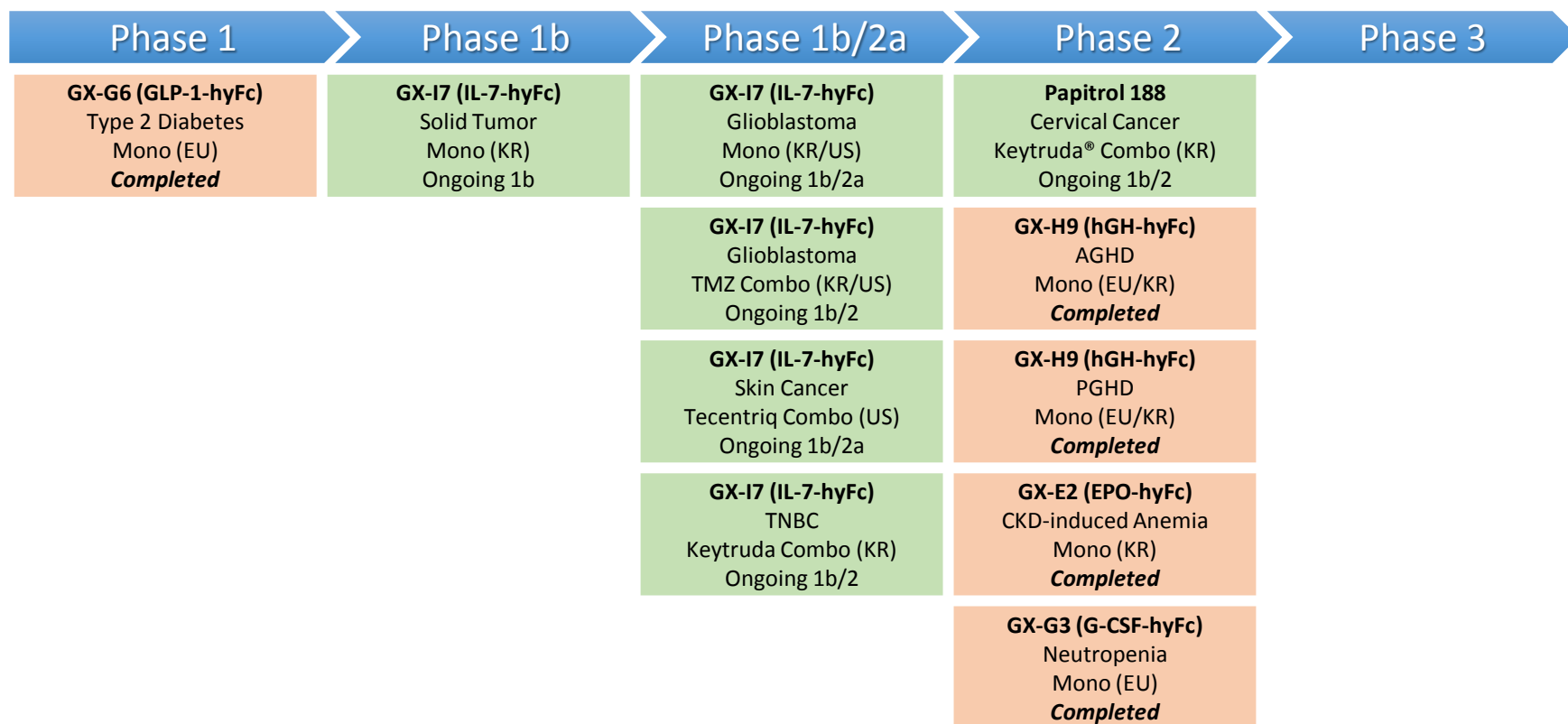
*hyFc™ is a platform technology to construct  
a long-acting Fc fusion protein hybridized with IgD and IgG4*

Human Ig Isotypes	IgG1	IgG4	IgD
Hinge flexibility	++	+	++++
Binding of FcγR of phagocytes (ADCC)	++++	++	-
Activation of C1q (CDC)	++	-	-
Binding of FcRn	++++	++++	-
In vivo serum half life (days)	21	21	3

*Immunology Fifth Edition, by Kuby etc. p 90  
J of Immunol. 1997 159: 3372  
J of Immunol. 2004 172: 2925*



# GX Pipelines in Clinical Stage



Bio-better  
 First-in-class

# Global Partnership and Collaboration



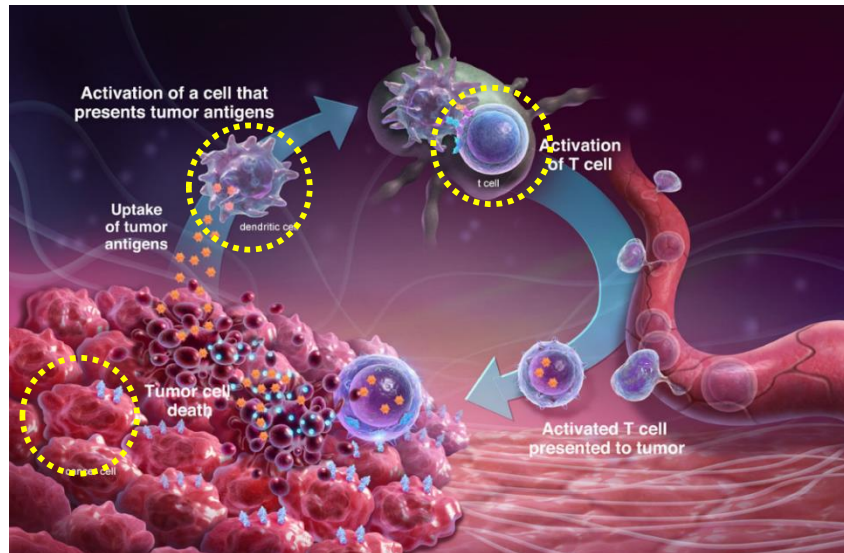
# GX-17

Interleukin-7-hyFc

Cancer and Lymphopenia

# T cell in Cancer Immunology

*How the immune response is generated against the tumor?*

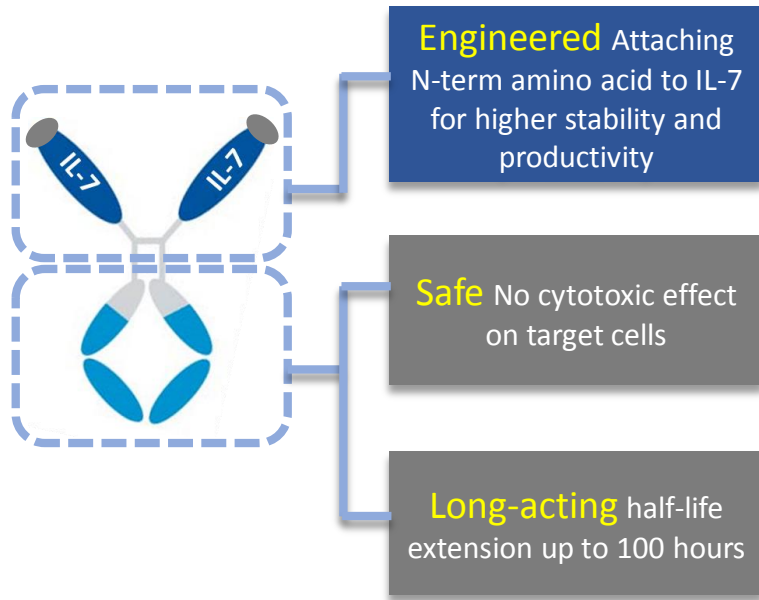


Source: Aduro Biotech image

*T cells are the **key** to destroying cancer*

- *Interleukin-7 : Homeostatic T cell growth factor*
- *GX-17 : Unique T cell growth factor to reconstitute and strengthen T cell immunity*
  - *Proliferation and survival of naïve and memory CD4+/CD8+ T cells*
  - *Generation of long-living T cells and correction of lymphopenia*
  - *Increase of Tumor Infiltrating Lymphocytes (TILs) in animal models*

# GX-17: hyFc-fused IL-7



## ✓ No cytotoxicity of hyFc on target cells

- No ADCC of IgD
- No CDC of IgG4

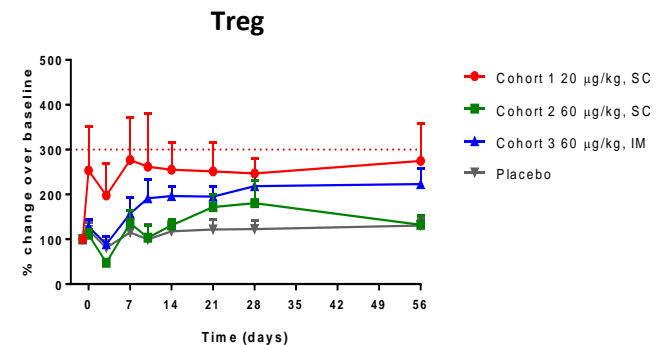
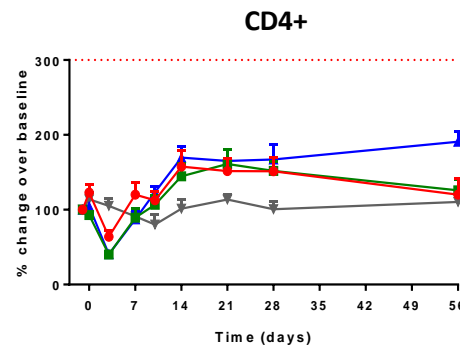
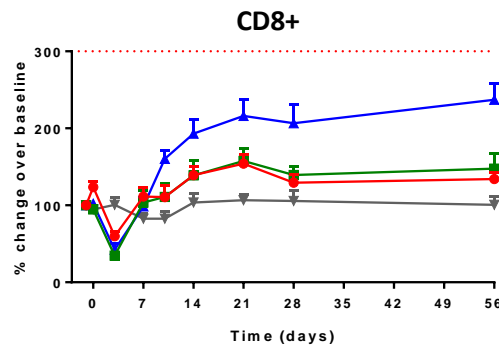
## ✓ Longer half-life in vivo than IL-7

- FcRn-mediated recycling
- Reduced renal clearance

## ✓ Higher stability & productivity than IL-7

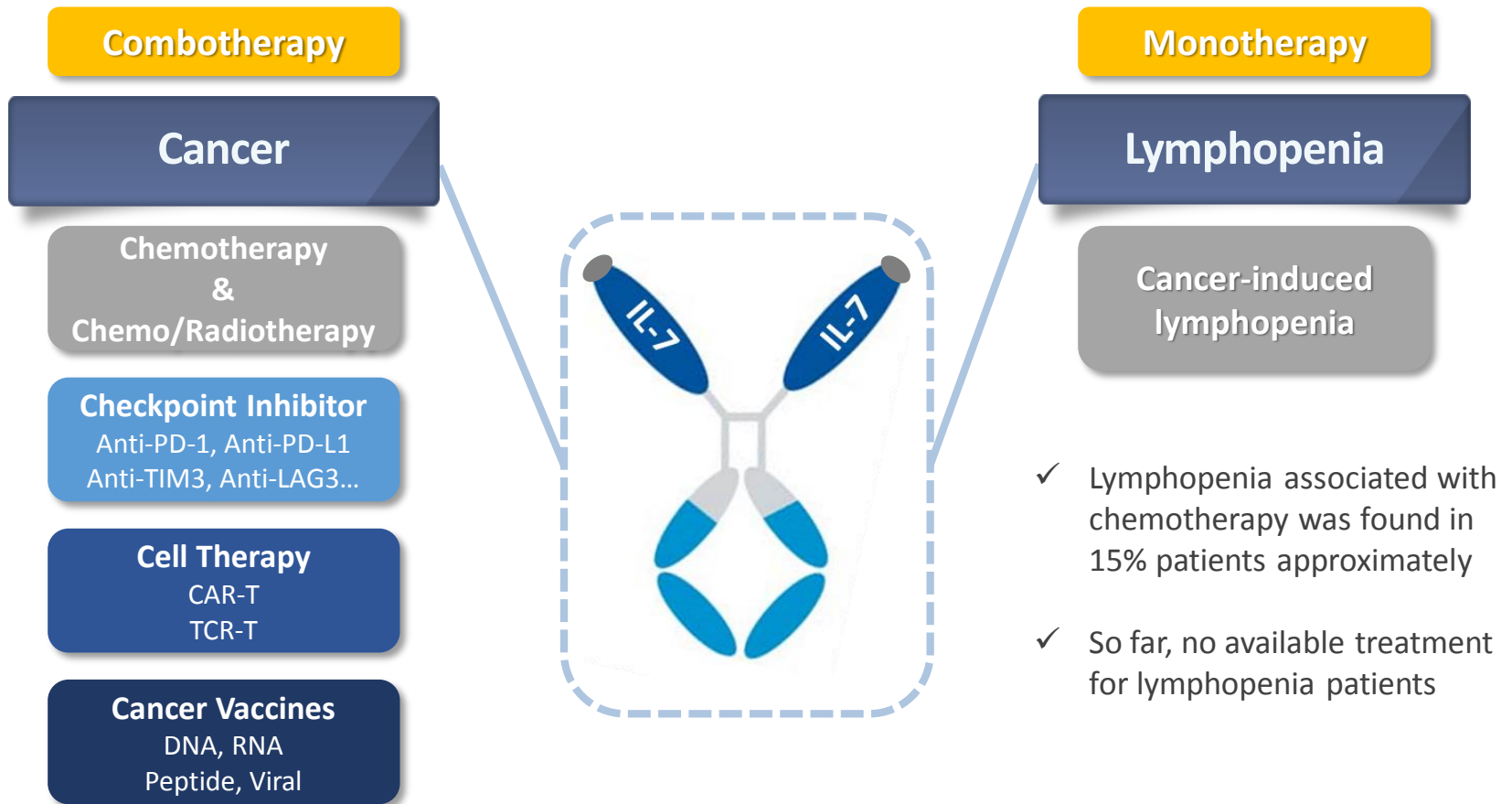
- N-term engineering of IL-7
- Ab Fc fusion of IL-7

## *GX-17 Increases CD4+ & CD8+ T cells, but not Treg cells in Healthy Volunteers*



[Park SH et al, Unpublished data]

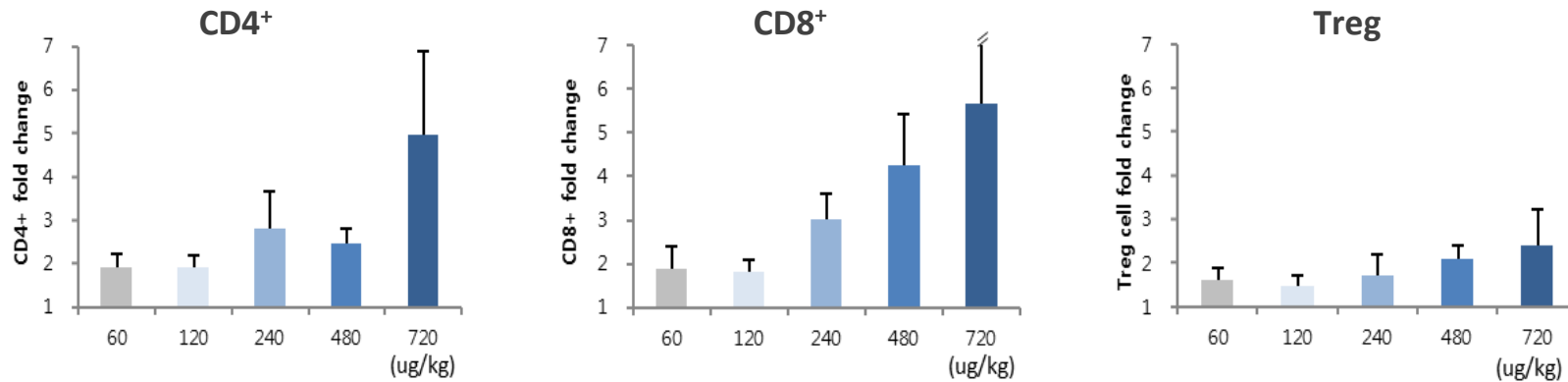
# GX-17 Potential Clinical Applications



*Key Player for Cancer Immunotherapy*

# GX-I7: Solid Tumor Mono Phase 1b (Interim)

## Dose-dependent Increase of T cells by GX-I7

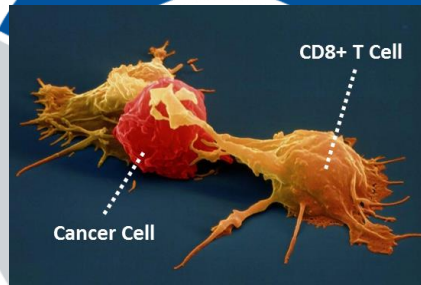


- GX-I7 increases T cell subsets dose-dependently but not Treg in end-stage cancer patients
- GX-I7 is safe and well-tolerated
- Interim data will be on SITC 2019 (Nov)

# Key Player in Immuno-Oncology Combo Therapy

## T cell Amplifier

- IL-7, GX-I7  
(Genexine/NeoImmuneTech)



## Blockade of T cell Suppressor

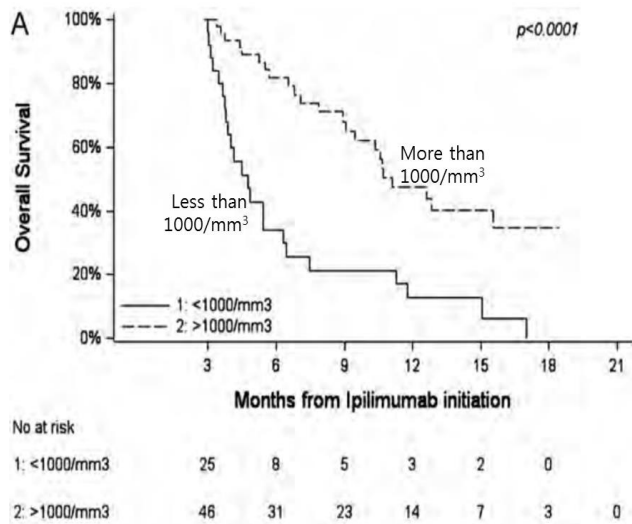
- Anti-PD1 (Merck, BMS, etc.)
- Anti-PD-L1 (Genentech, etc.)
- Anti-CTLA4 (BMS, etc.)
- Anti-TIM-3, anti-LAG-3, etc.
- IDO inhibitor, TIGIT, etc.

## T cell Activator

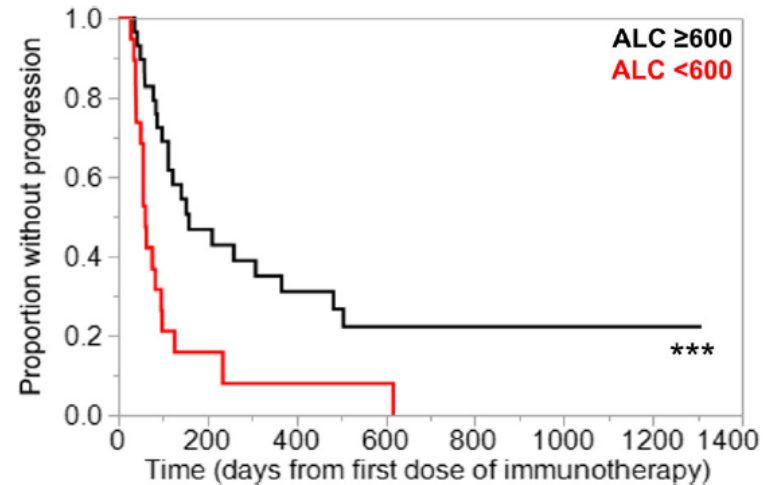
- CAR-T (Kite, Juno, Bluebird, etc.)
- Oncolytic virus (Amgen, Sillajen, etc.)
- Cancer vaccine (Genentech, etc.)
- IL-15 (Novartis, Altor, etc.),
- IL-2 (Nektar), IL-21, etc.
- CD137, OX40

# The Higher ALC, The Better Overall Survival ( OS )

## Treatment of Ipilimumab ( anti-CTLA4 ) in patients with metastatic melanoma



## Treatment of nivolumab & pembrolizumab in patients with HNSCC

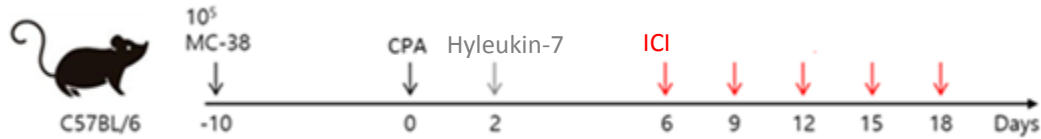


[Delyon J. et. al. *Annals of Oncology*. 24: 1697-1703. 2013]  
 [Ho et al. *Journal for ImmunoTherapy of Cancer*, 2018]

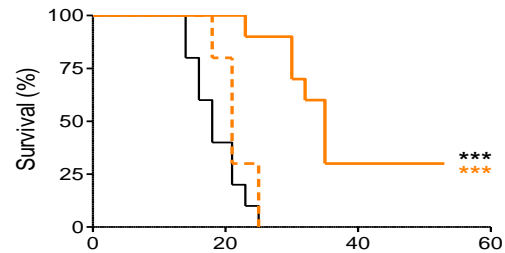
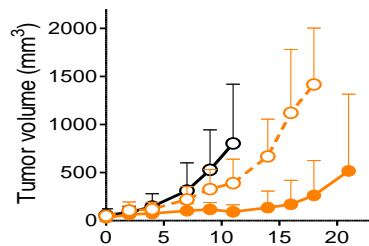
(A) The ALC at the time of the second course of Ipilimumab.

(B) The differential of lymphocyte count between the first 2 courses

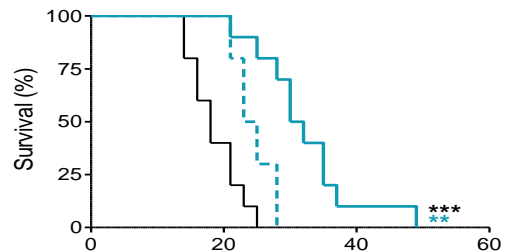
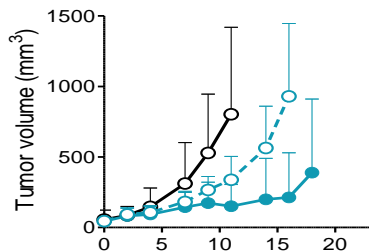
# GX-I7 Enhances Anti-Tumor Effect of ICI



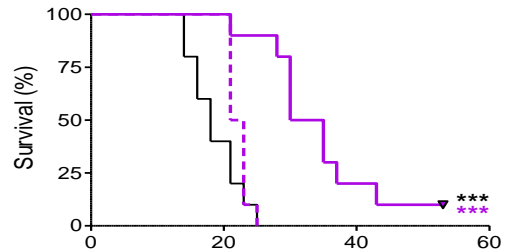
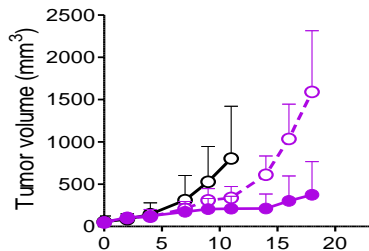
\*ICI: Immune checkpoint inhibitor



— Buffer  
 - - - CPA + Anti PD-1  
 — CPA + Anti PD-1 + Hyleukin-7



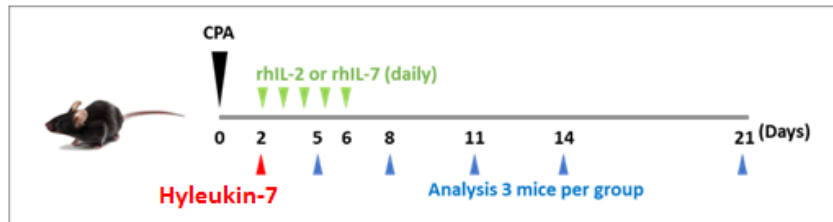
— Buffer  
 - - - CPA + Anti PD-L1  
 — CPA + Anti PD-L1 + Hyleukin-7



— Buffer  
 - - - CPA + Anti CTLA4  
 — CPA + Anti CTLA4 + Hyleukin-7

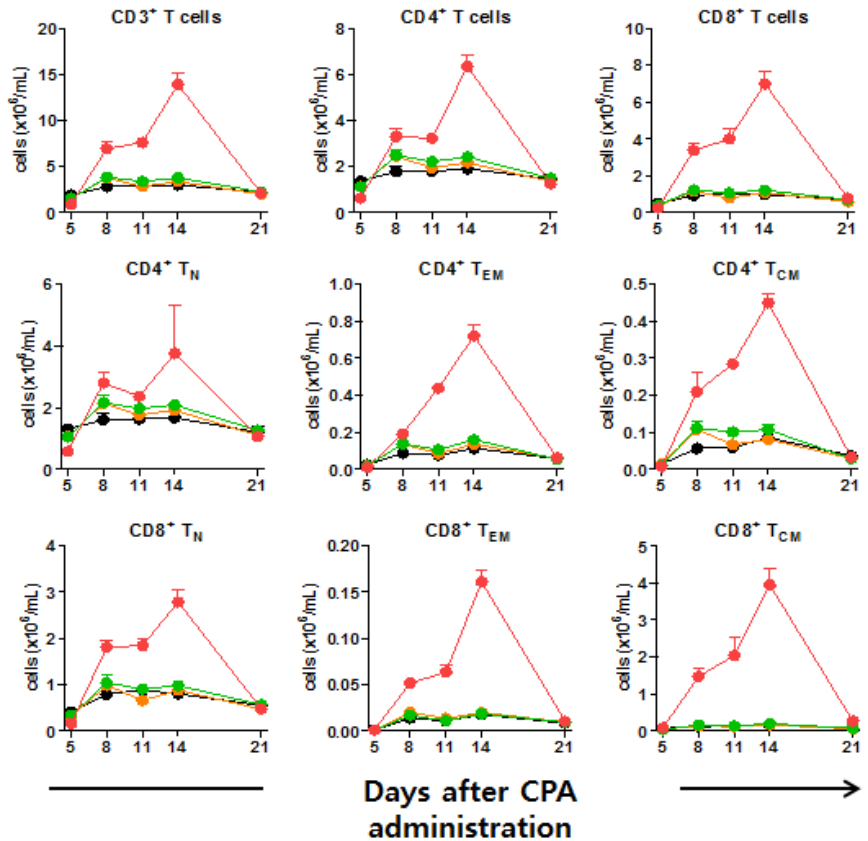
Time (Days) Days post-treatment start Time (Days)

# GX-I7 Increases T cells Better than IL-2 or IL-7



- CPA
- CPA → rhIL-2 X 5
- CPA → rhIL-7 X 5
- CPA → GX-I7

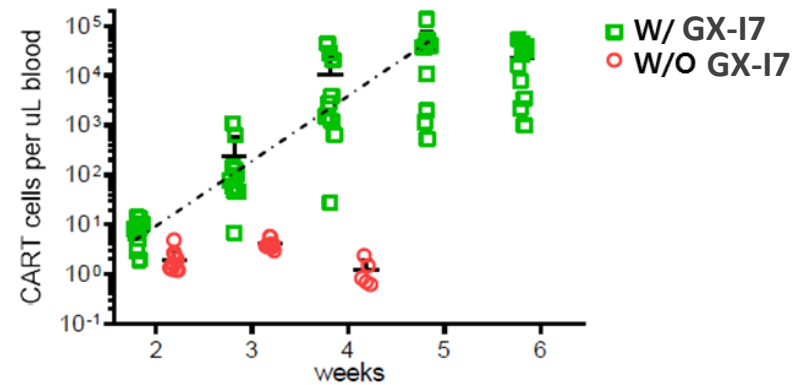
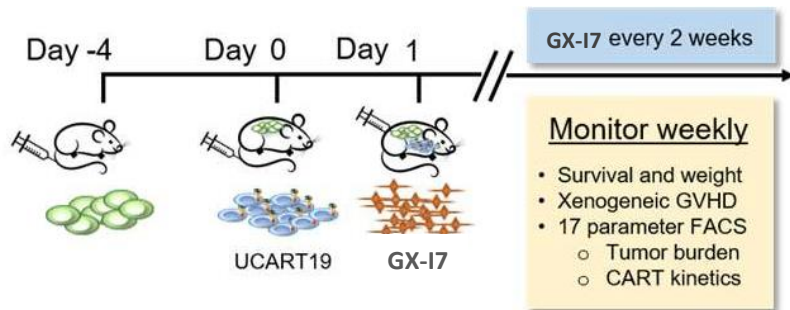
\*Cyclophosphamide is a medication used as chemotherapy and to suppress the immune system.



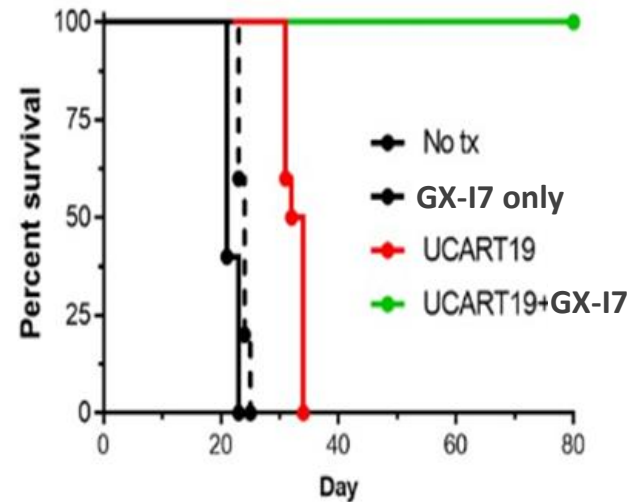
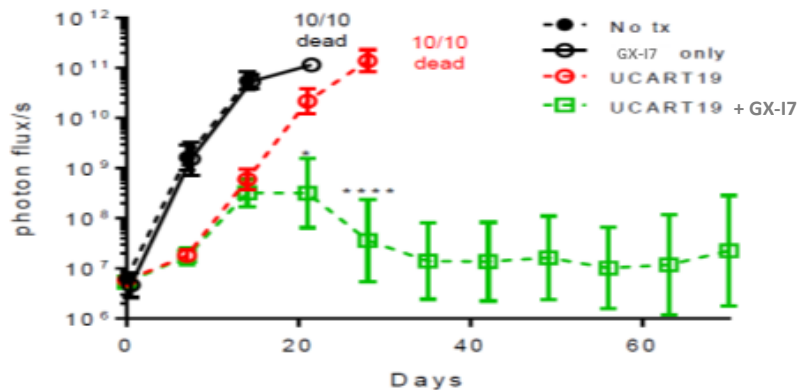
AACR2018, POSTECH SW Lee et al

# GX-I7 Combined Therapy with CAR-T

GX-I7 enhances CAR-T **expansion and persistence**



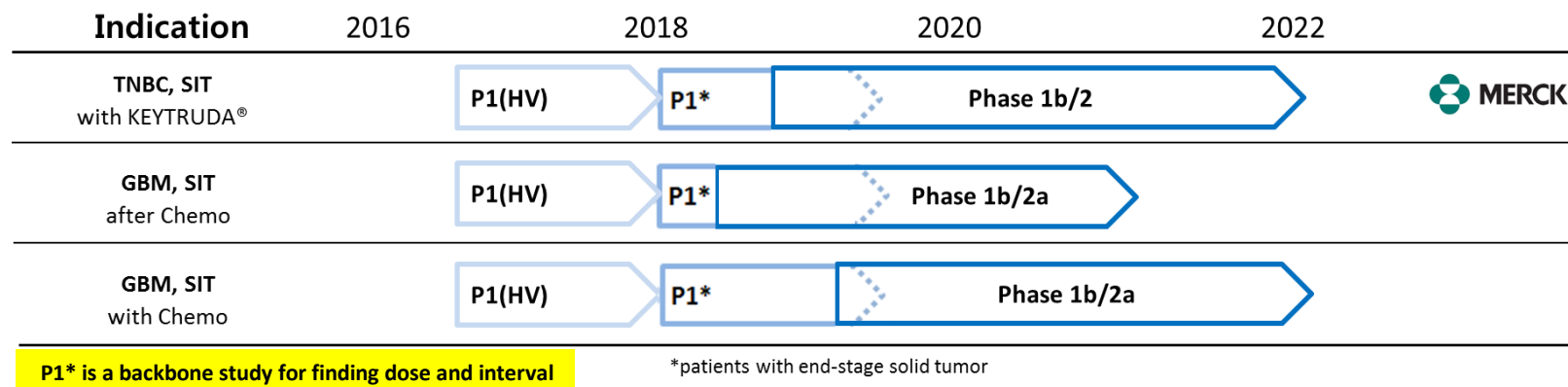
GX-I7 enhances CAR-T **efficacy**



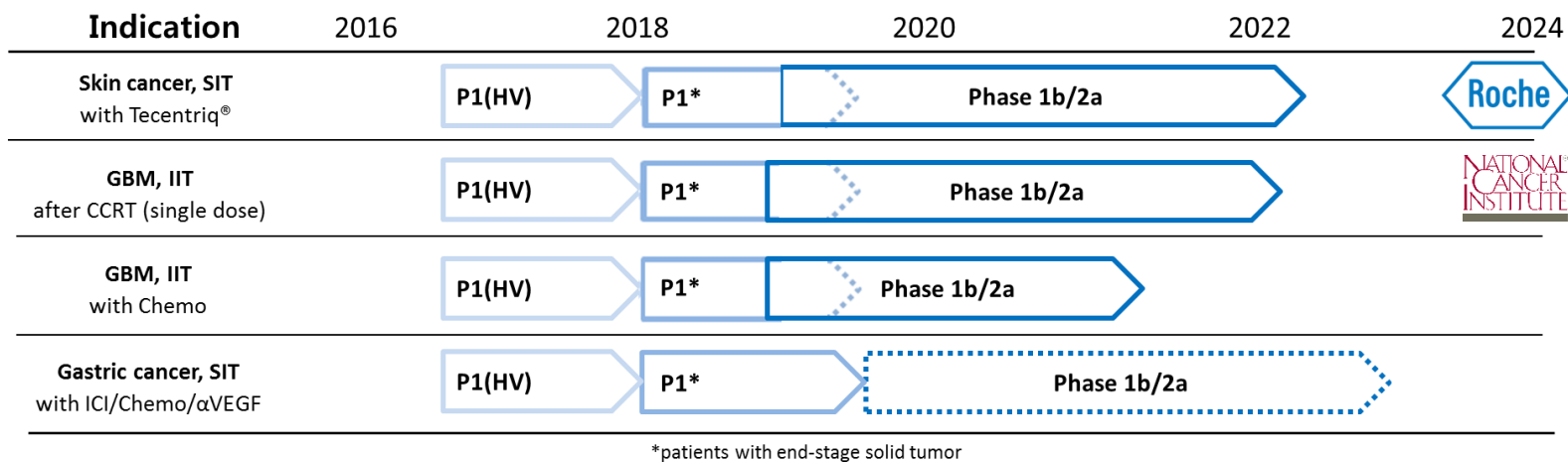
DiPersio J. et. al. ASH 2018

# GX-I7 : PoC Trials for Anti-tumor Effect in Combo Studies

KR



US NEOMIMUNETECH



# GX-H9

Long-acting Human Growth Hormone  
Human Growth Hormone Deficiency

# Unmet Medical Needs

## Daily Treatment

➤ **365** Injections/year

### Daily

- Painful
- Poor compliance
- Under-treated



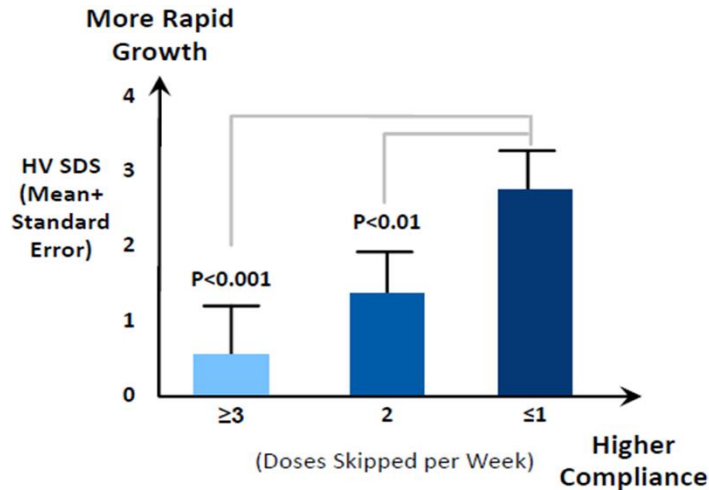
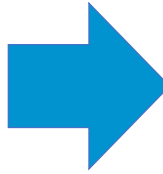
VS

## Weekly/Twice Monthly

➤ **52/26** Injections/year

### Weekly/ Twice-Monthly

- Improved Quality of Life
- Good compliance
- Full growth potential

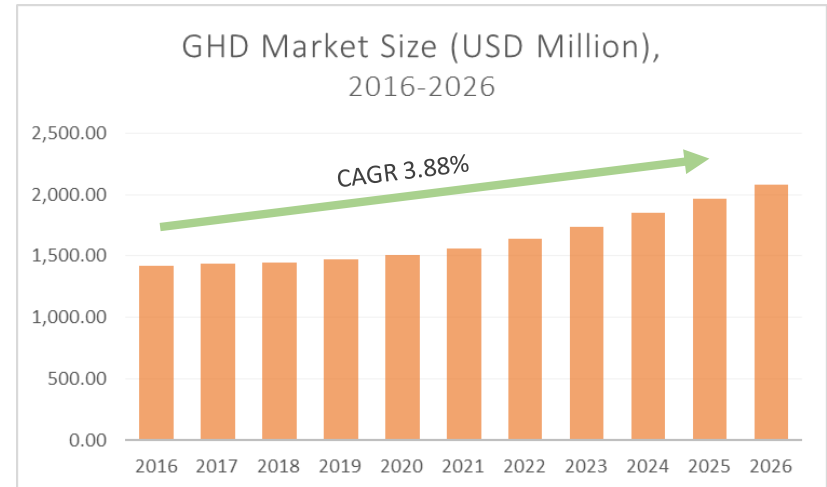
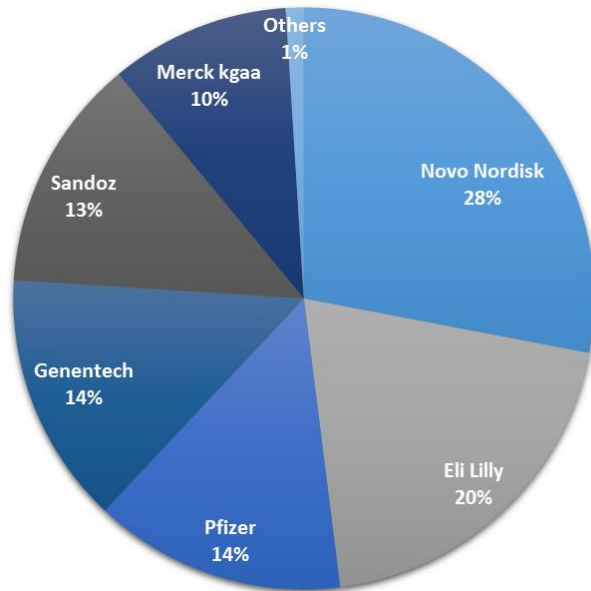


Age Range of  
Target  
Population:  
**5 -12 yrs old**

Average  
Treatment  
Period:  
**2-7 years**

# Growth Hormone Therapeutic Market

*Market Size of GH was recorded at **USD 3.87 billion\*** in 2017*



Source: GlobalData

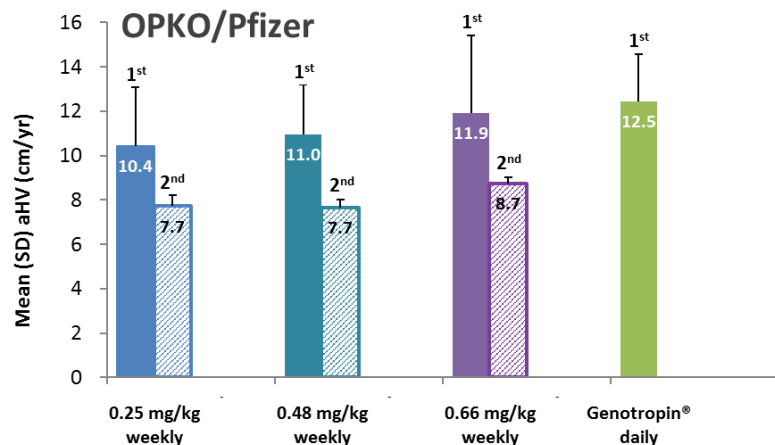
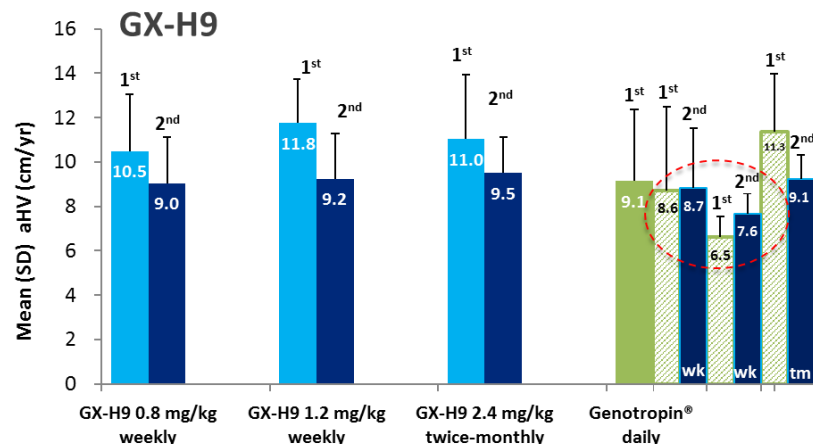
- Six market players take up 99% of the overall market
- Only *Novo Nordisk* and *Pfizer* are developing long-acting growth hormone

- Market size is expected to increase with ;
  - ✓ Income increase in emerging countries
  - ✓ Launching of long-acting therapies
  - ✓ Off label market has great potential

\*Reference: Market Research Future, Human Growth Market  
Research Report – Forecast to 2023

# GX-H9: Long-acting Growth Hormone

## Annualized Height Velocity in 1<sup>st</sup> and 2<sup>nd</sup> year







aHV; annual height velocity

## Key Summary

- Ph2 Completed in AGHD and PGHD
  - Effective in both weekly & twice-monthly
  - Showing good annual HV even in 2<sup>nd</sup> year
  - Pediatric patients grew better in 2<sup>nd</sup> year when switched from daily to GX-H9 weekly
- L/O to Tasly (China)
  - Established TASGEN → Merged as IMAB
- PGHD Ph3 in preparation
  - China Ph3 IND by IMAB in 4Q 2019
  - Global Ph3 IND by REZOLUTE



# Long-acting Growth Hormone Programs

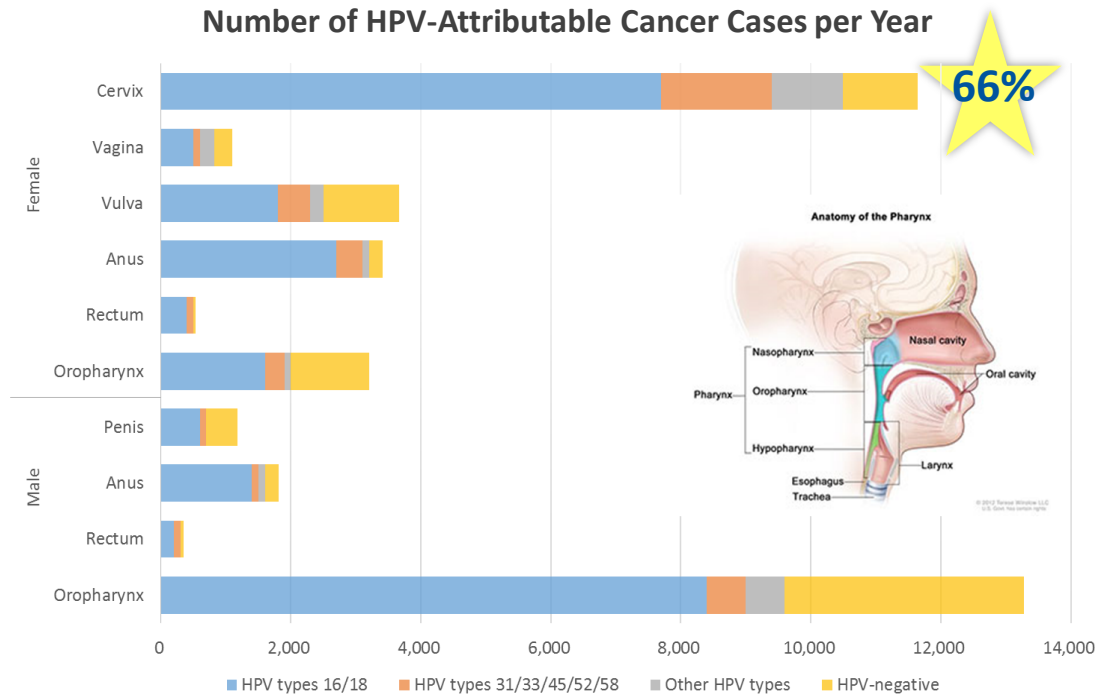
Company					
Drug		GX-H9	ACP-0001	MOD-4023	NNC0195-0092
Long-acting Technology		hyFc	TransCon PEG	CTP	Albumin
Frequency		Weekly Twice-monthly	Weekly	Weekly	Weekly
Stage of Development	Adult	Phase 2 completed	Phase 2 completed	Phase 3 failed	Phase 3 On-going
	Pediatric	Preparing for Phase 3 IND	Completes Pivotal Phase 3	Completes Pivotal Phase 3	Phased 2 completed
Height Velocity		<u>Ph2 12 month</u> 0.8mg 10.5cm/yr 1.2mg 11.76cm/yr 2.4mg 11.03cm/yr (EOW) Geno 0.03mg 9.14cm/yr	<u>Ph3 12 month</u> 0.24mg 11.2cm/yr Geno 0.034mg 10.3cm/yr	<u>Ph2 12 month</u> 0.25mg 10.44cm/yr 0.48mg 10.96cm/yr 0.66mg 11.93cm/yr Geno 0.034mg 12.46cm/yr	<u>Ph2 6 month</u> 0.04mg 8.0cm/yr 0.08mg 10.9cm/yr 0.16mg 12.9cm/yr Nord 0.034mg 11.4cm/yr
CMC		Genetic fusion	Chemical conjugation	Genetic fusion	Chemical conjugation

# GX-188E

## HPV Therapeutic DNA Vaccine

Human Papilloma Virus (HPV) Induced Cancer

# HPV induced Cancers

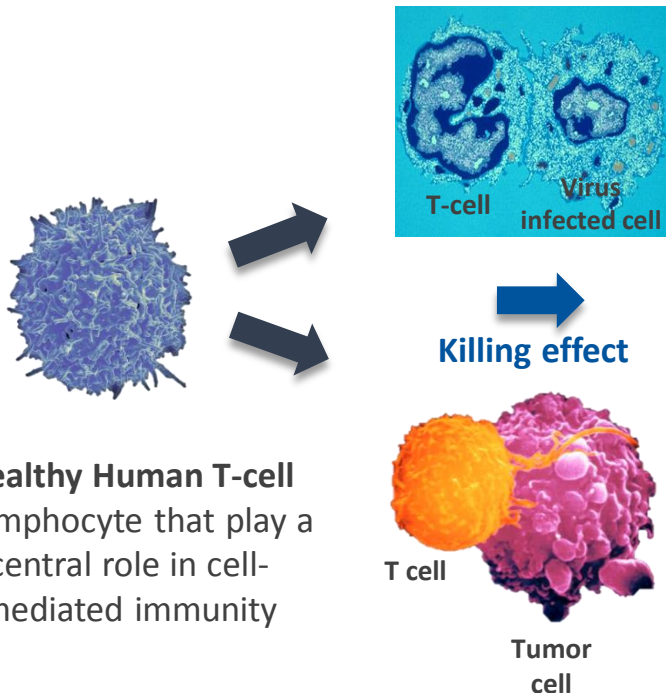


Source: Centers for Disease Control and Prevention (CDC), Number of HPV-Associated and HPV-Attributable Cancer Cases per Year, 2015

- About **270,000** women die from cervical cancer every year
- About 500,000 cervical cancer and other HPV-induced cancer patients builds up about **\$2~3 Billion market**
- **HPV 16/18 type causes**
  - **66%** of cervical cancer
  - **63%** of head and neck cancer

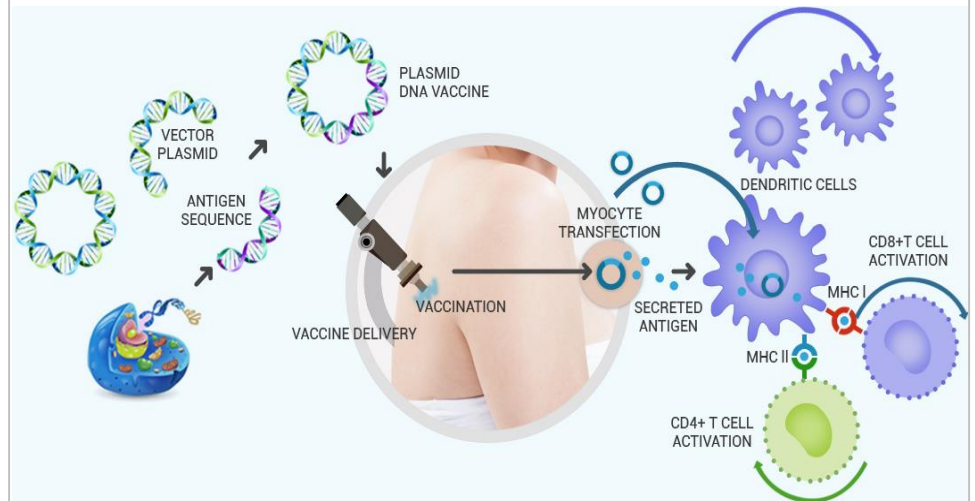
# HPV DNA Vaccine Technology

T-cell is the key player  
for curing cancers



Source: Britannica.com, scitechdaily.com

## DNA-based Immunotherapy

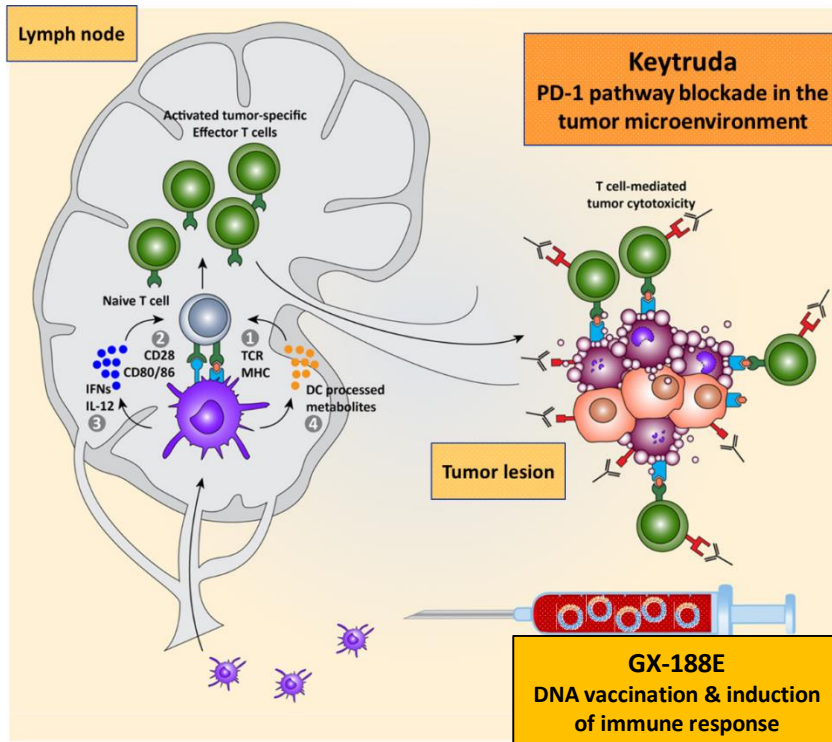


### *DNA-Based Immunotherapy*

- HPV 16/18-specific antigen encoded plasmid
- DNA vaccine delivery to cells by intramuscular injection
- HPV-specific antigen activates HPV specific T cells
- Killer CD8+ T cells eliminates HPV-infected cells

# GX-188E+Keytruda® Combo for Cervical Cancer

## Key Summary



- Clinical PoC trial design: Simon 2-Stage
- Study Protocol
  - Keytruda®: IV, 200mg, at every 3 weeks
  - GX-188E: IM, 1mg x 2 sites, at 1, 2, 4, 7, 13, 19, and 46 week (7 times/yr)
- Keynote-158 (Keytruda mono trial)
  - ORR 12.2% (12/98 advanced cervical ca.)
  - Accelerated approval by FDA as 2L
- GX-188E+Keytruda Combo in similar setting
  - 1 CR, 3 PR (4/10 advanced cervical cancer)
  - Recruitment for Ph2 stage 2 initiated
  - Plan to complete patient enrollment by 1Q 2020

# Development and Business Milestones

## *Tentative Development Milestone in 2020*

	4Q 2019	1Q	2Q	3Q	4Q
GX-I7	<i>Solid Tumor Ph1b interim data readout at SITC</i>		<i>TNBC Ph1b/2 interim data readout at ASCO</i>		
GX-H9	<i>CH Ph3 IND Submission by I-Mab</i>				<i>US FDA Ph3 IND Submission by Rezolute</i>
GX-188E			<i>Papitrol-188 &amp; Keytruda® combo Ph1b/2 interim data readout at ASCO</i>		

### ***Clinical Development***

- GX-I7 :
  - ✓ *Combo Studies (TNBC, GBM, Skin Cancer) : Combo trials were initiated and validate trend of efficacy (PoC)*
  - ✓ *1~2 additional indications : To get IND approvals and start trials*

### ***Business Development***

- *Licence-Out deal of Bio-Better Franchise pipelines*
- *GX-I7: Add more combo studies with top-notch global pharma*

# Financial Information

*As of 1H 2019*

( Million KRW)

	1H 2019	2018
Current Asset	130,970	177,518
Total Asset	389,853	374,811
Total Debt	61,571	54,304
Total Equity	328,283	320,507

(KRW)

Numbers for Reference		
Total issued # of shares		22,783,683
52 weeks stock price	high	111,500
	low	46,400
2018 R&D Expense		32,715M

# *Thank you*

**Genexine, Inc.**

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700 Daewangpangyo-ro, Bundang Gu,  
Seongnam Si, Gyeonggi Do, 463-400 Korea

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