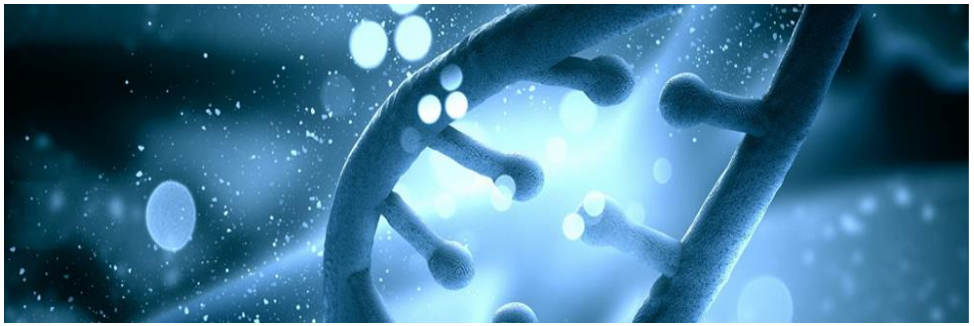
Genexine



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.

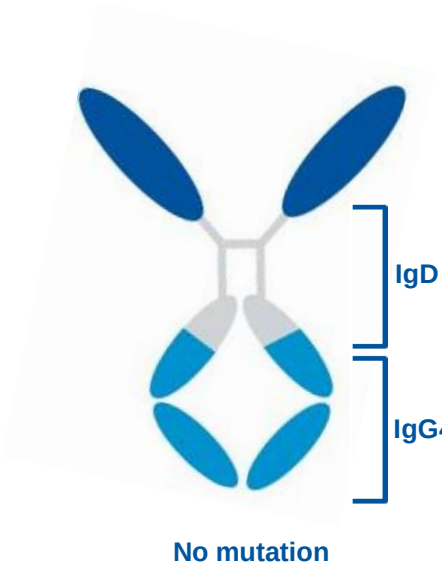
Chairman & Founder	• Young Chul Sung, Ph.D.
CEO	• You Suk Suh, Ph.D.
Key Milestones	• Established in June 1999 • Listed on KOSDAQ since 2009
Platform Technologies	• Hybrid Fc Fusion Technology • DNA Therapeutic Vaccine
Developing Area	• *Immuno-oncology* • *Bio-better* • *Therapeutic DNA vaccine*
Employees	• ~193 (MD 4, Ph.D 22, MS 78)
Location	• Korea Bio Park in Techno Valley (Pangyo)

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



Broad applicability

Retained bioactivity
(Flexible hinge,
less steric hindrance)

No Cytotoxicity
(No ADCC and CDC)

Long-acting
(Reduced renal clearance &
FcRn-medicated recycling)

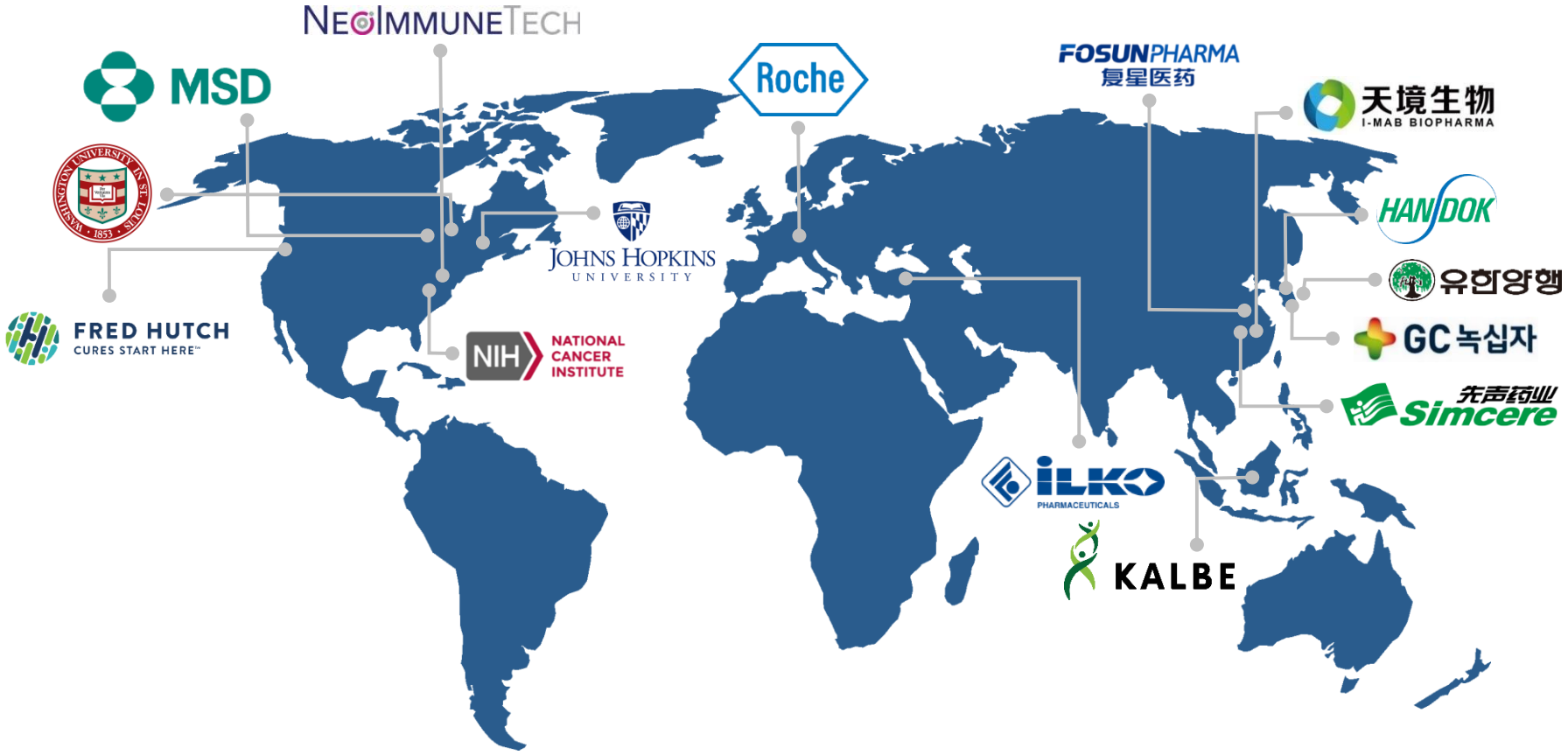
GX Pipelines in Clinical Stage

Phase 1	Phase 1b	Phase 1b/2a	Phase 2	Phase 3
GX-G6 (GLP-1-hyFc) Type 2 Diabetes Mono (EU) ***Completed***	**GX-I7 (IL-7-hyFc)** Solid Tumor Mono (KR) Ongoing 1b	**GX-I7 (IL-7-hyFc)** Glioblastoma Mono (KR/US) Ongoing 1b/2a	**Papitrol 188** Cervical Cancer Keytruda® Combo (KR) Ongoing 1b/2	
		GX-I7 (IL-7-hyFc) Glioblastoma TMZ Combo (KR/US) Ongoing 1b/2	**GX-H9 (hGH-hyFc)** AGHD Mono (EU/KR) ***Completed***	
		GX-I7 (IL-7-hyFc) Skin Cancer Tecentriq Combo (US) Ongoing 1b/2a	**GX-H9 (hGH-hyFc)** PGHD Mono (EU/KR) ***Completed***	
		GX-I7 (IL-7-hyFc) TNBC Keytruda Combo (KR) Ongoing 1b/2	**GX-E2 (EPO-hyFc)** CKD-induced Anemia Mono (KR) ***Completed***	
			GX-G3 (G-CSF-hyFc) Neutropenia Mono (EU) ***Completed***	

Bio-better

First-in-class

Global Partnership and Collaboration



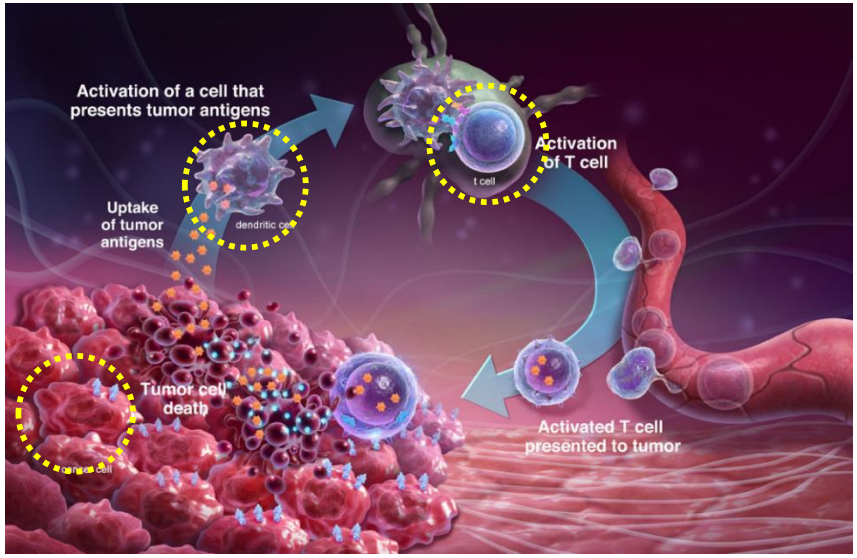
GX-I7

Interleukin-7-hyFc

Cancer and Lymphopenia

T cell in Cancer Immunology

How the immune response is generated against the tumor?

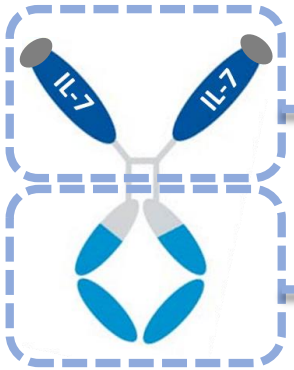


Source: Aduro Biotech image

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

- *Interleukin-7 : Homeostatic T cell growth factor*
- *GX-I7 : 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-I7: hyFc-fused IL-7



Engineered Attaching N-term amino acid to IL-7 for higher stability and productivity

Safe No cytotoxic effect on target cells

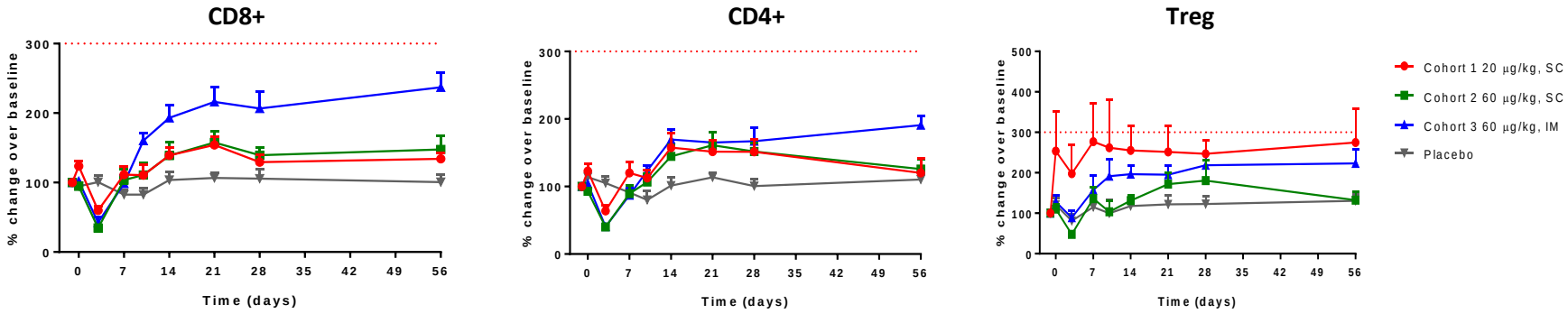
Long-acting half-life extension up to 100 hours

✓ **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-I7 Increases CD4+ & CD8+ T cells, but not Treg cells in Healthy Volunteers



[Park SH et al, Unpublished data]

GX-I7 Potential Clinical Applications

Combotherapy

Cancer

Chemotherapy & Chemo/Radiotherapy

Checkpoint Inhibitor
Anti-PD-1, Anti-PD-L1
Anti-TIM3, Anti-LAG3…

Cell Therapy
CAR-T
TCR-T

Cancer Vaccines
DNA, RNA
Peptide, Viral

Monotherapy

Lymphopenia

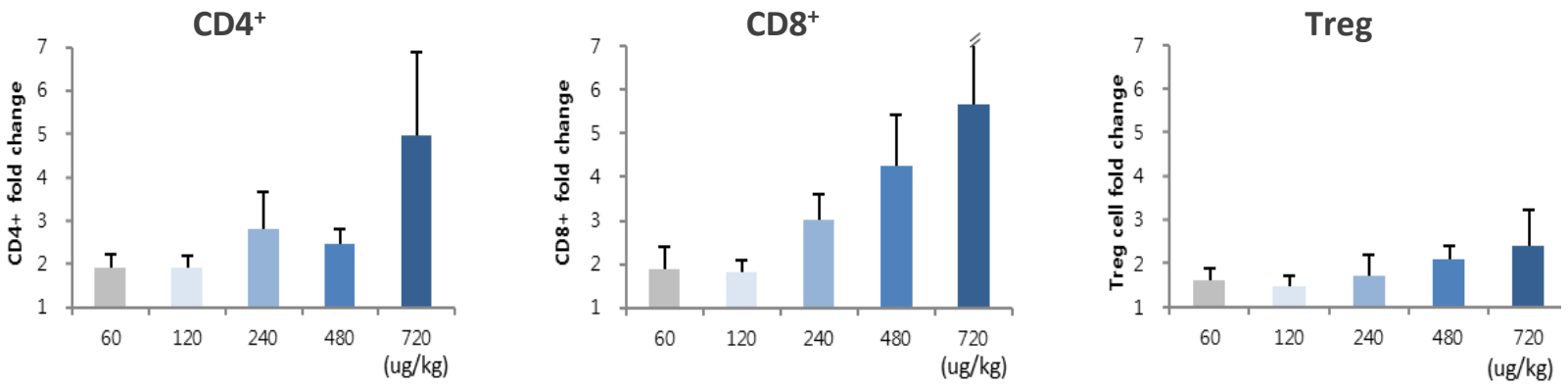
Cancer-induced lymphopenia

- ✓ Lymphopenia associated with chemotherapy was found in 15% patients approximately
- ✓ So far, no available treatment for lymphopenia patients

Key Player for Cancer Immunotherapy

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

Dose-dependent Increase of T cells by GX-I7

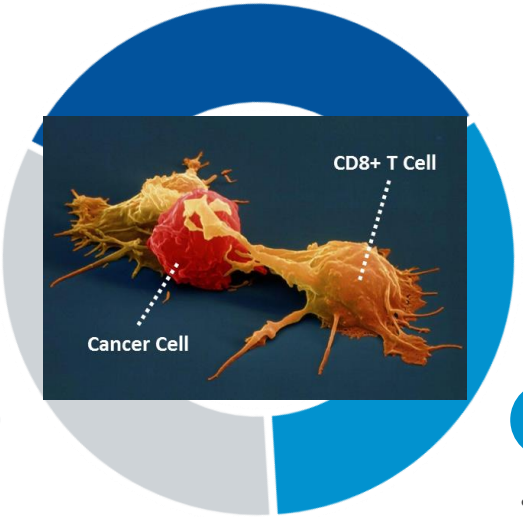


- GX-I7 increases T cell subsets dose-dependently but not Treg in end-stage cancer patients
- GX-I7 is safe and well-tolerated
- Interim data will be on SITC 2019 (Nov)

Key Player in Immuno-Oncology Combo Therapy

T cell Amplifier

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



Blockade of T cell Suppressor

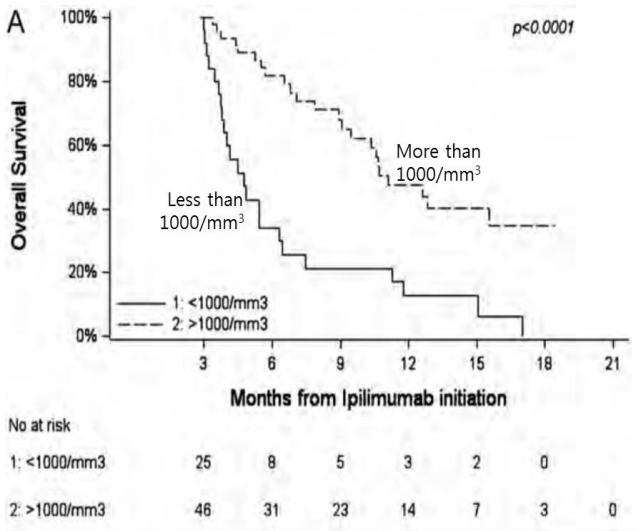
- Anti-PD1 (Merck, BMS, etc.)
- Anti-PD-L1 (Genentech, etc.)
- Anti-CTLA4 (BMS, etc.)
- Anti-TIM-3, anti-LAG-3, etc.
- IDO inhibitor, TIGIT, etc.

T cell Activator

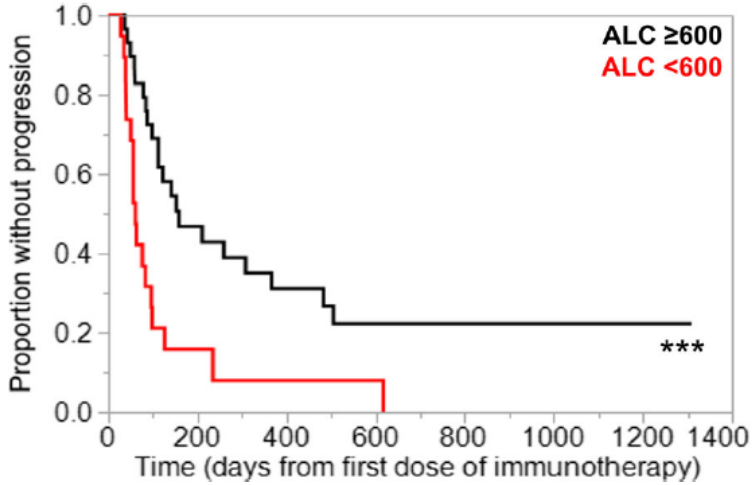
- CAR-T (Kite, Juno, Bluebird, etc.)
- Oncolytic virus (Amgen, Sillajen, etc.)
- Cancer vaccine (Genentech, etc.)
- IL-15 (Novartis, Altor, etc.),
- IL-2 (Nektar), IL-21, etc.
- CD137, OX40

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

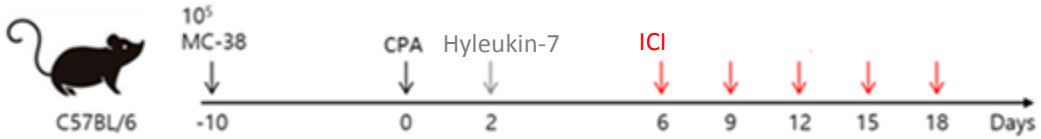


[Delyon J. et. al. Annals of Oncology. 24: 1697-1703. 2013]
[Ho et al. Journal for ImmunoTherapy of Cancer, 2018]

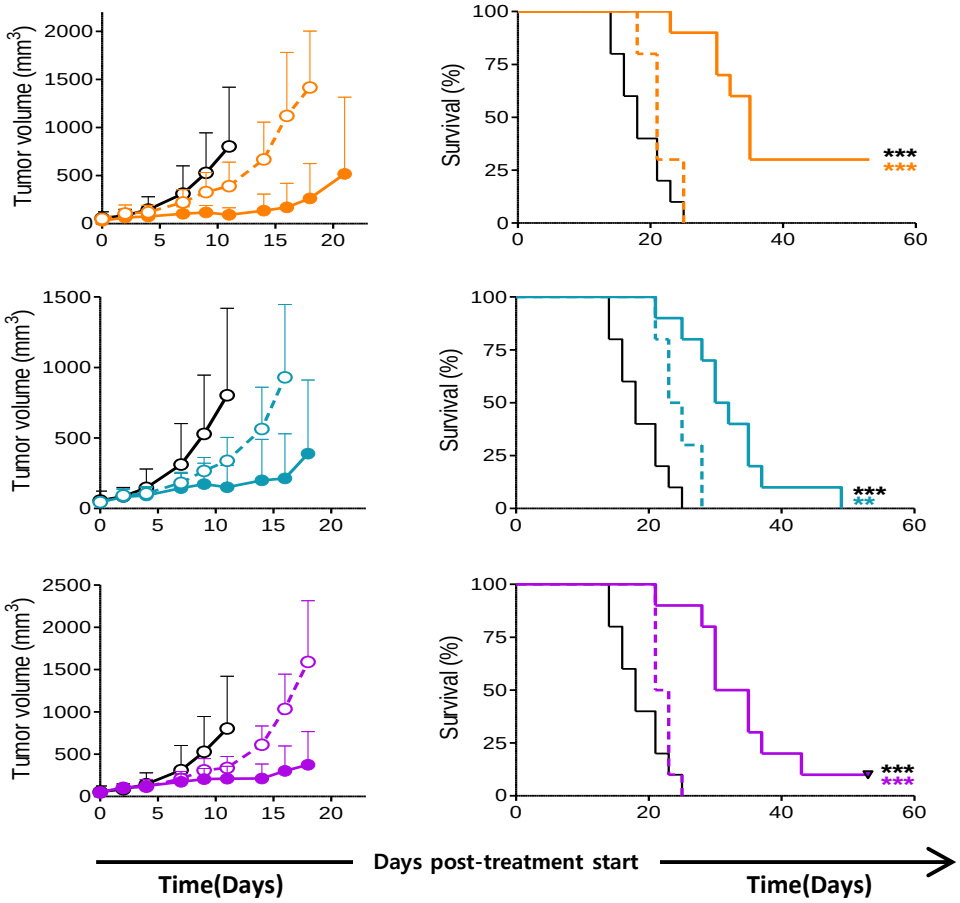
(A) The ALC at the time of the second course of Ipilimumab.

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

GX-I7 Enhances Anti-Tumor Effect of ICI

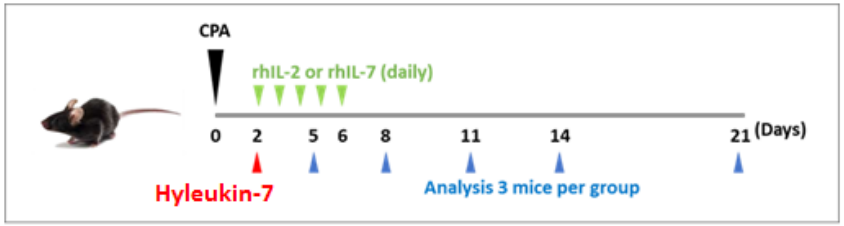


*ICI: Immune checkpoint inhibitor



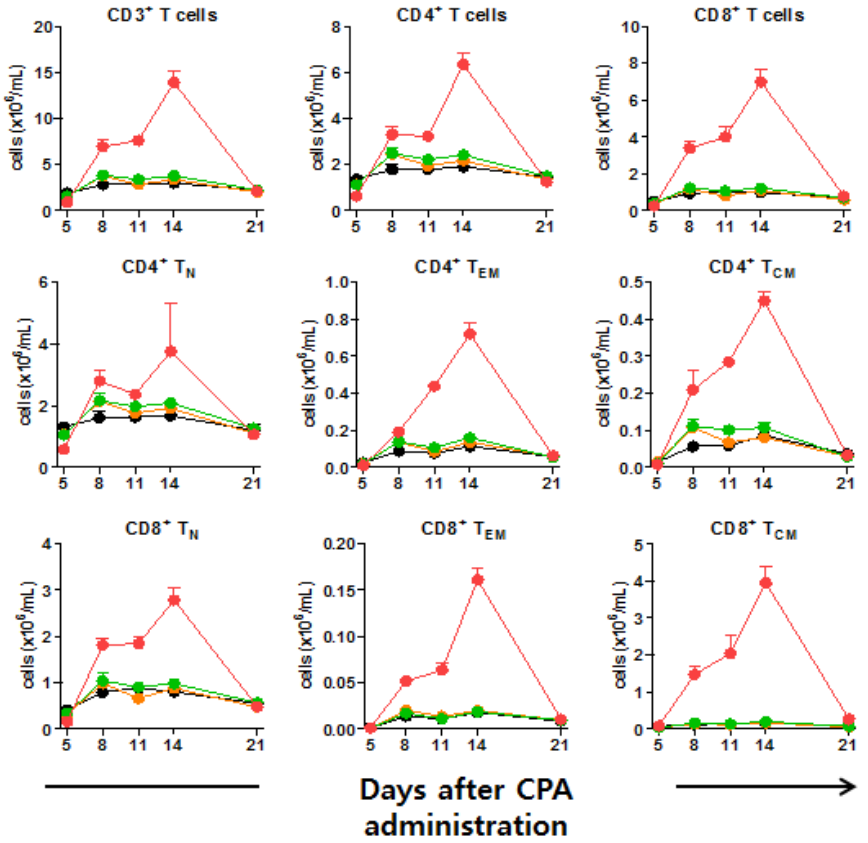
[Lee SW et. al. AACR 2019]

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

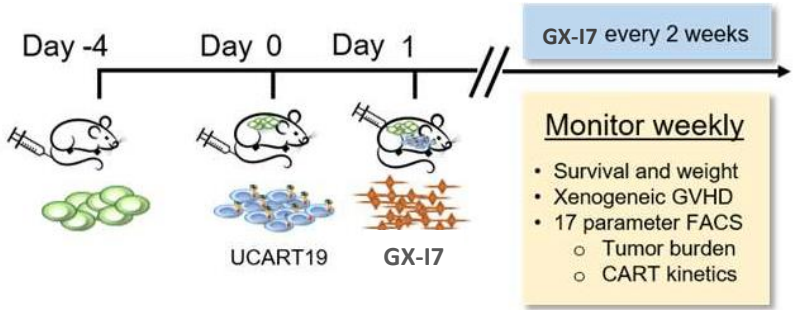
*Cyclophosphamide is a medication used as chemotherapy and to suppress the immune system.

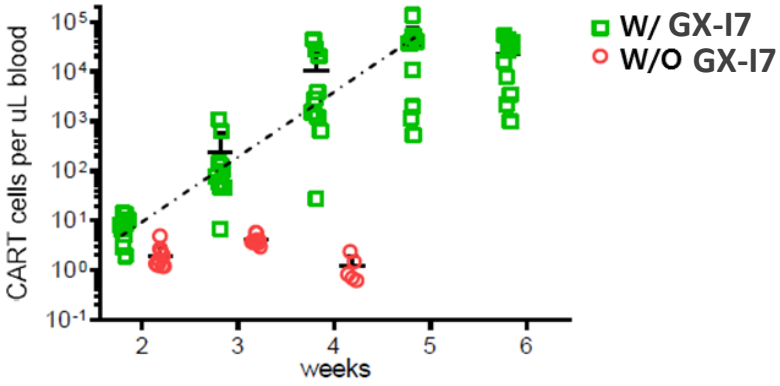


AACR2018, POSTECH SW Lee et al

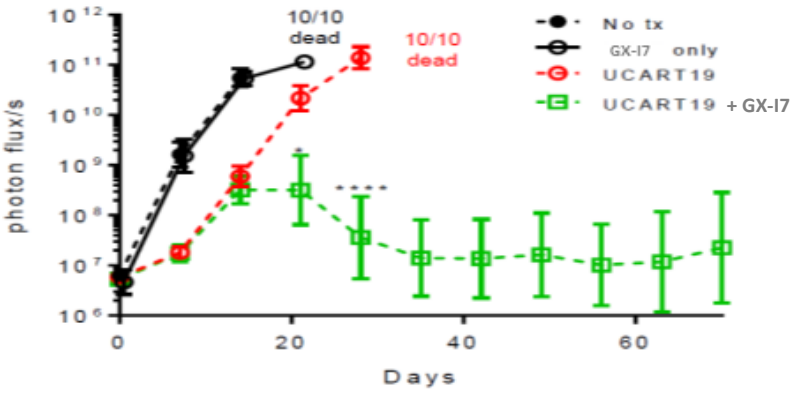
GX-I7 Combined Therapy with CAR-T

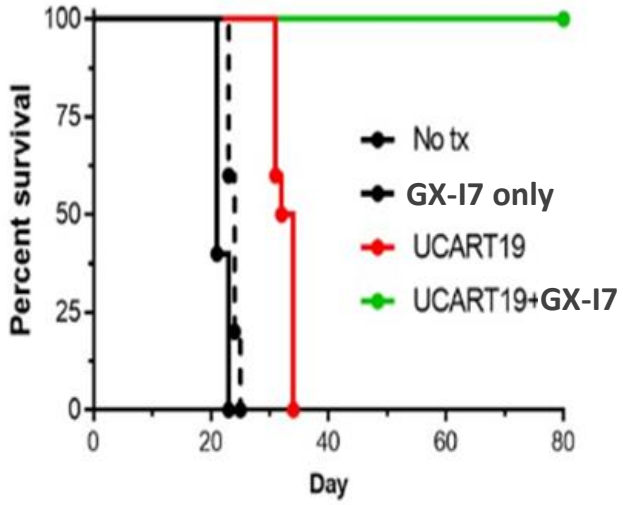
GX-I7 enhances CAR-T expansion and persistence





GX-I7 enhances CAR-T efficacy

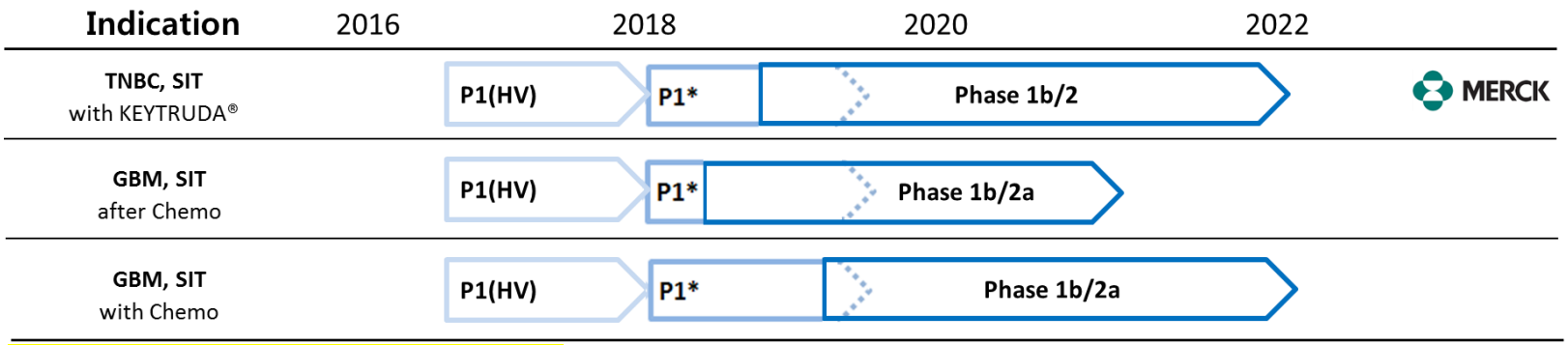




DiPersio J. et . al. ASH 2018

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

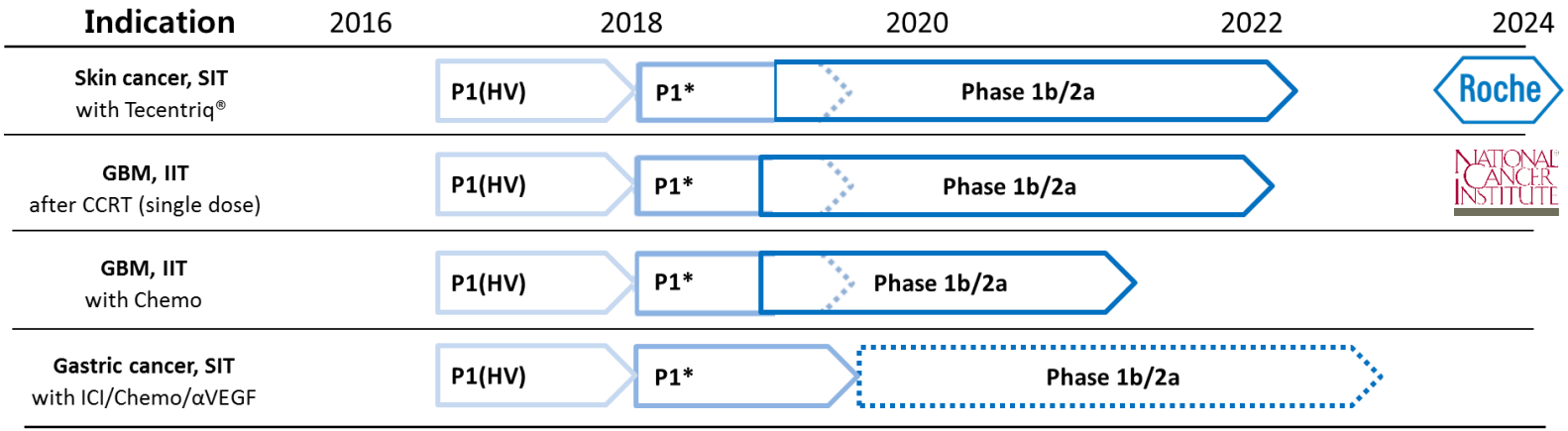
KR



P1* is a backbone study for finding dose and interval

*patients with end-stage solid tumor

US NEOIMMUNETECH



*patients with end-stage solid tumor

GX-H9

Long-acting Human Growth Hormone

Human Growth Hormone Deficiency

Unmet Medical Needs

Daily Treatment

➢ **365** Injections/year

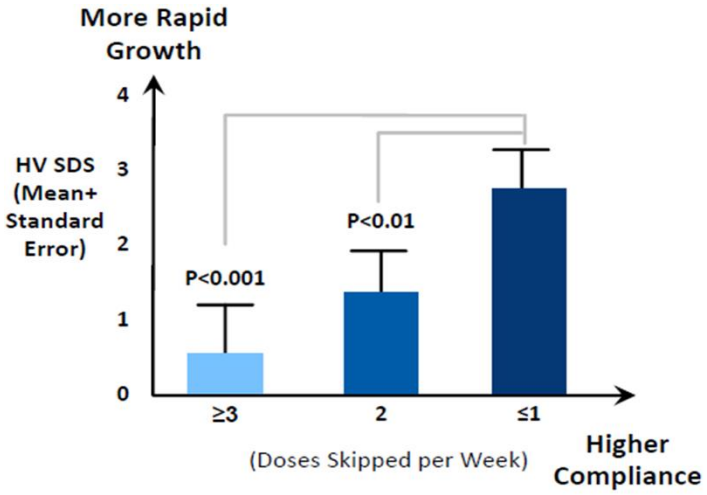
vs

Weekly/Twice Monthly

➢ **52/26** Injections/year

Daily
- **Painful**
- **Poor compliance**
- **Under-treated**

Weekly/ Twice-Monthly
- **Improved Quality of Life**
- **Good compliance**
- **Full growth potential**



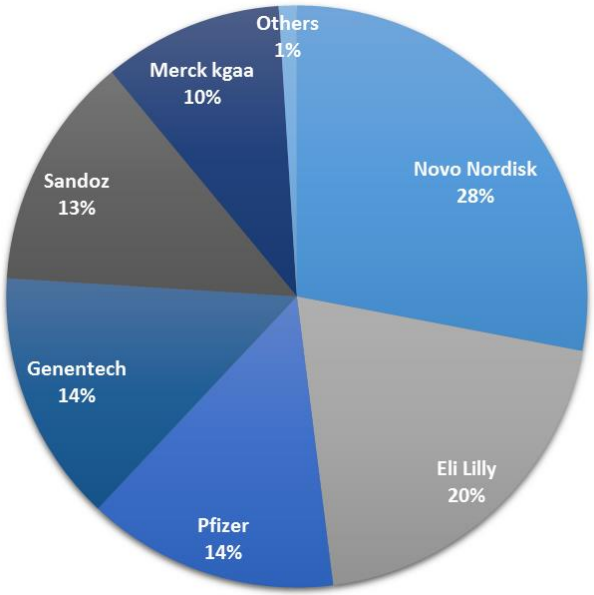
PLoS ONE Jan. 2011 Vol 6 Issue 1 e16223

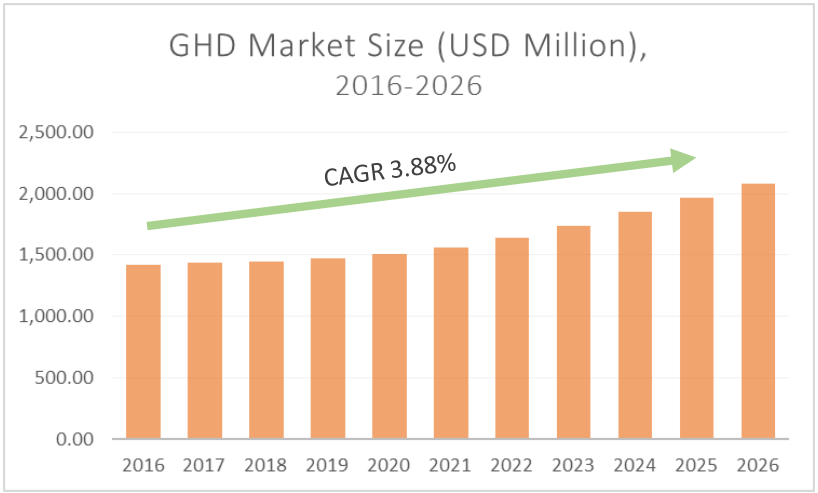
Age Range of Target Population:
5 -12 yrs old

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

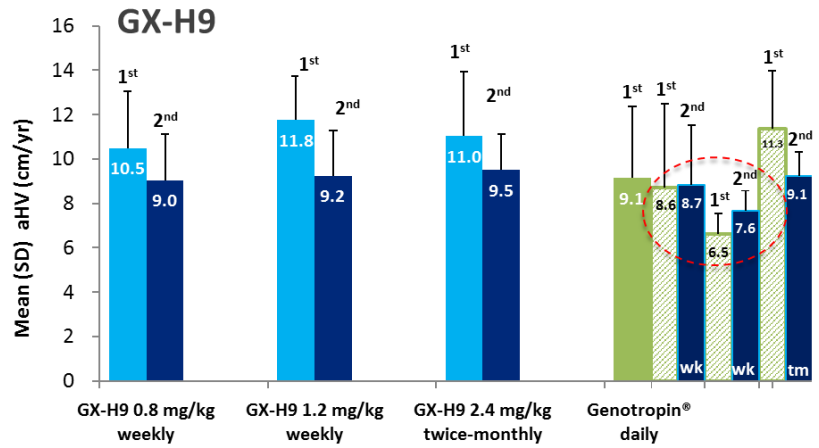
- Six market players take up 99% of the overall market
- Only *Novo Nordisk* and *Pfizer* are developing long-acting growth hormone

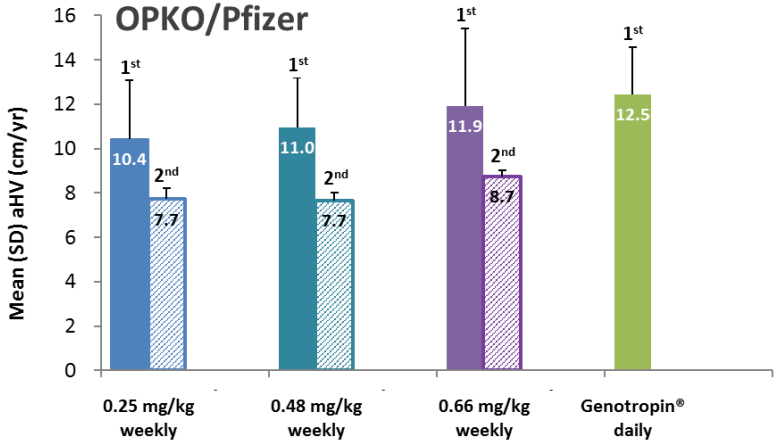
- Market size is expected to increase with ;
  - ✓ Income increase in emerging countries
  - ✓ Launching of long-acting theraphies
  - ✓ Off label market has great potential

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

GX-H9: Long-acting Growth Hormone

Annualized Height Velocity in 1st and 2nd 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 2nd year
  - Pediatric patients grew better in 2nd 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

REZOLUTE

天境生物 I-MAB BIOPHARMA

Long-acting Growth Hormone Programs

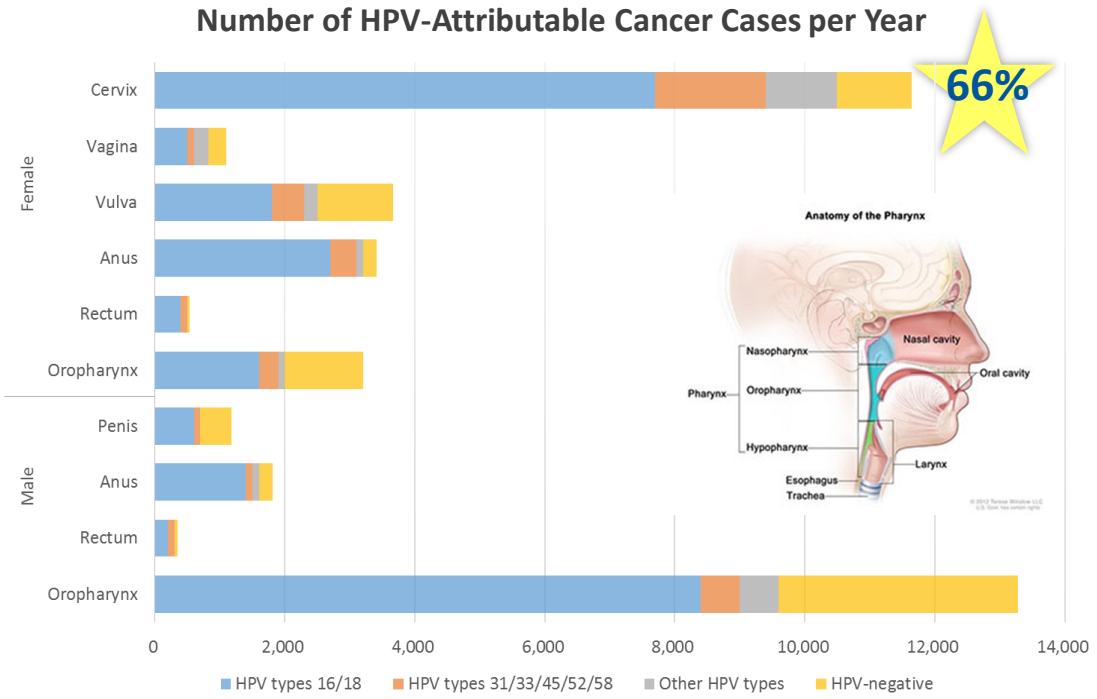
Company		Genexine	ascendis pharma	OPKO Pfizer	novo nordisk
Drug		GX-H9	ACP-0001	MOD-4023	NNC0195-0092
Long-acting Technology		hyFc	TransCon PEG	CTP	Albumin
Frequency		Weekly Twice-monthly	Weekly	Weekly	Weekly
Stage of Development	**Adult**	Phase 2 completed	Phase 2 completed	Phase 3 failed	Phase 3 On-going
	Pediatric	Preparing for Phase 3 IND	Completes Pivotal Phase 3	Completes Pivotal Phase 3	Phased 2 completed
Height Velocity		**Ph2 12 month** 0.8mg 10.5cm/yr 1.2mg 11.76cm/yr 2.4mg 11.03cm/yr (EOW) Geno 0.03mg 9.14cm/yr	**Ph3 12 month** 0.24mg 11.2cm/yr Geno 0.034mg 10.3cm/yr	**Ph2 12 month** 0.25mg 10.44cm/yr 0.48mg 10.96cm/yr 0.66mg 11.93cm/yr Geno 0.034mg 12.46cm/yr	**Ph2 6 month** 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

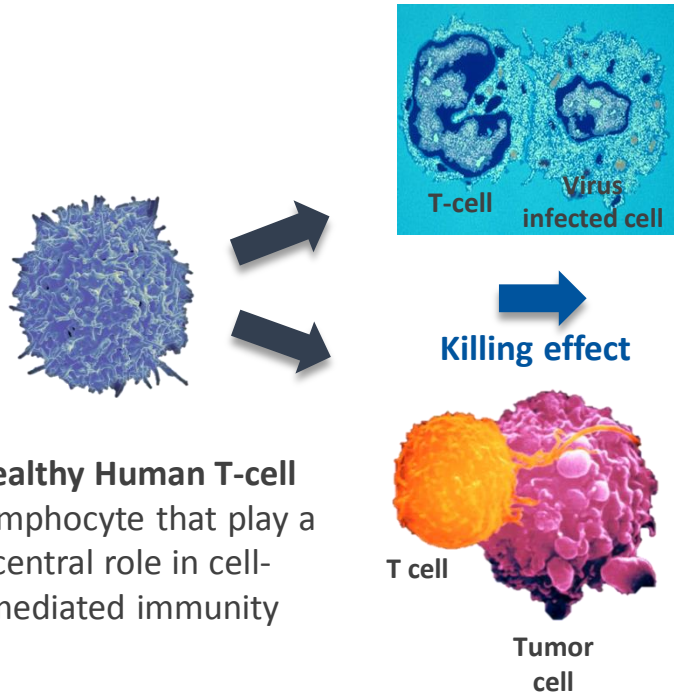


Source: Centers for Disease Control and Prevention (CDC), Number of HPV-Associated and HPV-Attributable Cancer Cases per Year, 2015

- 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

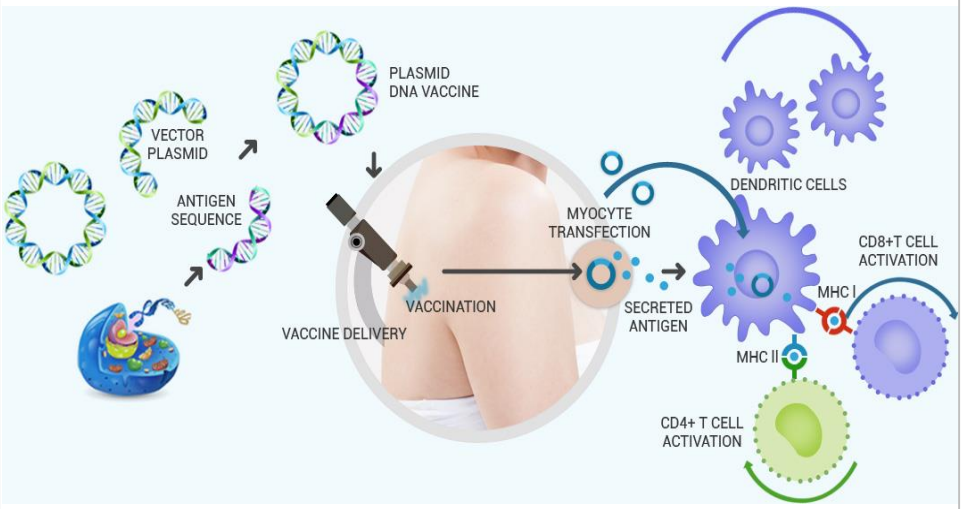
HPV DNA Vaccine Technology

T-cell is the key player for curing cancers



Healthy Human T-cell
: Lymphocyte that play a central role in cell-mediated immunity

DNA-based Immunotherapy



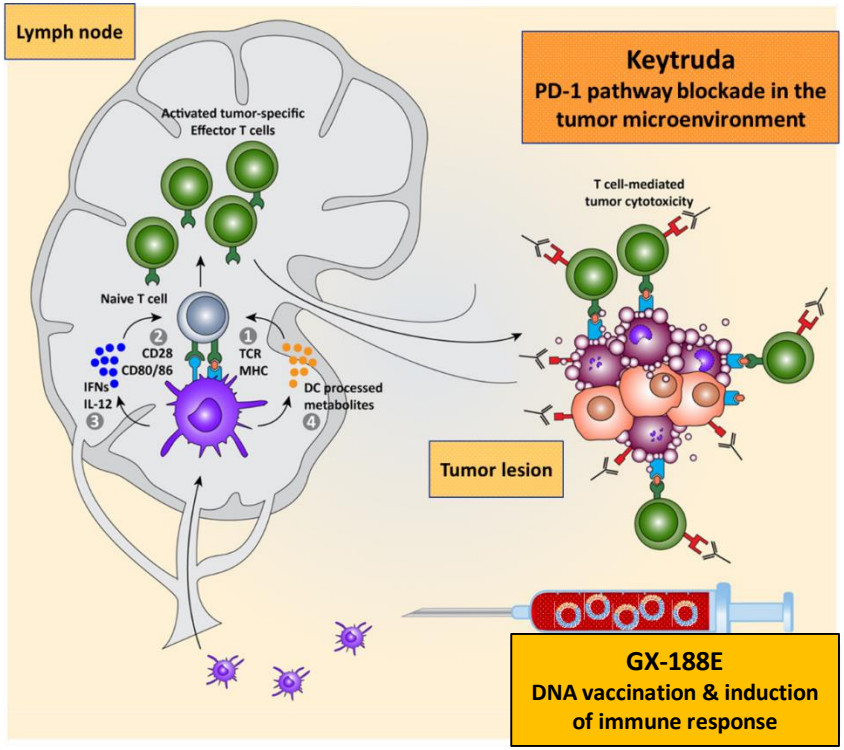
DNA-Based Immunotherapy

- 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

Source: Britannica.com, scitechdaily.com

GX-188E+Keytruda® Combo for Cervical Cancer

Key Summary



MERCK

- 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	*Solid Tumor Ph1b interim data readout at SITC*		*TNBC Ph1b/2 interim data readout at ASCO*		
GX-H9	*CH Ph3 IND Submission by I-Mab*				*US FDA Ph3 IND Submission by Rezolute*
GX-188E			*Papitrol-188 & Keytruda® combo Ph1b/2 interim data readout at ASCO*		

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

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