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### Global Bio Frontier ATGen

Bring the best diagnostics and therapeutics in the biotechnology and healthcare industry

# **Contents**

- Technologies and Vision
- NK Vue Kit
- SuperNK Therapy
- Appendix

# Technologies and Vision

Global Bio Frontier ATGen

Bring the best diagnostics and therapeutics in the biotechnology and healthcare industry

# "Global Leader in Biotech & Healthcare"

Accumulation of R&D know-how

Research
Reagents Business

4,500+ Protein & Antibody Reagents

Development of research reagents for more than 15 years

Base technology for development of ATGen platform

Stable growth and creating profit

Immune
Diagnosis Business

NK Vue Kit
In vitro Diagnostic Test

Commercialization of NK cell activity measurement technology

Exclusive rights and high growth potential

High growth potential

Cancer Immunotherapy Business



**SuperNK Cell Therapy** 

NK cell mass production technology with 99% purity and high killing ability

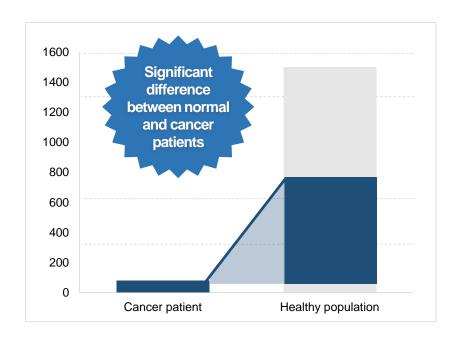
Patented culture method and composition of NK cell



# Simple and Easy to Identify NK Cell Activity

## **NK cell Activity**

- Resistance or immunity to cancer or disease
- Ability to respond to cancer cells or virusinfected cells without prior sensitization
- The NK cell activity is more important than the number of NK cells



## Advantage of NK cell Activity Test

- Check your body's immunity using a small amount of blood (1ml or 1cc)
- Derive results within 48 hours
- Commercialization of technology that can analyze many specimens through one test run
- Can be tested at any time without any preparation



# Various Applications of NK Cell Activity Test



# Parallel Check with other tests

- Health screening complementary such as DNA test, Antioxidant test, Biometric Age test
- Regular health checkup

- Independent Medical Checkup Institute including KMI, Hanaro, Hanshin Medipia and etc
- 18 branches of the Korean Industrial Health Association, 16 branches of Korea Association of Health Promotion
- Major General Hospitals' Health Checkup Centers



## **Pre-Screening**

- Screening before PET-CT and CT examination
- For biopsy pre-examination
- Early detection of recurrence

Colorectal cancer
 Gastroenterology journal in Jun, 2017 (Canada)
 JGH journal in Oct, 2017 (Korea)



# Complementary Diagnostics

- Tested with tumor marker tests
- Sensitivity and specificity improvement

- Prostate cancer
   Can J Urol journal in May, 2017 (Canada)
- Stomach cancer
   Oncotarget journal in Sept, 2017 (Korea)



Monitoring on treatment

- Predicting effects on various drugs and treatments
- Monitoring after chemotherapy
- Monitoring Pre-chemotherapy treatment ESMO (European Society for Medical Oncology) Poster in Sep, 2017 in Spain (Denmark Veile Hospital / Dr. Torben)

## **Domestic and Overseas Clinical Trials**

**Prognosis of liver cancer** patients and recurrence prediction



**NK cell activity** in ovarian cancer patients



Usefulness as a colorectal cancer screening test







Severity analysis with patients with malignant pancreatic cancer



Follow-up and customized

treatment of brain tumor

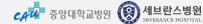
patients

**SNUH**<sup>®</sup>

Usefulness as a diagnostic tool for lung cancer



Follow-up of prognosis in **Prognosis of End-stage** patients with hematopoietic **Renal Failure Hemodialysis** stem cell transplantation **Patients** 





**Prognosis of multiple** sclerosis





**Association with lung** cancer imaging diagnosis





**Monitoring of Triple-Negative Breast Cancer Patients** 



cynvenio

Usefulness as a diagnostic test for high-risk colorectal cancer





Comparison image of prostate cancer and benign prostatic hyperplasia







**Pre-screening for PET-CT/** CT image of colorectal, breast, and lung cancer



Vejle Hospital ( Healthcare

Usefulness as a diagnostic tool for prostate cancer





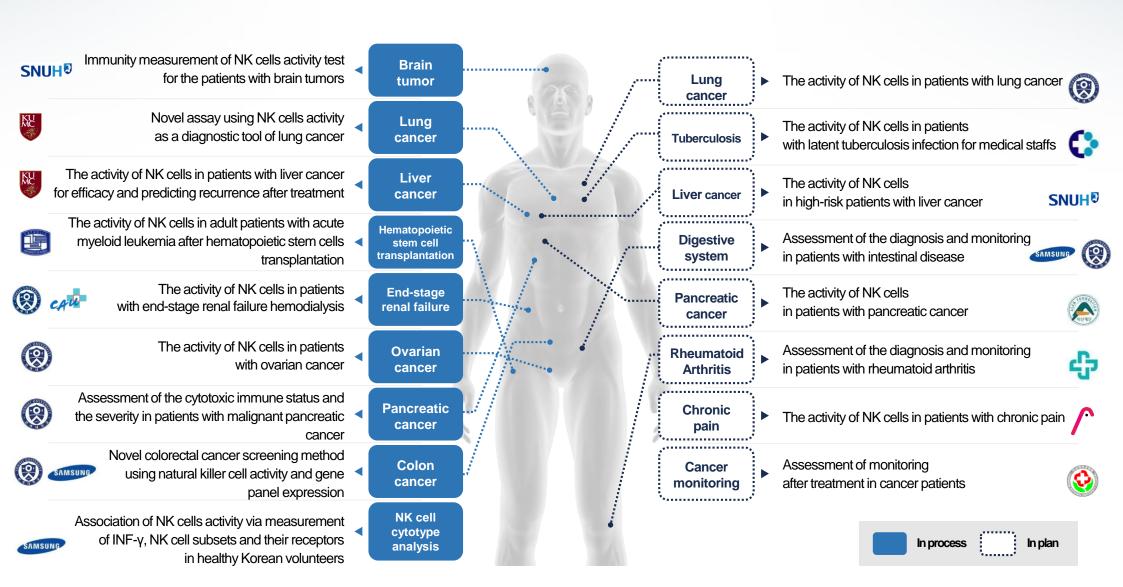
Monitoring of antibody therapeutic reactivity in cancer patients



Vejle Hospital ( Healthcare



## **Domestic Clinical Trials In Plan**



# Domestic Hospitals and Clinics with NK Vue

### Seoul/Gyeonggi/ Chungcheong province

#### **University Hospital**

Gangnam Severance Hospital, Seoul St.
Mary's Hospital, Konkuk University Medical
Center, Yoida Mokdong Hospital, Kangbuk
Samsung Hospital Suwon Medical Center,
Inha University Hospital, Gachon Gil Hospital,
Catholic University Incheon St. Mary's
Hospital, Chungnam National University
Hospital

#### Health check-up Center

Korea Industrial Health Association (5 branches), Korean Association of Health Promotion (2 branches), Hanaro Medical Foundation (2 branches), Korea Medical Institution (3 branches), Hansin Medipia

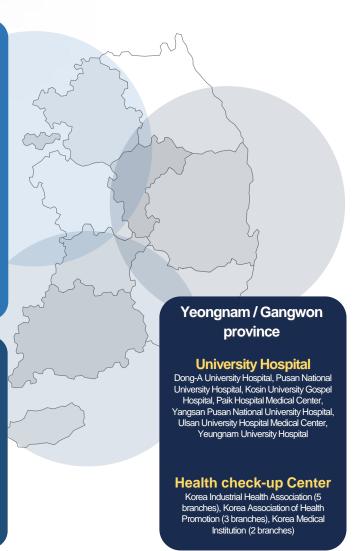
### Honam/Jeju province

#### **University Hospital**

Chonnam National University Hwasun Hospital, Cheju Halla General Hospital, Mokpo Korean Hospital, Yeosu Korea Hospital

### **Health check-up Center**

Korea Industrial Health Association (3 branches), Korea Association of Health Promotion (2 branches), Korea Medical Institution (1 branch)



## University Hospital

Gangnam Severance Hospital, Kangbuk Samsung Hospital, Yoida Mokdong Hospital, Seoul St. Mary's Hospital, Donga University Hospital, Pusan National University Hospital, etc.

## General Hospital

NK cell activity test Hospital: Hyosung Hospital, Incheon Hanlim Hospital, Sung Min

Hospital, Worldwide Hospital

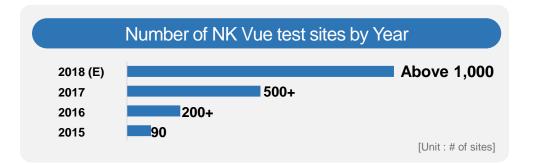
## Health Check-up Center

Korea Medical Institution, Hanaro Medical Foundation, Hanshin Medipia, Korea Industrial Health Association, Korea Association of Health

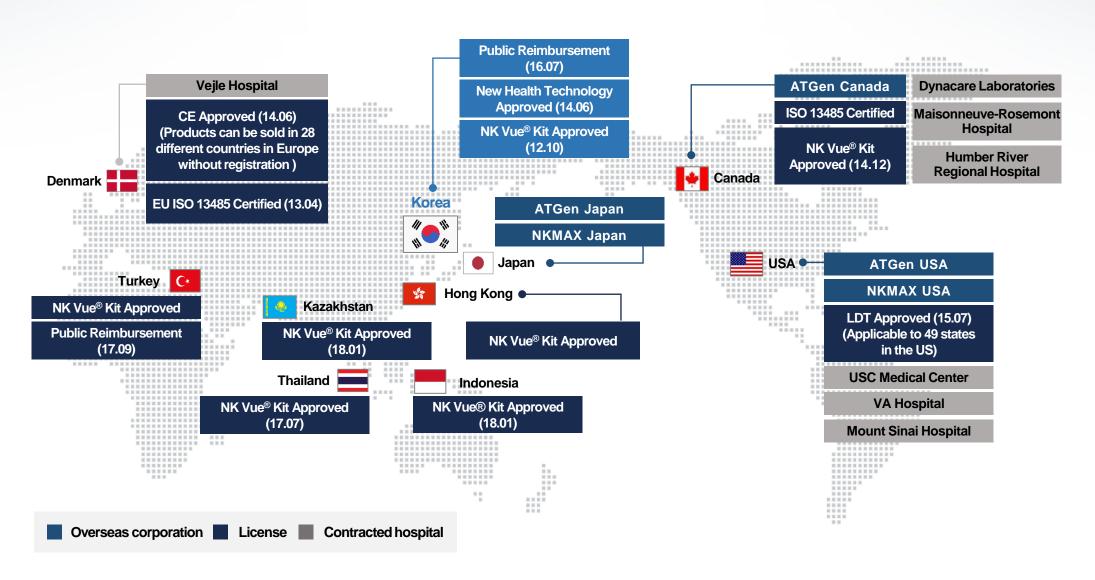
Promotion

### Clinical Laboratories Services

Green Cross Laboratories, Samkwang Medical Laboratories, Soul Clinical Laboratories, Seegene Medical Foundation, EONE Laboratories



## Global Networks for NK Vue





# **Advantages of SuperNK Therapy**

01 •---- 02 •---- 03 •---- 04

## Mass Production Available

NK cells proliferate at 1,000 to 10,000 times the source amount

## Superior Killing Ability

SuperNK cells display superior killing ability against cancer cells

# **Ability to Destroy Solid Cancers**

Confirmed its ability to destroy a variety of solid cancers including lung, colorectal, breast, and liver cancer

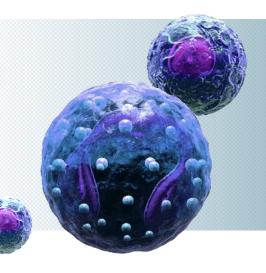
# Increased Persistence and Expansion in Cancer Patients

Improve immunity in cancer patients

# SuperNK

A New Immune Cancer Therapy

Developed an optimal anti-cancer immune therapy that composed of 99% pure NK cells to kill cancer cells

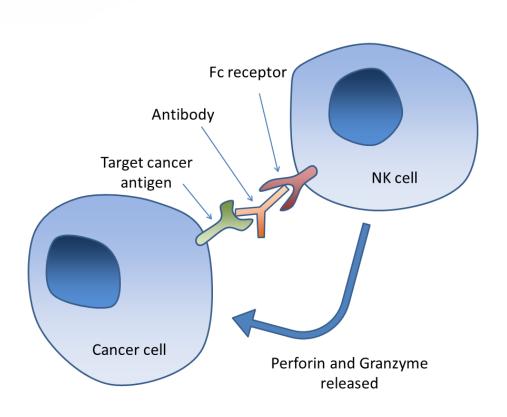


# Global Plan for SuperNK

Autologous NK Cell therapy is currently legal in Japan, Thailand, Italy, Mexico

- Initiated autologous treatment in Tokyo in March 2018 and will begin treating United States Patients as of June 2018 (inject in Mexico).
- Will begin IRB approved clinical trials in Thailand (Ramathibodi Hospital), Mexico (Angeles Hospital), and Italy in early summer 2018 for cancer, rheumatoid arthritis, Alzheimer's disease, and combination therapy.
- To submit US and Korean FDA IND application by late summer/early fall 2018.
- Plans to do most phase II trials in US and Korea.

# NK Cells Play a Major Role in Response to Antibody Therapy in Cancer



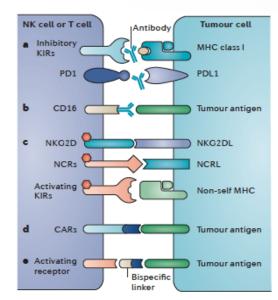


Figure 4 | Schematic representation summarizing the different NK cell-based therapeutic approaches. These strategies could be combined for optimal antitumour immune responses. Many natural killer (NK) cell receptors are also expressed on T cells, and T cells can also be transduced with chimeric antigen receptors (CARs) based on NK cell receptors; therefore, these immunotherapeutic combinations might involve both NK cells and T cells. KIR, killer cell immunoglobulin-like receptor; MHC, major histompatibility complex; NCR, natural cytotoxicity receptor; NCRL, NCR ligand; NKG2DL, NKG2D ligand; PD1, programmed cell death protein 1; PDL1, PD1 ligand 1.

Antibody-dependent cell-mediated cytotoxicity (ADCC) requires competent NK cells!

# Response to Herceptin in Metastatic Breast Cancer

Table 1 Pivotal Clinical Trials of Trastuzumab for Metastatic Breast Cancer				
	Cobleigh et al 1999[16]	Vogel et al 2002[17]	Baselga et al 2005[18]	Slamon et al 2001[15]
Phase	II	II	II	III
Patients enrolled	222ª	114 <sup>b</sup>	105 <sup>c</sup>	469ª
Line of therapy	2nd/3rd	1st	1st	1st
Intervention	WeeklyT	Weekly T	T every 3 wks	Weekly T with chemotherapy vs chemotherapy alone
ORR <sup>d</sup>	15%	26% (35%)	19% (23%)	50% vs 32% (P < .001)
OS	13 mos	24.4 mos	Not reached	25.1 vs 20.3 mos (P = .01)

ORR = objective response rate; OS = overall survival; T = trastuzumab (Herceptin).

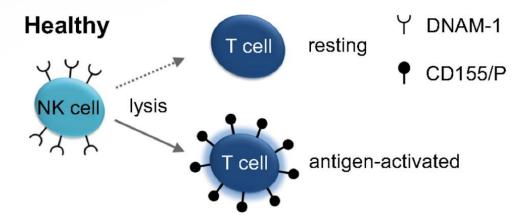
<sup>&</sup>lt;sup>a</sup>Enrolled patients were not selected for human epidermal growth factor receptor 2 (HER2) overexpression.

bEnrolled patients were not selected for HER2 overexpression, but retrospective analysis assessed the association of HER2 overexpression and clinical activity.

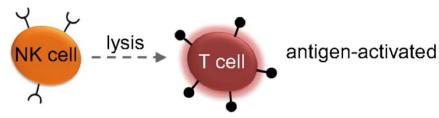
Enrolled patients were required to have HER2 overexpression, but discordance between local and central testing was noted.

dORRs in parentheses are for confirmed HER2 overexpression.

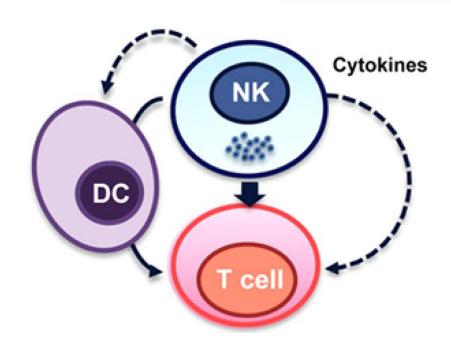
# NK Cells Regulate T Cells



## **Multiple Sclerosis**



[ Impaired NK-mediated regulation of T-cell activity in multiple sclerosis is reconstituted by IL-2 receptor modulation. Proc Natl Acad Sci U S A. 2016 May 24;113(21):E2973-82.]

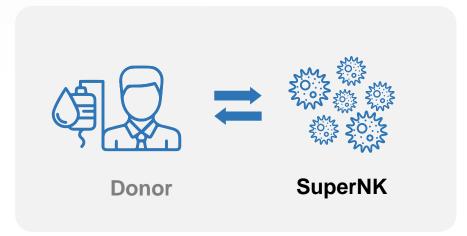


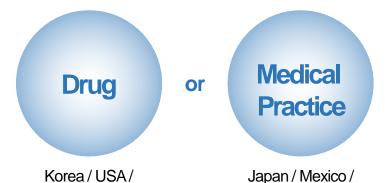
[ "Natural Regulators": NK Cells as Modulators of T Cell Immunity.Front Immunol. 2016 Jun 14;7:235.]

# **Market Classification of Cancer Immunotherapy**

## **Autologous Immune Cell**

European countries

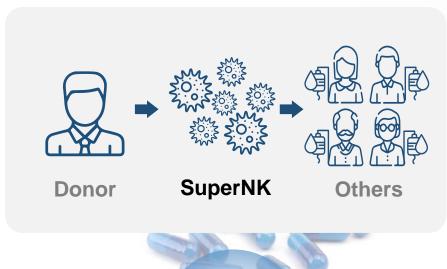




Indonesia / Australia / Canada

some other countries

## Allogeneic Immune Cell





Korea / USA / Japan / Taiwan etc.
In most countries

# Global Market Strategy for SuperNK Therapy

## **Autologous**

## Japan



- Founded NKMAX Japan
- Founded ATGen Japan
- Cell Expansion facility in Tokyo
- Commercialization started in Q1 2018

### **Thailand**



■ IRB Approved Clinical Trial in 2018

### EU



Plan Commercialization in 2018

### **Mexico**



- Commercialization starts in Q2 2018
- Supply contract with Hospital Angeles
- Supply US produced GMP products

### Italy



■ IRB Approved Clinical Trial in 2018

### Russia



Plan Commercialization in 2018

## **Allogeneic**

2018	2019	2020~
KOREA	KOREA	KOREA
Apply for IND Phase I clinical trial	Phase I/IIa clinical trial	Phase IIb clinical trial Apply for NDA
MEXICO	USA	USA
Apply for IND Phase I clinical trial	Apply for IND Phase I/IIa clinical trial	Phase I/IIa clinical trial



Global Bio Frontier ATGen

Bring the best diagnostics and therapeutics in the biotechnology and healthcare industry

# Infinite Growth with Constant Changes and Challenges

	<b>Foundation</b>	(0
RIIIAINA	Follogation	(Start_2005)
		i Olai i-Zuudi

### **Growth** (2006-2010)

### **Global Expansion** (2011~)

2002	ATGen founded
	Venture Company Certification
2003	R&D center certification
2004	Reagent supply agreement
	signed with overseas companies
2005	Patent registration completed for
	4 patents

2006	Designated as Promising Export	
	Company	
2007	INNO-BIZ Certified	
2008	Patent registration completed for	
	5 patents	
2009	Developed test kit for influenza	
	enzyme linked immunosorbent assay	
	Established Direct online sales system	
2010	About 100 overseas client companies	

2011	Patent application [Cancer Diagnosis Method that
	measures NK Cell Activity]
2012	Overseas revenue \$1M
	NK Vue® Kit manufacturing facility / Approval from Ministry of
	Food and Drug Safety in Korea
2013	Selected as promising SME by Gyeonggi-do (province)
	ISO 13485 certification
2014	Set up ATGen Canada

2014 Set up ATGen Canada
New Health Technology approved in Korea
GMP certificate, Canada ISO certification
Europe CE certification

2015 ATGen Listed in KOSDAQ
2016 NKMAX on ATGen offiliate company (NK G

2016 NKMAX, an ATGen affiliate company (NK Cell Therapy Company) founded.

NK Vue® public reimbursement in Korea

**2017** NK Vue® supply agreement signed with USA, Indonesia, and Kazakhstan

NK Vue® supply agreement signed with major commercial laboratories in Korea

NK Vue® product approval in Thailand

NK Vue® product approval / public reimbursement in Turkey Set up ATGen Japan



# **Company Profile**

## **ATGen**

Company	ATGen Co., Ltd.
CEO	Sang Woo Park
Established	January 14, 2002
Employees	112 (as of December 31, 2017)
Headquarters/ Factory	<ul> <li>Headquarters: 6F/1F SNUH Health Care Innovation Park, 172 Dolma-ro, Bundang-gu,         Seongnam-si, Gyeonggi-do, Republic of Korea</li> <li>Factory: KoreaBioPark, Sampyung-Dong, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea</li> </ul>
Corporation	<ul> <li>USA : Los Angeles, California</li> <li>Canada : Laval, Quebec</li> <li>Japan : Tokyo</li> </ul>
Business	Diagnostic Test Kit, Research Reagents, SP Technology related R&D Business
-	

## **NKMAX**

Company	NKMAX Co., Ltd.
CEO	Sang Woo Park
Established	January 6, 2016
Employees	27 (as of November 31, 2017)
Headquarters/ Factory	<ul> <li>Headquarters: 1F SNUH Health Care Innovation Park, 172 Dolma-ro, Bundang-gu, Seongnam-si,         Gyeonggi-do, Republic of Korea</li> <li>GMP: 1F SNUH Health Care Innovation Park, 172 Dolma-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea</li> <li>USA: Irvine, California</li> </ul>
Business	Immune Cancer Therapy

# More Competitive Together To Provide Total Healthcare Solution

Diagnostic, Cell Therapy, and Prevention Promote a Total Health Care Service

**ATGen** 

In Vitro Diagnostics

Manufacturing Technology



**Highly Active NK cell** 

Mass Culture Technology



# Innovative R&D Strategy

Continuous
expansion of
platform-based
pipeline
Strengthening R&D
strategy



# **Expansion to Global Market**

Agreement with the major corporations and exclusive distributors in various countries



# Maximizing Synergy Effect

Maximizing synergy
effect in diagnostic and
therapeutic market
Arranging a foundation
of personalized
disease prevention
system



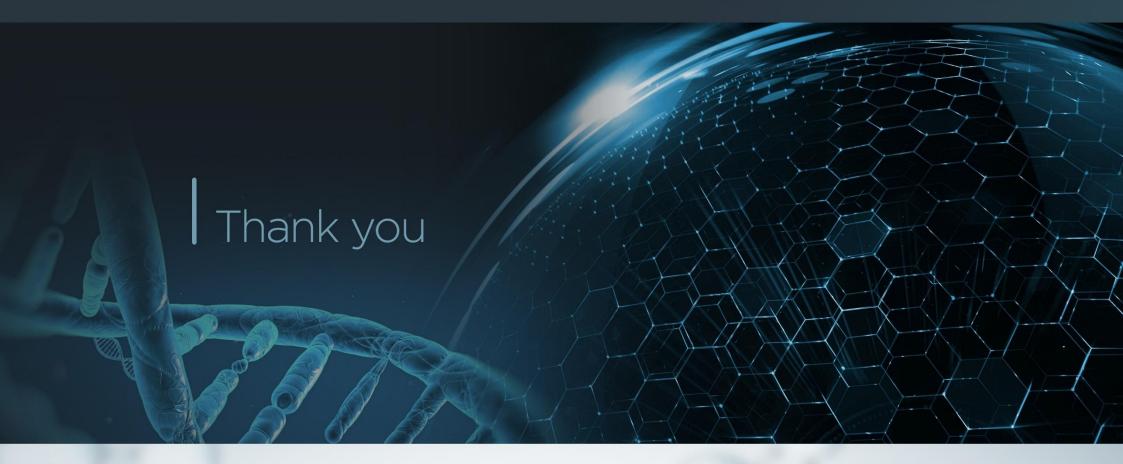
### **TOP Brand**

A goal to become top brand with differentiated marketing strategy

## Global Bio Frontier ATGen

Bring the best diagnostics and therapeutics in the biotechnology and healthcare industry





Health is the greatest wealth