



# Information Material about GTS Strategic Direction

Challenge GTS3.0 –
 June 28, 2018



### **Cautionary Statement**

This information material is provided for understanding Gene Techno Science ("GTS"), not for soliciting investment in GTS shares.

Information provided in this material may contain so-called "forward-looking statements." These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Risks and uncertainties include success rate of R&D projects, new regulations and rules, relations with partners in the future, etc.

This material includes information on pharmaceutical products and regenerative medicine (or related products), etc., which is being developed or launched. However, this is not intended to promote our products or provide medical advices.



# **Company Overview**

	Founded	March, 2001					
General Information	IPO	November, 2012年(Mothers @ Tokyo Stock Exchange)					
	Shareholders Capital	100 million ye	n(common stock, as of Augu	st 1, 2017)			
	Location	Headquarter	, Sapporo				
		Tokyo Office	o Office 2-10-8 Nihonbashi, Chuo-ku, Tokyo				
		Research Lab	Sapporo n for Platform for Research on Biofunctional y Creative Research Institution				
	Directors	Representative	e Director, President & CEO	Masaharu Tani			
		Director		Ryo Noguchi (New)			
		Outside Direct	or	Norikazu Eiki (New)			
Management	Corporate Officers	Chief Business Officer (CBO)		Munechika Sakabe			
		Chief Technology Officer (CTO)		Masayuki Kawakami			
		Head of Admir	nistration	Masakuni Ueno			
		Head of Corpo	rate Planning	Yasuo Sakae			
Major Shareholders	Noritsu Koki Co., Ltd. (Parent company)						
	NanoCarrier Co., Ltd., JSR Corporation, Senju Pharmaceutical Co., Ltd., ITOCHU CHEMICHAL FRONTIER Corporation						
Business Description	Research	·R&E	) for new biologics				
	developme	nt of •R&E	) for biosimilar				
	biologic	:s •R&E	) for regenerative medicine				



# **History**



-Acquisition of basic biotech technology -

#### Founded as a spin-out venture from Hokkaido Univ.

- Research Collaboration with Hokkaido Univ.
- Out-licensed anti-a9 integrin antibody to Kaken Pharmaceutical Co., Ltd.
- Signed joint development agreement for filgrastim (G-CSF) biosimilar with Fuji Pharma, Co., Ltd.

-Stabilization of management through launching BS product-

#### Listed at Mother Section of TSE

- Listed on the Tokyo Stock Exchange Mothers Section and obtained marketing approval for filgrastim biosimilar
- Signed joint development agreement for biosimilars with Sanwa Kagaku Kenkyusho, Senju Pharmaceutical and Mochida Pharmaceutical, respectively
- Formed capital and business alliance for biosimilars with JSR and ITOCHU CHEMICAL **FRONTIER**
- Formed capital and business alliance with Japan Regenerative Medicine (JRM)

### -Further Business Expansion-

#### **Biotech Engineering Company**

- Ready for challenging various biotechrelated business based on the technologies and commercialization know-how acquired through BS business
- Strive for creating healthcare solutions for rare disease, intractable disease and pediatric disease by collaborating with academia and biotech ventures aggressively



# Financial results overview up to FY2017

		FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
Sales	(1,000 yen)	207,124	60,534	301,348	321,658	1,160,890	1,089,360	1,059,727
Ordinary Loss (△)	(1,000 yen)	△317,602	△373,657	△516,780	△790,234	△785,785	△1,176,763	△903,215
Net Loss (△)	(1,000 yen)	△320,992	△377,047	△519,301	△792,179	△787,685	△1,224,554	△904,557
Net Loss per share $(\triangle)$	(yen)	△134.05	△119.10	△120.08	△165.93	△151.45	△137.01	△94.54
Total Asset	(1,000 yen)	508,070	922,429	1,886,777	1,146,755	1,694,117	3,706,224	3,025,172
Net Asset	(1,000 yen)	341,355	888,008	1,052,839	270,659	403,290	3,500,246	2,604,037
Net Asset per share	(yen)	131.96	213.35	220.80	52.07	66.22	363.39	268.74
Number of employee		8	8	13	14	19	20	21
Fund raised Partner/Method IPO WHIZ Partners Itochu Chemical Frontier NK JSR			<b>783,840</b> 783,840	1,416,830 1,215,040 201,790		<b>479,990</b> 479,990	3,921,876 1,119,976 301,897 2,000,001 500,000	

<sup>1.</sup> Net loss per share is calculated based on average of the number of outstanding shares during the fiscal year. Net asset per share is calculated based on the number of outstanding shares as of fiscal year end.

<sup>2.</sup> A share split (100 for 1) was implemented as of August 8, 2012(100 for 1) and October 1, 2016 (2 for 1).

In the table above, each "per share"-number is calculated based the assumption that a share split was implemented at the beginning of FY2012.



# **New Management Team**



Board of Directors

### New Management Team -

- Quick and appropriate decision making by directors with biotech knowledge and experience
- Improvement of governance by directors from GTS and NK as well as one outside directors

<Member>

Masaharu Tani President & CEO

Ryo Noguchi CEO of Japan Regenerative Medicine Co., Ltd.

Norikazu Eiki Former chairman of Bayer Yakuhin, Ltd. Outside Director

### **Executive Members**

Business Development
Research & Development
Manufacturing
Planning & Administration

# Experts from each functionssupporting new Management Team -

#### <Member>

Munechika Sakabe CBO Masayuki Kawakami CTO

Masakuni Ueno Head of Administration

Yasuo Sakae Head of Corporate Planning/IR

GTS

Outside



### **Executive Officers**

#### Masaharu Tani President & CEO

The Univ. of Tokyo, MSc, MBA

Joined the clinical development dept. at Suntory, implementing clinical trials and moved to Takeda Pharmaceutical, where worked at the Business Development Department and Strategic Product Planning Department. After Takeda, joined Whiz Partners, a Japanese investment company in 2013 and joined GTS in 2014. Appointed as CFO in 2015 and CEO in 2017 at GTS.

#### Munechika Sakabe Corporate Officer, CBO

Bachelor of Faculty of Chemical Engineering Saitama Univ.

Involved in the Japanese human genome project of Science and Technology Agency at Seiko Instruments Inc. Nihon Millipore Corporation (Merck), Applied Biosystems (Thermo), and joined in Fujifilm Corporation, worked for Business Development of Lifescience and Pharmaceutical Div. Joined GTS in 2016.

### Masayuki Kawakami Corporate Officer, CTO, Research & Development Div.

Kyoto Univ. Graduate School of Engineering, Ph.D

Worked for research laboratories of FUJIFILM Corp. mainly in oncology area with Harvard Univ. and Novartis (then Sandoz). Worked for Toyama Chemical Corp. and then for FUJIFILM Pharmaceuticals USA to promote an anti-influenza drug clinical development. Joined GTS in April, 2017 and appointed as CTO in April, 2018.

### Masakuni Ueno Corporate Officer, Head of Administration

Bachelor of Faculty of Science and Engineering, Kinki Univ.

Long experience in administration area including General Affairs, Accounting, etc. Involved in IPOs of two companies based in Sapporo, joined GTS in 2010 and became Corporate Officer, Head of Administration

#### Yasuo Sakae Head of Corporate Planning/IR

Bachelor of Faculty of Sociology, Hitotsubashi Univ.

Sales & Marketing at Commerz Securities (affiliate of Commerzbank) Tokyo Branch and HQ in Germany and then joined in Yamanouchi/Astellas, worked mainly for globalization of finance function including establishment of Corporate Venture Capital. CFO at Astellas US, VP, Procurement, VP, Corporate Finance & Control at Astellas Pharma, Japan and VP, Corporate Strategy & Communications at Astellas Europe. Joined GTS in April, 2018.

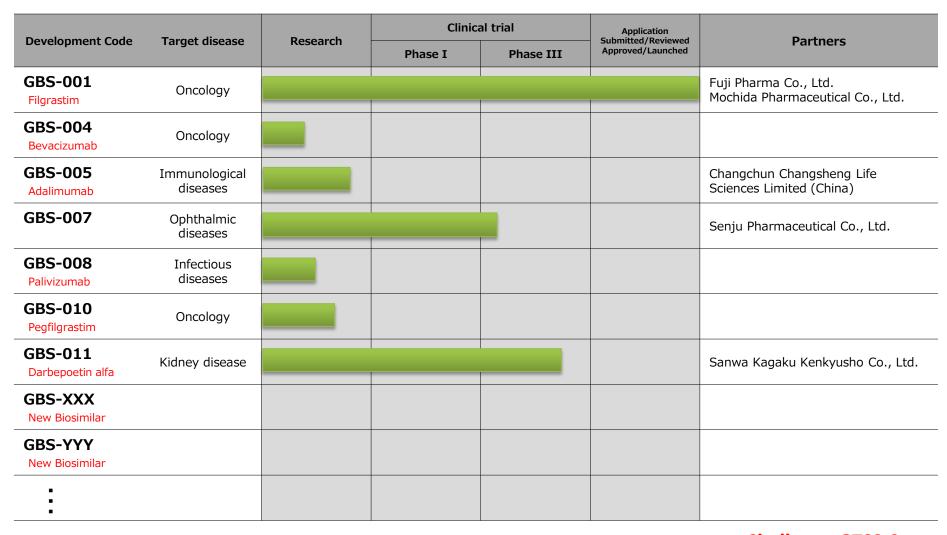


# **Biosimilars Business**



### **Biosimilars Business**

# Overview of R&D Pipeline



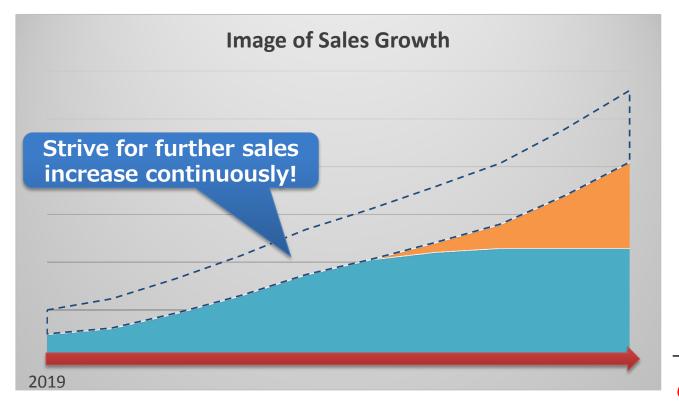


# Biosimilars Business - Strategy -

### Strengthen mid, long-term business foundation

#### **Action Plans**

- Maximize sales of Filgrastim and launch 3 products from existing pipeline for achieving sales target
- Launch 1- 2 products from new pipeline for strengthening our business foundation further
- Pursue out-licensing opportunities to overseas partners



Additional sales by out-licensing to overseas partners

Further increase by new pipeline products

Maximize sales of existing pipeline products



# **Towards GTS3.0**



# **Our Strategic Direction**



# Biotech Engineering Company, striving for value creation

Aiming at providing comprehensive healthcare solutions for patients as well as families and caregivers



Explore a new business opportunities by providing a healthcare solution for the therapeutic area where a current solution is insufficient

### **Our Focus**

- Pediatric disease (including juvenile one)
- Rare disease
- Intractable disease
- Asia-endemic disease



# **History of our Expertise**

Move forward to the stage where we can create a new value by combing a cuttingedge bio-technology with the technology/know-how that we have accumulated since start-up



 Create drug candidates with a new value including cell therapy by leveraging our expertise underpinned by accumulated experience of both new biologic researches and biosimilar business activities

 Create a value by providing pharmaceutical products as well as other services related to healthcare

GTS 2.0  Technology and know-how of manufacturing a protein with the same performance as targeted

Manufacturing of API for pharmaceuticals on commercial scale

 Technology and know-how of manufacturing a protein with high quality and a cell line with standardization hurdles

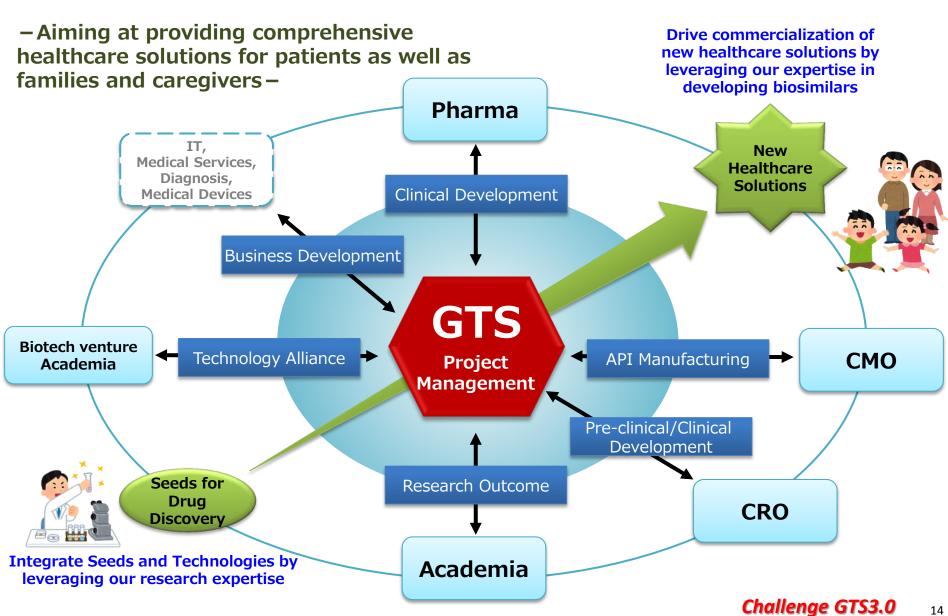
GTS 1.0



Basic technologies of creating antibody



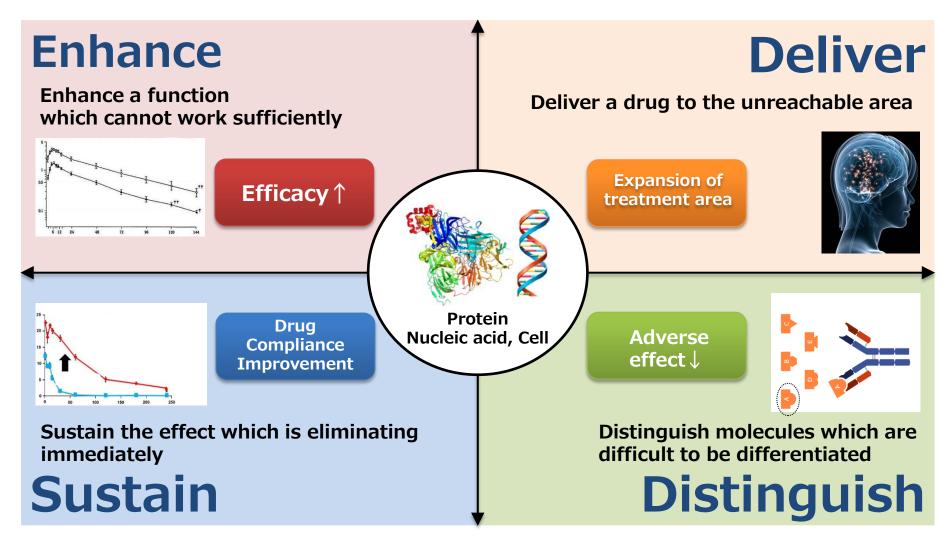
# **Providing New Healthcare Solutions**





# **Integrate Seeds and Technologies**

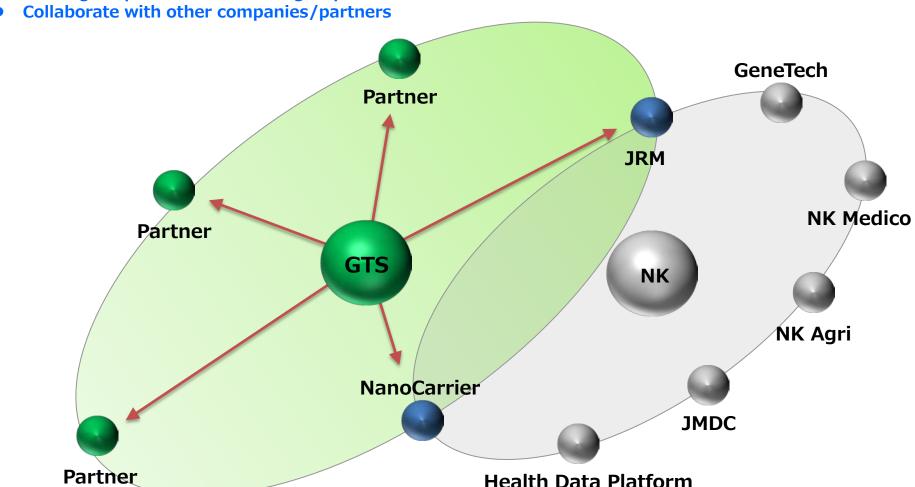
- Technologies to be focused -





# For Comprehensive Healthcare Solutions

- Create an environment which allows us to collaborate with the best partner -
- Provide a new healthcare solution by integrating each technology
- Foster an environment for a new healthcare solution (Support/Improve environment surrounding patients)
- Leverage capabilities within NK group





### Financing for Supporting Strategic Direction

#### Overview of this financing;

- The number of dilutive shares; 1,500,000 shares (100 shares per stock acquisition rights), dilution ratio is 15.68%
- Amount of funds raised (Estimated amount of net proceeds calculated assuming all of the stock acquisition rights is exercised at the initial exercise price.): 3,059,455,000 yen
- Allotment date: June 19, 2018
- Exercise period: 2 years (July 2, 2018 to July 2, 2020)

Purpose	<ul> <li>Raise funds for enhancing enterprise value in line with strategic direction, focusing on rare and intractable disease, especially, pediatric disease</li> <li>Drive development plan for biosimilars pipeline for next 2- 3 years robustly</li> <li>Drive both new biologics business and regenerative medicine business which have high growth potential</li> <li>Improve market liquidity by expanding investors number and diversity (Maximize the effect with share split implemented as of July 2, 2018)</li> </ul>				
Basic Policy	<ul> <li>Manage this financing in a flexible and controllable manner by using our right to accelerate/suspend Daiwa's execution, considering our business plan, cash balance, cashflow forecasts and equity market trends</li> <li>Buy back and cancel the outstanding stock options in case no financing is necessary at our discretion</li> </ul>				
	1. Finalization of manufacturing method, preparation for supplying products for commercialization and preparation of application for the marketing authorization for 1,350 million ye three products among GBS-002 – 011				
Use of Proceeds	2. Development of manufacturing process, quality test and pre-clinical studies for new biosimilars (1-2 products)  650 million ye				
	3. Research and development of existing new biologics portfolio, in-licensing of new biologics and exploring new biotech business including regenerative medicine 1,059 million years.				



### Trends in Pharma/Healthcare Industry

- From a disease with mass patients to the one with more segmented (smaller number of) patients
- From "blockbuster" (Worldwide sales more than 100 billion yen) to "personalized" products.
- Worldwide pharmaceuticals market: more than 100 trillion yen

#### **Vitamins/Antibiotics**

Drugs for intestinal disease/Lifestyle disease

**Drugs for Autoimmune disease/Immunosuppressive** 

**Drugs for Oncology/CNS** 

**Drugs for Intractable/Rare disease** 

**Drugs for Pediatric/Juvenile disease** 

1960 1980 2000 2020 2040 **Approximate** \*??? Trillion 100trillion 20trillion 50trillion worldwide sales of yen pharmaceuticals ven yen yen!! (\*est.)

- ✓ Disease with mass patients
- ✓ Blockbuster products

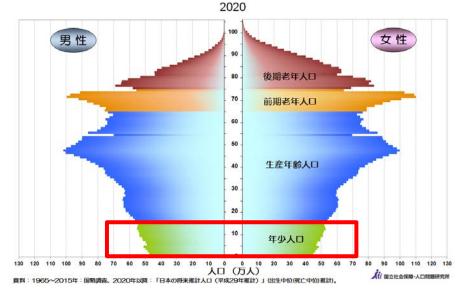
- ✓ Segmented disease
- ✓ Personalized healthcare solution
- **❖** Personalized healthcare solution will be more important
- Neglected disease such as intractable/rare/pediatric disease is to be focused



### **Potential of Pediatric Disease**

 Importance of improving the quality of comprehensive healthcare services for child and juvenile

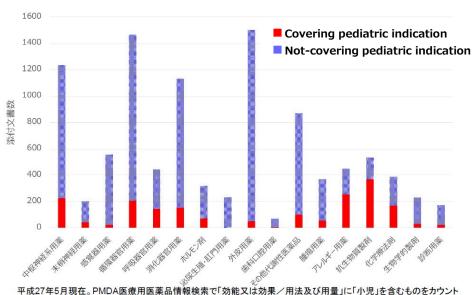
### **Age Pyramid of Japan**



Source: http://www.ipss.go.jp/

- The population of many countries including Japan shows "inverse" pyramid style
- The portion of child/juvenile population (less than 15 years old) in Japan is approx. 12.5% of total population and tremendously getting lower.
- The decrease of child/juvenile population who would be a key for Japanese and global economic growth in the future should endanger maintenance of a solid and sustainable society.

### The number of package inserts obtaining marketing authorization for pediatric indication



Source: http://www.pmda.go.jp/)

- The number of drugs which have pediatric indication and dosage is limited although they are available for adult.
- Healthcare cost dispensed at pharmacy for pediatric disease (less than 15 years old) is approx. 500 billion yen in 2015, approx. 6.25% of total healthcare cost at pharmacy in Japan (approx. 8 trillion yen).
- Considering the number of package inserts including pediatric indication, we estimate there should be a considerable number of patients who do not receive sufficient healthcare service and, therefore, a market potential should be larger.

Challenge GTS3.0



# **Gene Techno Science**





Biotech Engineering Company, striving for value creation