



FY2018

Consolidated Financial Results

- Financial Results Review
- Revision of “Medium-Term Management Plan FY2020”

Takara Bio Inc.

May 15, 2018

Consolidated Financial Results for FY2018 (Year ended Mar. 31, 2018)

(millions of yen)

	FY2018	Compared with previous forecast as of Nov. 7, 2017		Year on year	
		Change	Ratio	Change	Ratio
Net sales	32,312	▲ 687	▲ 2.1%	+2,937	+10.0%
Cost of sales	13,657	▲ 661	▲ 4.6%	+1,234	+9.9%
Gross profit	18,655	▲ 25	▲ 0.1%	+1,702	+10.0%
SG&A expenses	15,099	▲ 81	▲ 0.5%	+1,349	+9.8%
Operating income	3,555	+55	+1.6%	+352	+11.0%
Ordinary income	3,861	+61	+1.6%	+282	+7.9%
Net income attributable to owners of the parent	2,335	+334	+16.7%	+982	+72.6%

FY2018 Consolidated Financial Results

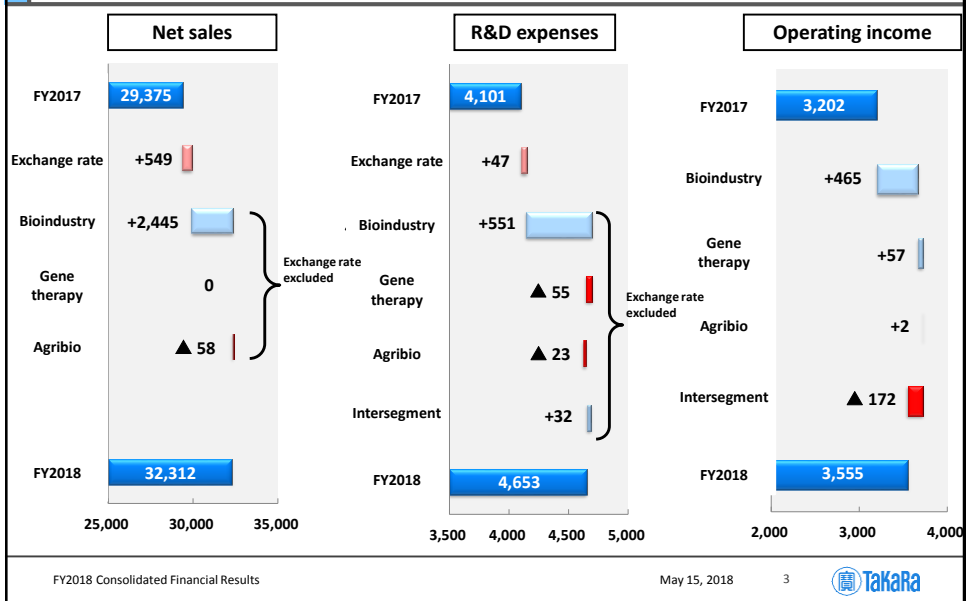
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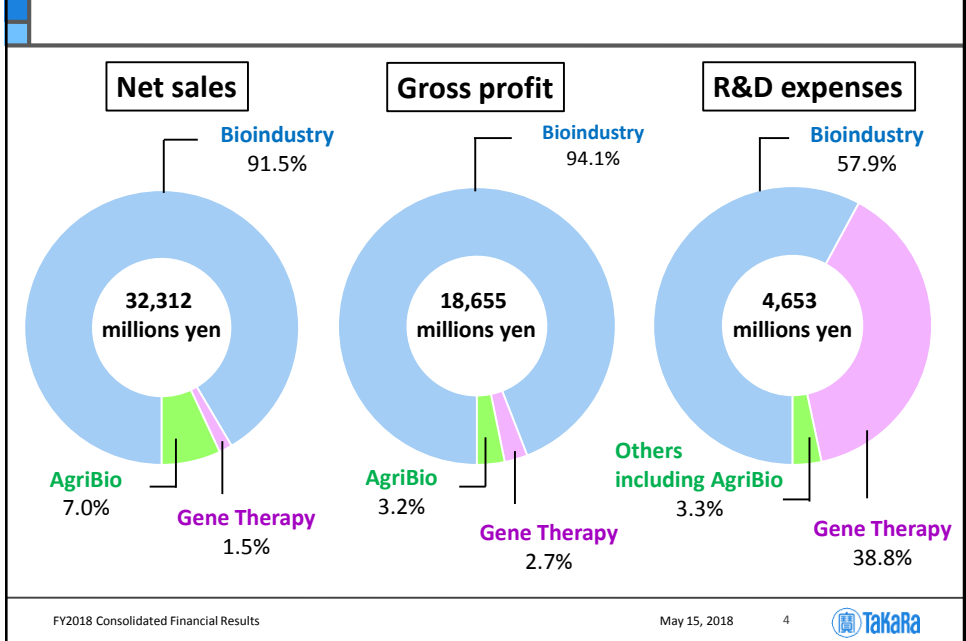


Analysis of Results for FY2018 compared with Previous Fiscal Year

(millions of yen)

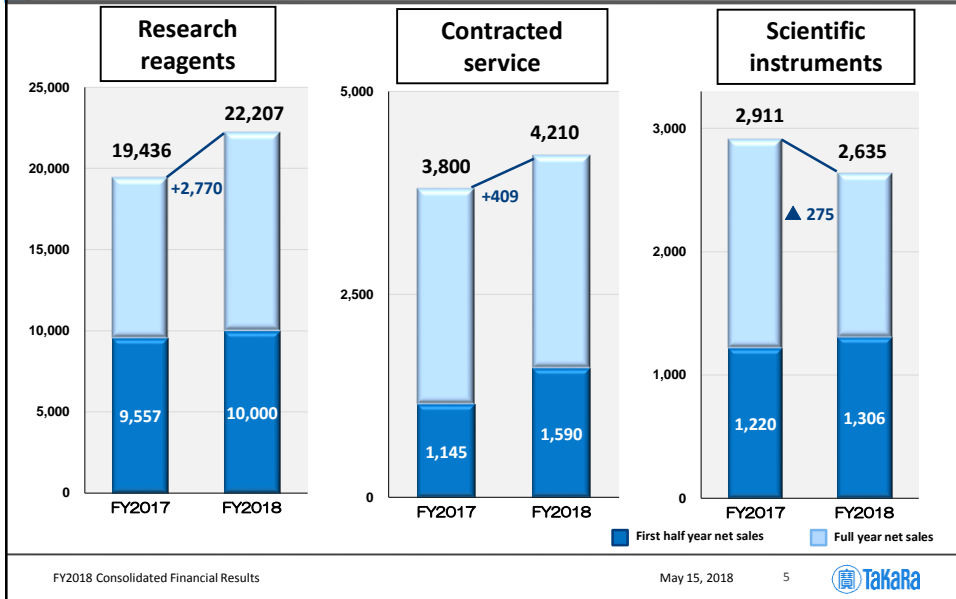


Business Segment Analysis for FY2018



Sales Composition in Bioindustry Business

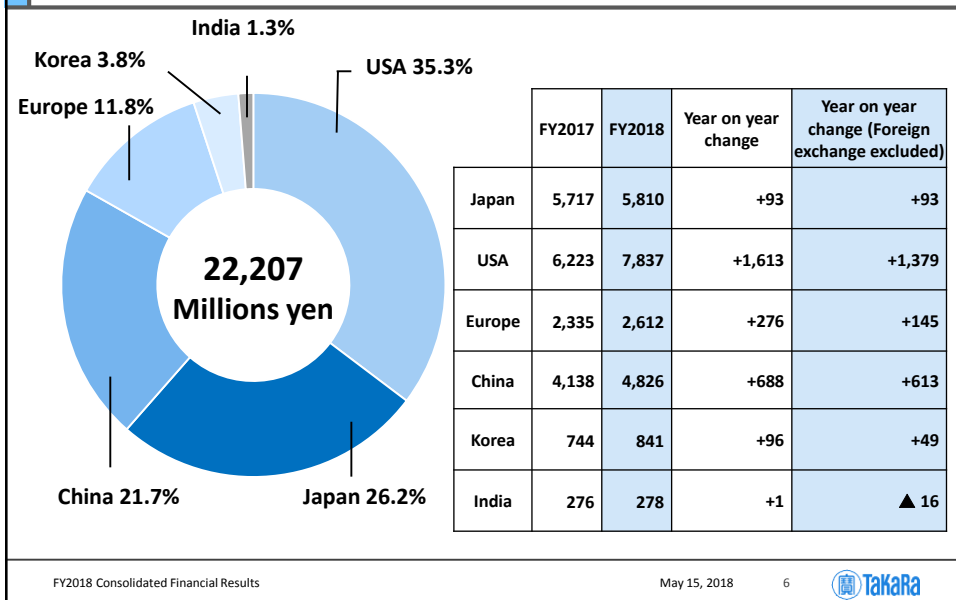
(millions of yen)



Sales by Country for Research Reagents

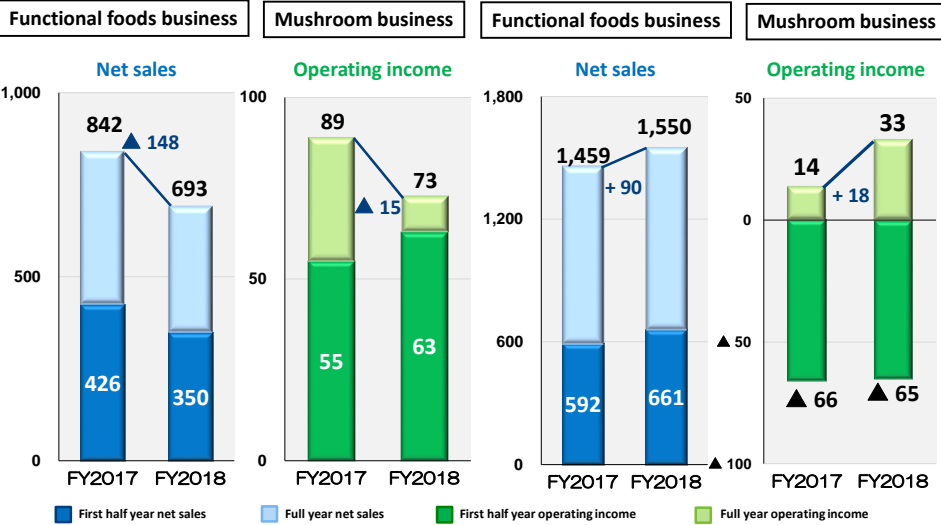
Overseas Sales Ratio : 74%

(millions of yen)



Net sales and Operating income in AgriBio Business

(millions of yen)



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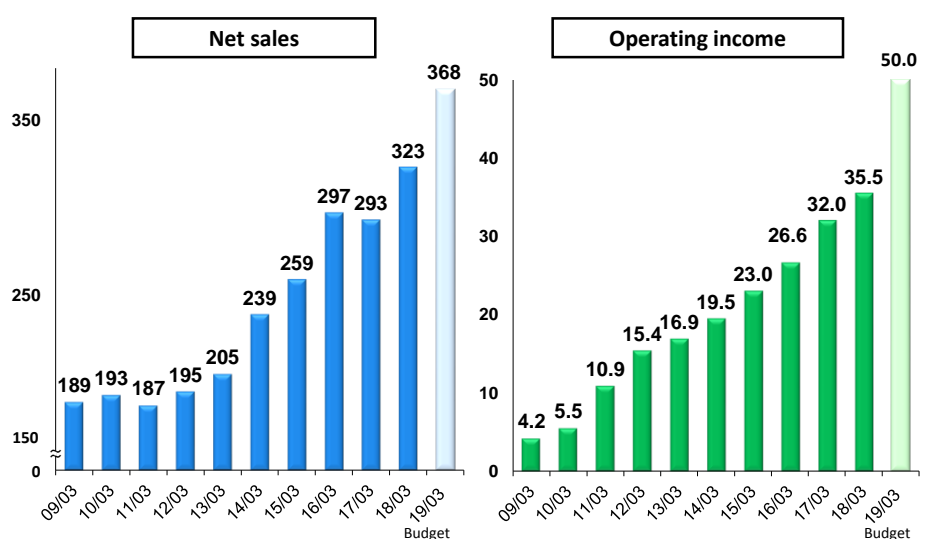
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Transition of Net sales/Operating income in last 10 years

(100 millions of yen)



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Budget for FY2019 vs Actual

(millions of yen)

	FY2018 Actual	FY2019 Budget	Year on year	
			Change	Ratio
Net sales	32,312	36,800	+4,487	+13.9%
Cost of sales	13,657	15,122	+1,464	+10.7%
Gross profit	18,655	21,677	+3,022	+16.2%
SG&A expenses	15,099	16,677	+1,577	+10.5%
Operating income	3,555	5,000	+1,444	+40.6%
Ordinary income	3,861	5,200	+1,338	+34.6%
Net income attributable to owners of the parent	2,335	3,100	+764	+32.8%

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Progress Status of Takara Bio Medium-Term Management Plan FY2020

	Business goal	Results for initial year
Bioindustry	Regenerative medical products-related CDMO business No.1	<ul style="list-style-type: none"> • Business expansion focused on viral vector production and Cell processing/testing • Decision on new facility to accommodate future increase in orders
Gene therapy	Approval acquisition of gene therapy products	<ul style="list-style-type: none"> • HF10 Phase II targeting melanoma in Japan, Completion of recruiting, Application preparation underway for approval • Cooperation with Otsuka Pharma regarding two gene-modified T cell therapy projects
AgriBio	Building a platform for stable profits	<ul style="list-style-type: none"> • Stable profitability • Unification of manufacture and sales in Mushroom business (Integration into subsidiaries)

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Progress Status of Takara Bio Medium-Term Management Plan FY2020

Medium-Term Management Plan FY2020 formulated in May, 2017

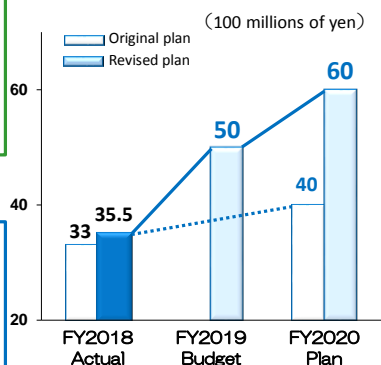
FY2020 Takara Bio consolidated results
Net sales 38.5 billion yen
Operating income 4.0 billion yen

Expect to be early achievement of operating income targets

Revised Medium-Term Management Plan FY2020

FY2020 Takara Bio consolidated results
Net sales 38.5 billion yen
Operating income 6.0 billion yen

Operating income



R&D expenses	46	52	56
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AgriBio Business Building a Platform for Stable Profits

(millions of yen)

Build a platform for the stable supply of products to Takara healthcare Inc.

- ◆ Maintain stable supply system of product
- ◆ Strengthen quality assurance system
- ◆ Realize cost down

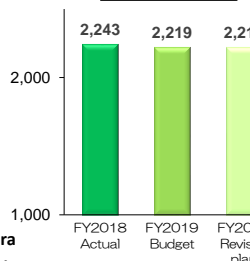
Efficient business development by system change to unification of manufacture and sales

- ◆ Transfer mushroom marketing function of Takara Bio to Mizuho Norin and unify manufacture and sales

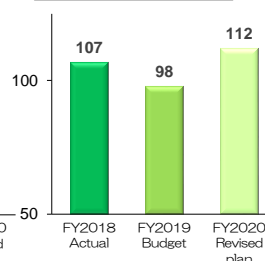
Build brand strategy for mushroom products

- ◆ Utilize certification as "Kyoto Brand Goods"
- ◆ Strengthen the sales of frozen mushrooms
- ◆ Focus on sales suited to high-value added channel

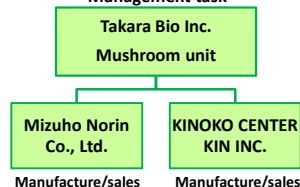
Net sales



Operating income



Management task



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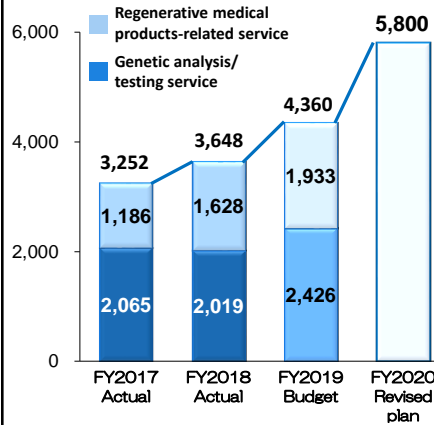
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Bioindustry Business ① CDMO Business Expansion : Regenerative Medical Products-related Contracted Service No.1

CDMO business (Contracted service) Net sales transition

(millions of yen)



Vector manufacturing/ Cell processing service

- ◆ Establish newly for research and manufacturing facility dedicated to regenerative medical products (Scheduled for completion in December 2019)
- ◆ Manufacturing development of GMP grade vector
- ◆ Cell processing development
- ◆ Expansion of quality testing for Regenerative medical products

Gene analysis/Gene test

- ◆ Expansion of service menu for gene analysis such as whole genome sequencing
- ◆ Strengthen the fields of single cell analysis and clinical sequencing

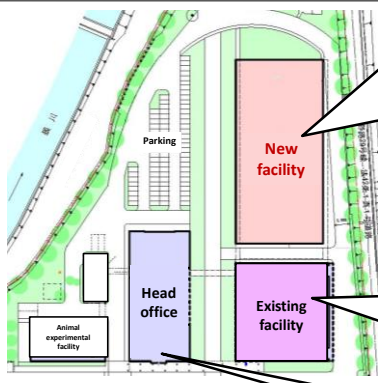
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Bioindustry Business ② New Establishment of the Research and Manufacturing Facility for Regenerative Medical Products



New facility

- Scheduled for completion in September 2019
- 14,100 m² (4,600 m² not installed space)
- Contracted service such as manufacturing and quality testing for regenerative medical products
- Research of new technology development for regenerative medical products
- Technology development and manufacturing related to research reagents
- Vector manufacturing, Cell processing, Cell banking, GMP aseptic filling

Gene and Cell processing center

- Completed in October 2014
- 6,700 m²
- Vector manufacturing, Cell processing, Cell banking, GMP aseptic filling, Cell testing, etc

Main research facility

- Completed in August 2015
- 1,197 m²
- Gene analysis, Area for basic research



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Bioindustry Business ③

Status of Post Merger Integration of Former WaferGen Bio-systems, Inc. and Rubicon Genomics, Inc.

- ◆ Post merger integration completed nearly
- ◆ R&D and Management dept. merger integration followed by promotion of manufacturing transfer to Takara Biotechnology (Dalian) Co., Ltd.
- ◆ Started R&D activity and Marketing sales activity fully
 - ✓ WaferGen :
New launch of SMARTer™ ICELL8® cx
 - ✓ Rubicon :
Promotion of NGS-related product ThruPlex and PicoPlex series

New single cell analysis system
SMARTer™ ICELL8® cx



Automatic library generating system
SMARTer™ Apollo™
Library Prep System

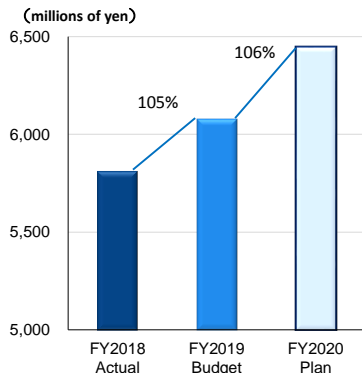


Ultra-low nucleic acid analysis reagents
ThruPlex, PicoPlex series

Bioindustry Business ④-1

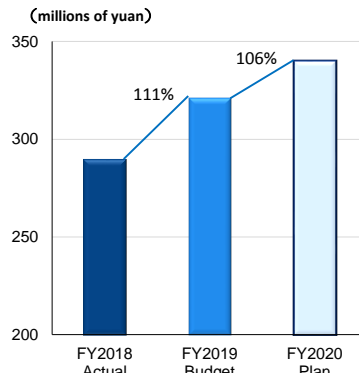
Sales Plan for Research Reagents by Country

Japan



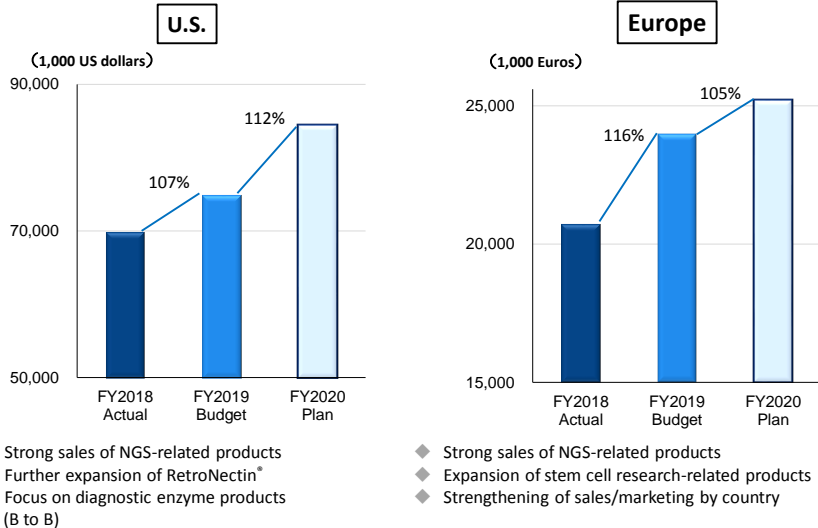
- ◆ Share remains high on the maturing market
- ◆ Strengthening of stem cell/genome editing-related products
- ◆ Focus on applied field of PCR products

China



- ◆ Continuous market enhancement
- ◆ Strong sales of Clontech brand product
- ◆ Well-balanced expansion ranging from general to advanced research purposes

Bioindustry Business ④-2 Sales Plan for Research Reagents by Country



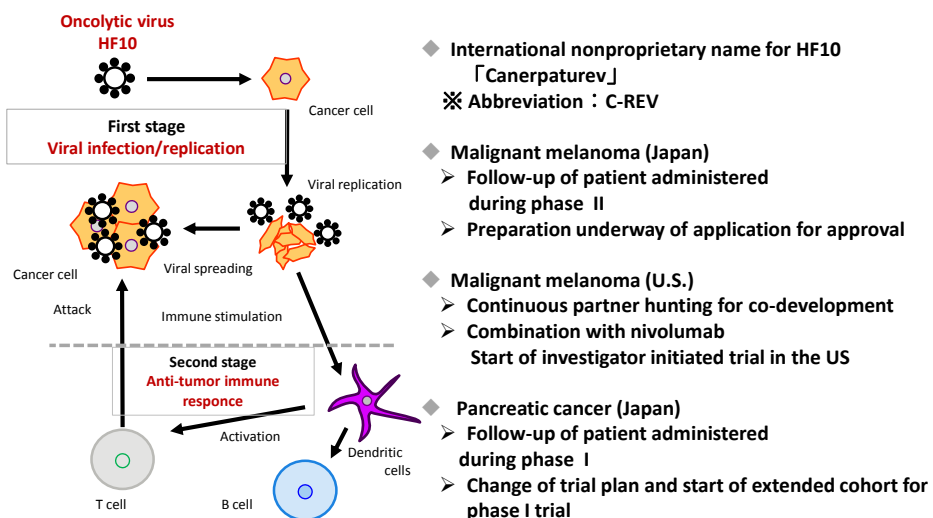
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Gene therapy Business ①-1 HF10 Functional Mechanism and its Project Overview



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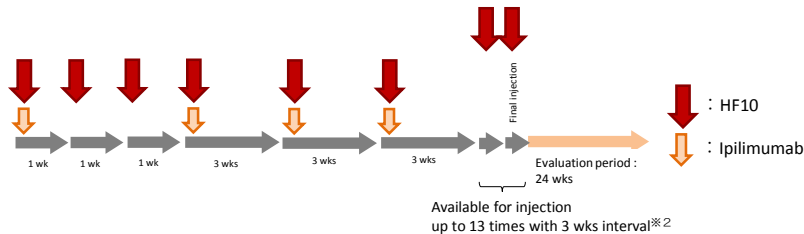
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Gene therapy Business ①-2 HF10 Phase II Clinical Trial in Japan and its Protocol for Malignant Melanoma

- Study patient : Patient with stage IIIB-IV unresectable or metastatic melanoma
- Target number of cases : 25 cases (Administered for 28 cases)
- Trial site : National Cancer Center Hospital and Others (12 sites in total)
- injection method/Dose : 1×10^7 TCID₅₀※1/mL x 6 times (Combination with Ipilimumab)
- Protocol :



- ※1 : Median (50%) tissue culture infectious dose
 ※2 : Clinical trial treatment is acceptable, treatment reactivity is observed and SD, otherwise no critical PD in clinical practice

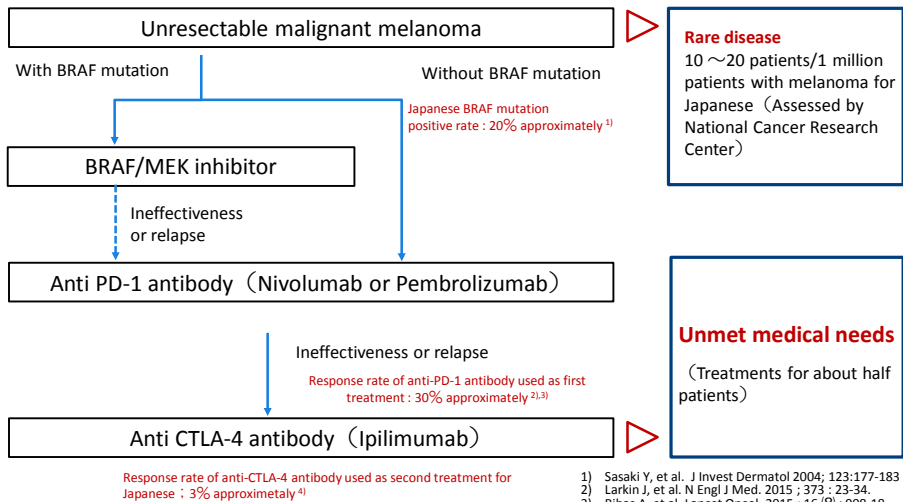
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Gene therapy Business ①-3 HF10 Study Patients Layer on Treatment for Malignant Melanoma



- 1) Sasaki Y, et al. J Invest Dermatol 2004; 123:177-183
- 2) Larkin J, et al. N Engl J Med. 2015 ; 373 : 23-34.
- 3) Ribas A, et al. Lancet Oncol. 2015 ; 16 (8) : 908-18
- 4) Fujisawa Y, et al. J Dermatol Sci. 2018; 89: 60-66

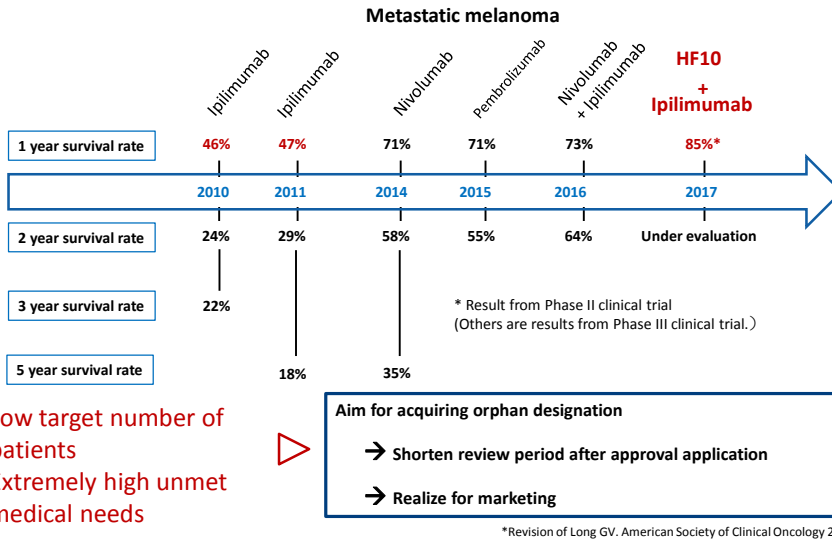
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Gene therapy Business ①-4 Application Plan in FY2019 for HF10 Targeting Melanoma in Japan



- Low target number of patients
- Extremely high unmet medical needs

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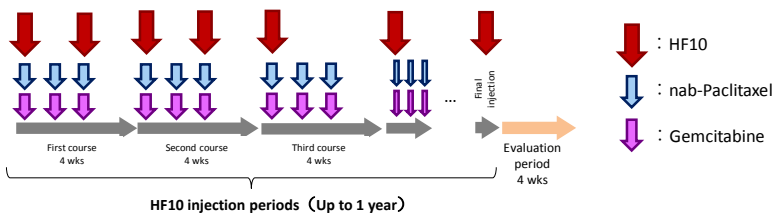
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Gene therapy Business ①-5 Protocol for HF10 Phase I Clinical Trial Targeting Pancreatic Cancer in Japan

- Study patients : Targeted for unresectable pancreatic cancer (Stage III or IV)
- Target number of cases : 6 cases (Administered for 6 cases)
- Practice place : Kanagawa Cancer Center/National Cancer Center Hospital East
- Injection plan/Dose : Cohort 1 : 1×10^6 TCID₅₀^{※1}/mL x 5 times
Cohort 2 : 1×10^7 TCID₅₀^{※1}/mL x 5 times
(Combination with Gemcitabine and nab-Paclitaxel)
- Protocol :



※1 : Median (50%) tissue culture infectious dose

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Gene therapy Business ①-6

Overview of HF10 Phase I Clinical Trial Targeting Pancreatic Cancer/Extended Cohort in Japan

Trial name	HF10 phase I clinical trial (TBI-1401) for chemotherapy combination treatment in patients with unresectable pancreatic cancer
Study patients	Patients with unresectable pancreatic cancer (Stage III, IV)
Combination drug (Injection lesion)	Cohort① S-1 (Primary lesion) Cohort② S-1 (Primary lesion + hepatic metastatic lesion) Cohort③ Gemcitabine/nab-Paclitaxel (Primary lesion)
Evaluation item	Safety (adverse effect), Effectiveness (Response rate, duration of progression-free survival), etc
Number of cases	30 cases in total (10 cases each)
Trial period	1.5 year (Registered period : 5 months)
Trial practice place	National Cancer Center Hospital East and other 6 places

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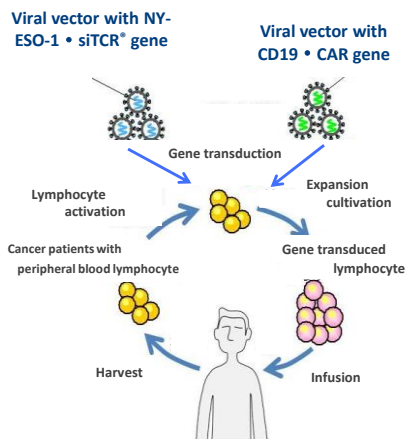
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Co-development/Exclusive Sales Agreement for NY-ESO1 • siTCR[®] and CD19 • CAR Gene Therapy Products with Otsuka Pharmaceutical Co., Ltd.

Engineered T cell Therapy



Purpose

- ◆ Enhancement/Expansion for clinical development
- ◆ Sales activity after marketing

Contractual coverage

- ◆ NY-ESO1 • siTCR[®] gene therapy product (TBI-1301, TBI-1301-A)
- ◆ CD19 • CAR gene therapy product (TBI-1501)
- ◆ All indications
- ◆ In Japan (First refusal right for 9 Asian countries outside Japan)

Responsibility

- ◆ Takara Bio : Manufacturing/quality control, etc.
- ◆ Otsuka Pharma : Clinical trial, regulatory submissions for manufacture and sales approval/safety data collection of products, etc.

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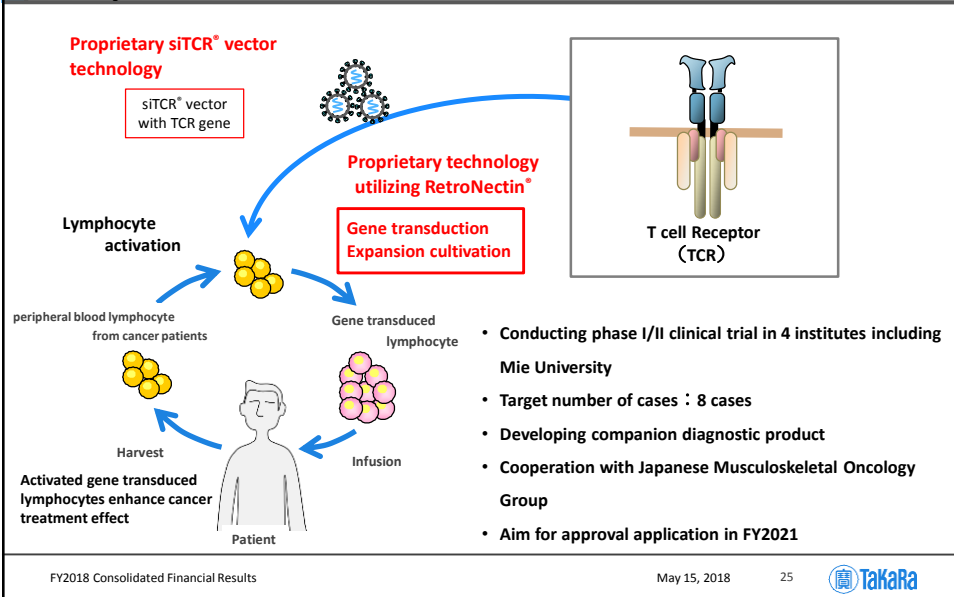
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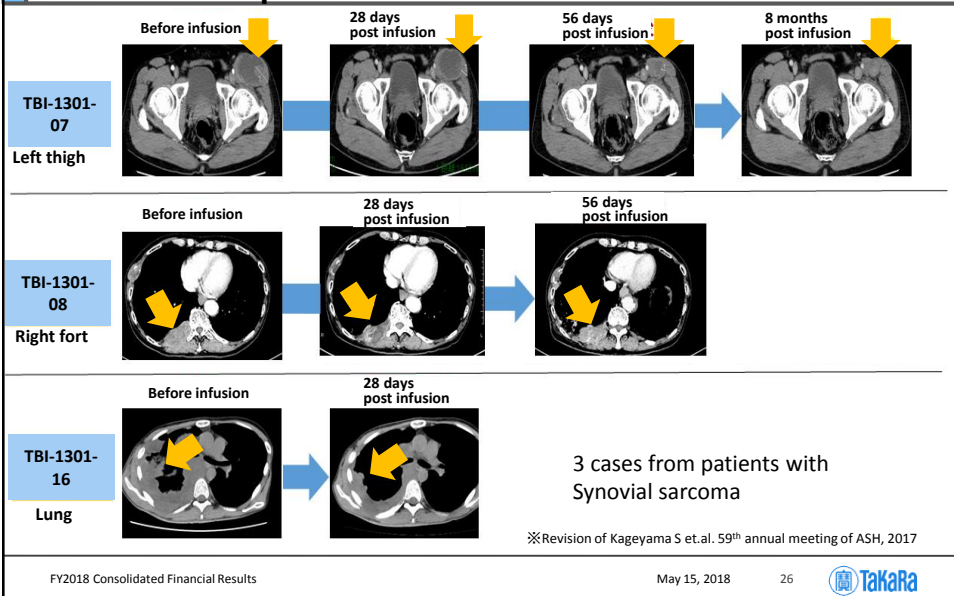
Gene Therapy Business ②-1

Status of NY-ESO-1 • siTCR® Project Targeting Synovial Sarcoma in Japan



Gene Therapy Business ②-2

Status of Investigator Initiated Clinical Trial targeting NY-ESO-1 • siTCR® in Japan

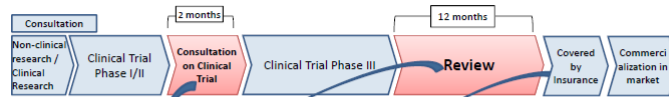


Designation of NY-ESO-1 • siTCR[®] for Synovial Sarcoma under “SAKIGAKE Designation System” as Regenerative Medicine Products (March 27, 2018)

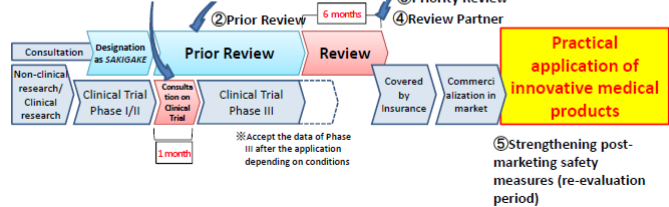
SAKIGAKE Designation System?

System aiming at shorting premarket review period for innovative new medical products that satisfy certain criteria, providing prioritized process for consultation and review regarding pharmaceutical approval (Ministry of Health, Labour and Welfare, Japan)

【Ordinal Review】



【Review under SAKIGAKE Designation System】



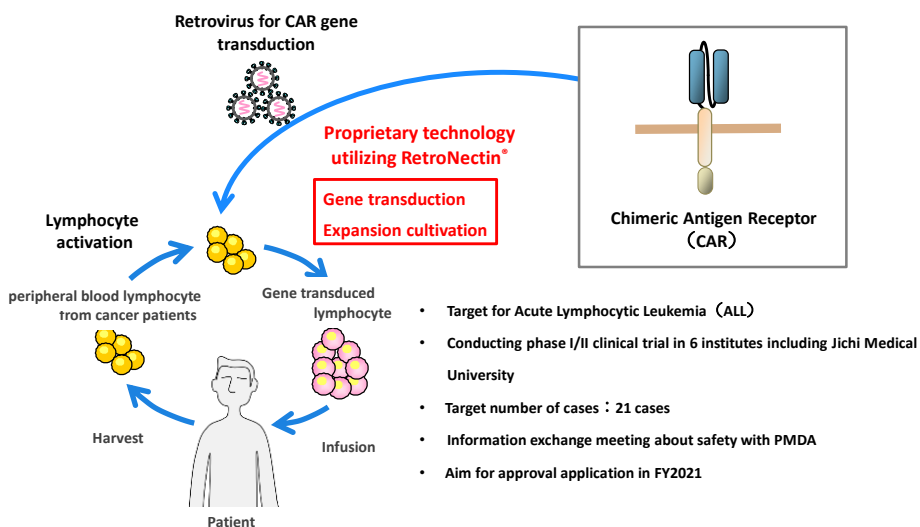
Five benefits

- ① Prioritized consultation
- ② Prior evaluation
- ③ Prioritized review
- ④ Review partner system
- ⑤ Safety strategy after manufacturing sales

⑤ Strengthening post-marketing safety measures (re-evaluation period)

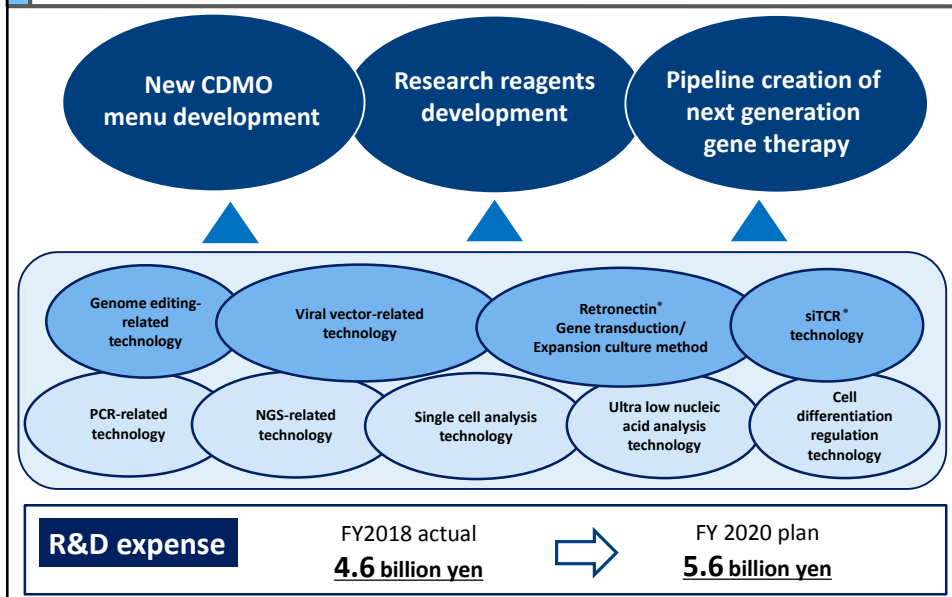
※ General Timeframe of SAKIGAKE, Summary of Strategy of SAKIGAKE, Ministry of Health, Labour and Welfare

Gene Therapy Business ③-1 Overview of CD19 • CAR Project



- Target for Acute Lymphocytic Leukemia (ALL)
- Conducting phase I/II clinical trial in 6 institutes including Jichi Medical University
- Target number of cases : 21 cases
- Information exchange meeting about safety with PMDA
- Aim for approval application in FY2021

Strengthen R&D Basis and Create Gene Therapy Project continuously via Enhancement of Bioindustry Business



Forward-Looking Statements

Statements in this news release, other than those based on historical fact, concerning the current plans, prospects, strategies and expectations of the Company and its Group represent forecasts of future results. While such statements are based on the conclusions of management according to information available at the time of writing, they reflect many assumptions and opinions derived from information that includes major risks and uncertainties. Actual results may vary significantly from these forecasts due to various factors. Factors that could influence actual results include, but are not limited to, economic conditions, especially trends in consumer spending, as well as exchange rate fluctuations, changes in laws and government systems, pressure from competitors' prices and product strategies, decline in selling power of the Company's existing and new products, disruptions to production, violations of our intellectual property rights, rapid advances in technology and unfavorable verdicts in major litigation.

For more information: PR・IR Department, Takara Bio Inc.
E-mail: bio-ir@takara-bio.co.jp

Reference Information

- Segmental sales Breakdown for FY2018
(Previous Forecast as of November, 2017 vs Actual)
- Results by Consolidated Subsidiary (Budget for FY2019 vs Actual)
- Segmental sales Breakdown for FY2019 (Budget for FY2019 vs Actual)
- Results by Business Segment (Budget for FY2019 vs Actual)
- Sales by Country for Research Reagents (Budget for FY2019 vs Actual)
- Pipeline Status for developing in Gene Therapy Business

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Segmental sales Breakdown for FY2018

[Reference]

(Previous Forecast as of November, 2017 vs Actual)

(millions of yen)

	FY2018	Compared with previous forecast As of Nov. 7, 2017		Year on year	
		Change	Ratio	Change	Ratio
Bioindustry	29,568	▲ 648	▲ 2.1%	+2,995	+11.3%
Research reagents	22,207	▲ 123	▲ 0.6%	+2,770	+14.3%
Scientific instruments	2,635	▲ 309	▲ 10.5%	▲ 275	▲ 9.5%
Contracted service	4,210	▲ 234	▲ 5.3%	+409	+10.8%
Others	514	+20	+4.2%	+90	+21.3%
Gene therapy	500	-	-	-	-
AgriBio	2,243	▲ 39	▲ 1.7%	▲ 58	▲ 2.5%
Functional foods	693	▲ 18	▲ 2.7%	▲ 148	▲ 17.7%
Mushrooms	1,550	▲ 20	▲ 1.3%	+90	+6.2%
Net sales total	32,312	▲ 687	▲ 2.1%	+2,937	+10.0%

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Results by Consolidated Subsidiary					[Reference]
(Budget for FY2019 vs Actual)					(millions of yen)
	Number of employee**	FY2018 Actual		FY2019 Budget	
		Net sales	Operating income	Net sales	Operating income
Takara Bio	471	20,976	900	21,970	1,822
Mizuho Norin	24	729	28	1,480	33
Takara Bio Farming Center	0	26	9	21	4
KINOKO CENTER KIN	7	197	4	213	17
Takara Bio Europe SAS*	47	2,740	245	3,498	449
Takara Bio Europe AB*	29	511	▲ 75	720	▲ 113
Takara Biotechnology (Dalian) *	517	3,613	884	3,747	906
Takara Biomedical Technology (Beijing) *	73	5,448	655	5,887	820
Takara Korea Biomedical *	26	998	148	1,037	156
DSS Takara India Pvt. Ltd. *	56	336	▲ 14	390	17
Takara Bio USA Inc. *	198	10,725	1,122	11,991	1,520
Takara Bio USA Holdings Inc*	0	-	▲ 50	-	▲ 3

** As of Mar. 31, 2018
* Financial report from January to December

Segmental sales Breakdown for FY2019					[Reference]
(Budget for FY2019 vs Actual)					(millions of yen)
	FY2018 Actual	FY2019 Budget	Year on year		
			Change	Ratio	
Bioindustry	29,568	32,719	+3,150	+10.7%	
Research reagents	22,207	24,071	+1,864	+8.4%	
Scientific instruments	2,635	3,262	+627	+23.8%	
Contracted service	4,210	5,002	+791	+18.8%	
Others	514	382	▲ 132	▲ 25.7%	
Gene therapy	500	1,860	+1,360	+272.1%	
AgriBio	2,243	2,219	▲ 23	▲ 1.1%	
Functional foods	693	555	▲ 137	▲ 19.8%	
Mushrooms	1,550	1,664	+113	+7.3%	
Net sales total	32,312	36,800	+4,487	+13.9%	

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Results by Business Segment (Budget for FY2019 vs Actual)					【Reference】
(millions of yen)					
<FY2018 Actual>	Bioindustry	Gene therapy	Agribio	Intersegment	Total
Net sales	29,568	500	2,251	▲ 7	32,312
Gross profit	17,553	500	601	-	18,655
Selling, general and administrative expenses	10,870	1,822	494	1,912	15,099
Operating income from above	2,693	1,804	6	148	4,653
Operating income	6,683	▲ 1,322	107	▲ 1,912	3,555
<FY2019 Budget>	Bioindustry	Gene therapy	Agribio	Intersegment	Total
Net sales	32,719	1,860	2,219	-	36,800
Gross profit	19,209	1,850	617	-	21,677
Selling, general and administrative expenses	11,686	2,159	518	2,312	16,677
Operating income from above	2,703	2,139	0	385	5,229
Operating income	7,523	▲ 309	98	▲ 2,312	5,000

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Sales by Country for Research Reagents (Budget for FY2019 vs Actual)					【Reference】
(millions of yen)					
	FY2018 Actual	FY2019 Budget	Year on year change	Year on year change (Foreign exchange excluded)	
Japan	5,810	6,079	+268	+268	
USA	7,837	8,317	+480	+567	
Europe	2,612	3,140	+527	+424	
China	4,826	5,279	+452	+523	
Korea	841	881	+39	+51	
India	278	373	+95	+101	

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【Reference】

Pipeline Status for developing in Gene Therapy Business

Independent development projects			Indications	Status	Launch target			
Oncolytic Virus	HF10 (TBI-1401)		Japan	Malignant melanoma	Phase II in progress Preparation underway for application	FY2019 (Sales/Otsuka Pharma)		
Joint projects			Indications	Status	Partner, etc			
Oncolytic Virus	HF10 (TBI-1401)		Japan	Pancreatic cancer	Phase I in progress	Otsuka Pharma		
			USA	Malignant melanoma	Phase III preparation underway	Seeking		
Engineered T cell Therapy	siTCR	NY-ESO-1 (TBI-1301)	Japan	Synovial sarcoma	Phase I / II in progress	Otsuka Pharma		
				Solid cancer	Phase I in progress	Investigator initiated		
				Under review	Preparation underway	Otsuka Pharma		
	CAR	MAGE-A4 (TBI-1201)	Japan	Esophageal cancer, etc	Phase I in progress	Investigator initiated		
				CD19 + CAR (TBI-1501)	Japan	Adult ALL*	Phase I / II in progress	Otsuka Pharma
						Childhood ALL, etc	Under review	Otsuka Pharma

ALL : Acute lymphoblastic leukemia