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NEWS RELEASE

Announcement on revision of Takara Bio Medium-Term Management Plan FY2020

Kusatsu/Shiga, Japan-May 11, 2018 – Takara Bio Inc. (Takara Bio), today announced the revision of target in final fiscal year stated on Takara Bio Medium-Term Management Plan FY2020 ("Medium-Term Management Plan") disclosed on May 9, 2017, considering recent business progress and change in management environment as described below.

1. Revision reason and description

Medium-Term Management Plan aims to strengthen the three business segments, namely, the Bioindustry, Gene Therapy, and AgriBio businesses and the business base that supports these efforts, to enhance the standing as a global and industrial company for regenerative medical products. Under this overall policy, the net sales and the operating income as the targets for fiscal 2020, the final year of the medium-term management plan has been set 38.5 billion yen and 4.0 billion yen, respectively*[1].

As announced already, Gene Therapy business is expected to increase the net sales and profit due to the execution of the agreement for co-development/exclusive sales with external institute unplanned originally*[2].

Bioindustry business is expected to expand the reagents/instruments-related products overseas, increase the sales growth by broad range of fields including industry and medical applications and the sales profits of contracted service focused on the development/manufacturing supporting business relating to regenerative medical products (CDMO business). In response to this situation, Takara Bio made a decision on the investment in newly-establishing for the R&D and manufacturing facility dedicated to regenerative medical products in head office site of Kusatsu/Shiga*[3].

In R&D, Takara Bio will accelerate the development against research reagents/instruments/contracted service menu and gene therapy products by spending R&D funding exceeding the original plan. Also, more investments will be spent on the fundamental technologies development based on the next generation Gene Therapy, leading to strengthen a cross-organizational R&D activity.

The possible risk factors surrounding our management environment holds the slow growth of R&D funding accompanying changes in trends of each country's governmental policy and the intensified competition with a number of companies entering new market in CDMO business. Nevertheless, Takara Bio will make the utmost effort and will take countermeasures against such risks by launching continuously new products/new service via the strengthened R&D activities.

Under these circumstances, the net sales for fiscal 2020, the final year of the medium-term management plan has been unchanged from original plan, while the operating income for the same period of the fiscal year has been upwardly revised as described below.

Targets for fiscal 2020, the final year ending March 2020 of the medium-term management plan

(Hundred millions of yen)

	Original plan	Revised plan	Increase (decrease)
Net sales	385	385	0
R&D expenses	48	56	+8
Operating income	40	60	+20

R&D expenses by reportable segment

(Hundred millions of yen)

	Fiscal year ended Mar 31, 2018 (Actual)	Fiscal year ending Mar 31, 2019 (Budget)	Fiscal year ending Mar 31, 2020 (Plan)
Bioindustry	27	27	
Gene therapy	18	21	
Others/Common	2	4	
Total	47	52	56

Note 1: Formulation of Medium-Term Management Plan FY2020 (Released on May 9, 2017)

Note 2: Takara Bio entered into an agreement for co-development/exclusive sales of NY-ESO-1・siTCR™ and CD19・CAR gene therapy with Otsuka (Released on April 9, 2018)

Note 3: Takara Bio to Establish a New Facility for the Research and Manufacturing of Regenerative Medical Products (Released on January 30, 2018)

2. Future plan for each business segment

Bioindustry business

The business aims to apply prodigious growth by simultaneously expanding business overseas of reagents/instruments along with synergistic maximization through businesses with two U.S. companies (WaferGen Bio-systems Inc. and Rubicon Genomics Inc.) acquired and strengthening domestic business focusing on CDMO business enhanced by manufacturing capabilities of regenerative medical products in Japan. Also, further attempt is to establish the system in order to accelerate the development of research reagents based on the Bioindustry business and strengthen the fundamental technologies in order to create next generation gene therapy project continuously.

<Key point>

The overview is presented in the following table.

Policies for each field	
Research reagents	Rapid commercialization of cutting-edge technologies that leverage the open innovation approach
Contracted services	Develop structure based on GMP/GCTP*4, CAP-LAP*5, and other quality assurance and accuracy control systems in order to expand contracted services involving regenerative medical products and the clinical field
Scientific instruments	Combine devices and reagents to perform systematized single-cell analysis methods and develop PCR-related products

Priority R&D Areas for the Bioindustry Business
1. Develop fundamental technologies for regenerative medical products and establish quality control methods
2. Develop an ultra-low-input nucleic acid analysis method
3. Develop new technologies necessary for clinical sequencing
4. Utilize PCR in industrial applications and deploy it in the clinical field
5. Develop new technologies connected to genome editing

Note 4: GMP is an abbreviation for Good Manufacturing Practice and refers to the Standards for Manufacturing Control and Quality Control for Pharmaceuticals and Quasi-drugs that must be observed in the manufacture of pharmaceuticals. GCTP is an abbreviation for Good Gene, Cellular, and Tissue-based Products Manufacturing Practices and refers to the Standards for Manufacturing Control and Quality Control for Regenerative Medical Products Manufacturers.

Note 5: CAP (College of American Pathologists) is U.S.-based organization whose primary functions include providing quality management system tools, accrediting laboratories, and providing education. LAP (Laboratory Accreditation Program) is run by CAP and is the world's largest international clinical trial laboratory accreditation program. Inspections of laboratories are carried out once a year, targeting both tangible assets (e.g., clinical testing labs' hardware) and the intangible assets for running such labs (e.g., software).

Gene therapy business

In fiscal 2018, the business aims to acquire the manufacture and sales approval of HF10, with a first gene therapy product for cancer on the Japanese market. Also, further attempt is to conduct joint development with partners in Japan and cooperate with partners in overseas.

<Key point>

The status of each clinical development project is presented in the following table.

Projects			Disorders Targeted	Country	Status	Partners
Oncolytic Virus	HF10 (Canerpaturev)		Melanoma	Japan	Phase II in progress Approval application in fiscal 2018 planned	Otsuka Pharma Co-development/exclusive sales
				United States	Phase II completed	Preparations underway
			Pancreatic cancer	Japan	Investigator initiated Phase II in progress	Otsuka Pharma Co-development/exclusive sales
Engineered T-cell Therapy	siTCR™	NY-ESO-1	Synovial sarcoma	Japan	Phase I in progress	Otsuka Pharma Co-development/exclusive sales
			Solid cancer	Japan	Phase I/II in progress	Investigator initiated
			Solid cancer	Canada	Investigator initiated Phase Ib in progress	Preparations underway
		MAGE-A4	Esophageal, etc.	Japan	Phase I in progress	Investigator initiated
	CAR	CD19-CAR	Adult ALL*6	Japan	Phase I/II in progress	Otsuka Pharma Co-development/exclusive sales

Note 6: ALL: Acute lymphocytic leukemia

AgriBio business

The business aims at building a stable platform by continuing the profitable business for functional foods and mushrooms.

<Key point>

- Build a platform for the stable supply of products suited to the sales plan from Takara Healthcare Inc. (Functional foods business)
- Expand business efficiently through the unification of manufacture and sales systems (Integration into Mizuho Norin Co., Ltd. and KINOKO CENTER KIN Inc.) (Mushroom business)
- Build the brand strategy approaching to the market for each mushroom product (Mushroom business)

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This article is translated from press release in Japanese for your convenience.

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.