

Biotechnology-related Business

Accelerating Business Expansion by Streamlining the System for Early Profitability



Principal Companies

Intermediate Holding Company: SBI ALA Hong Kong

- SBI Biotech
- SBI Pharmaceuticals
- SBI ALApromo

Priority Measures

> SBI Biotech

- Steady progress on multiple drug development pipelines, including those in Phase III of SBI Biotech and its wholly owned subsidiary Quark Pharmaceuticals of the U.S.
- SBI Biotech is endeavoring to achieve full-year profitability on a non-consolidated basis by advancing the earning capacity of the drug development pipeline through an out-licensing (including joint R&D) measure
- Advancing into the development of a cancer immunotherapy agent by applying its proprietary drug platform “pDC (plasmacytoid Dendritic Cell) Modulation”

> SBI Pharmaceuticals

- Streamlining the business structure for 5-ALA-related business and establishing an exclusive global R&D system, upon the incorporation of photonamic as a wholly owned subsidiary of SBI ALA Hong Kong in January 2016
- Enhancing the sales structure of pharmaceuticals overseas by leveraging the global sales channel of photonamic, in over 25 countries centered on Europe, which has been cultivated through its existing sales partners
- Advance toward early profitability by driving rigorous distinctions of research and development pipelines, from the standpoint of importance based on medical needs and the progress in R&D, in order to thoroughly reduce cost

> SBA ALApromo

- Launched sales of ALAplus Tou (Sugar) Down, the first food with function claims which contains 5-ALA in December 2015
- Aggressive implementation of efficient promotions of products, including the full-fledged start of joint promotions with the RIZAP GROUP
- Promoting the development of new foods with function claims that follows ALAplus Tou (Sugar) Down

Full-year Profit before Income Tax Expense of the Biotechnology-related Business (based on IFRSs)

	FY2014	FY2015
Biotechnology-related Business	(7,310)	(6,572)
SBI Biotech	(637)	(297)
Quark Pharmaceuticals	(1,436)	(2,572)
SBI Pharmaceuticals	(1,220)	(1,425)
SBI ALApromo	(426)	(587)

(Millions of yen)

5-ALA-related products



ALAplus / ALAplus Gold



ALAplus CoQ10



ALAplus Sports High-performance



ALAplus Tou (Sugar) Down



ALAplus Cosmetic Series



Takeshi Irie

SBI Biotech Co., Ltd.
Representative Director and
President



Favorable Progress on the Drug Development Pipeline, Including the Start of Two Phase III Clinical Trials at SBI Biotech's Subsidiary Quark Pharmaceuticals

Monetization of the Drug Development Pipeline

SBI Biotech is a bio-venture engaged in the development of medical treatments and innovative new drugs for intractable diseases, such as cancer and autoimmune disorders.

The company has multiple promising drugs in the pipeline in addition to the Anti-ILT7 antibody, which is a molecularly targeted drug for autoimmune disorders licensed to MedImmune LLC of the U.S., a member of the AstraZeneca Group of the U.K. Through the out-licensing of these drugs, including joint R&D, SBI Biotech advances the earning capacity of its pipeline as it endeavors to make a full-year profit on a non-consolidated basis.

SBI Biotech's proprietary drug platform, pDC (plasmacytoid Dendritic Cell) modulation, can be applied to agents for cancer immunotherapy, which is a drug in the spotlight these days. The pDC technology consists of cells that modulate the suppression and activation of immune reactions. Cancer treatments are believed to be possible by activating the immune reaction through its action on pDC, and which until now has been cultivated in the treatment of autoimmune disorders. SBI Biotech plans to capture the growth potential that revolves around cancer immunotherapy agents through the activation of pDC.

Two New Drug Candidates Progressed towards Phase III Clinical Trials at Quark Pharmaceuticals of the U.S.

Quark Pharmaceuticals, Inc., a wholly owned subsidiary of SBI Biotech, holds superior technology in the field of small interfering RNA (siRNA) and has made sound progress on its multiple drugs in the development pipeline. One drug in the pipeline is QPI-1002 (licensed to Novartis International AG of Switzerland), which is proceeding to Phase III clinical trials as a preventive agent for the failure of kidney function following an organ transplant (delayed graft function), and has Phase II clinical trials under way for acute kidney injury.

Phase II/III clinical trials have also started for QPI-1007 (licensed to Biocon of India) for non-arteritic anterior ischemic optic neuropathy as an indication. Furthermore, Phase II clinical trials in the U.S., Vietnam and Singapore for application to acute angle-closure glaucoma ended in June 2015, and the final results are scheduled to be reported this summer. Going forward, Quark will be migrating to the clinical stage of the next generation drug development pipeline, in accordance with generating a revenue source such as royalty income levied against the value of sales as the result of Phase III drug development pipeline being placed on the market.

Major Drug Pipelines Researched and Developed by SBI Biotech

Pipeline (Licensing partner)	Adaptation disease	Progress	
Anti-ILT7 antibody (MedImmune, Inc. of the U.S.*1)	Autoimmune disorders	Pre-clinical (Completion)	MedImmune will initiate Phase I clinical trial during the second quarter of FY2016. After the start of the clinical trial, receipt of a predetermined amount of milestone payments is expected.
GNKS356 (Independently)	Psoriasis / Systemic Lupus Erythematosus (SLE)	Pre-clinical	Selected as Japan Agency for Medical Research and Development's (AMED) pre-designation review as an orphan drug commercialization candidate for their project promoting support for drug discovery (from FY2015 to FY2017) (Maximum subsidy: ¥200 million per fiscal year)
SBI 3150/9674 (Independently)	Autoimmune disorders	Non-public	Considering out-licensing
Cdc7 inhibitor (Carna Biosciences, Inc.)	Cancers	*2	Intellectual property rights assigned to Carna Biosciences in June 2014. → In accordance with Carna Biosciences entering into an out-licensing agreement with ProNai Therapeutics, as announced in May 2016, a partial milestone payment is expected at an early date. Further receipt of milestone payments due to development progress of Cdc7 is also expected.

*1 Subsidiary of AstraZeneca PLC of the U.K.

*2 Carna Biosciences initiates R&D



Endeavoring to Become the World's "One and Only Company" in the 5-ALA-related Business

Satofumi Kawata

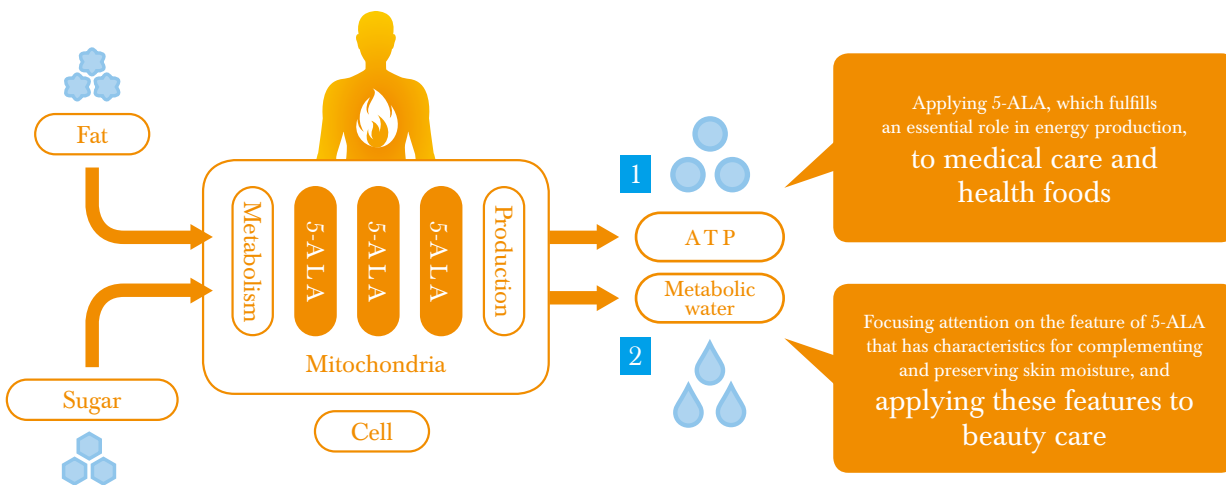
SBI Pharmaceuticals Co., Ltd.
Representative Director,
Senior Executive Vice President



What is 5-ALA (5-Aminolevulinic Acid)?

5-ALA is a type of natural amino acid contained in living cells of plants and animals. 5-ALA works to aid photosynthesis in plants, as well as to preserve energy production and moisture retention in humans and animals that plays an essential role in preserving health. Recent research confirms its usefulness in a variety of fields including beauty care, health and medical care, which results from a well-balanced ingestion of 5-ALA and minerals such as iron (Fe).

Action of 5-ALA in mitochondria, the "energy factory" of cells

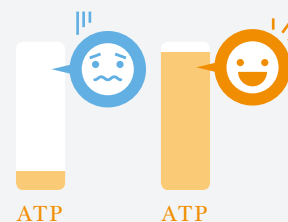


1 Inside the mitochondria, sugar and fat are metabolized and energy is produced in the form of ATP, which is indispensable to maintaining good health.

2 As a result of ATP production, metabolic water is produced for the crucial role in retaining the body's moisture.

ATP (Adenosine Triphosphate), a Health Barometer

ATP production efficiency is believed to atrophy as people age and their metabolism slows down. Fatigue and low activity will then occur as a result. In order to remain healthy, it is absolutely essential to maintain the mitochondrial function of producing ATP.



Favorable Progress in R&D through Alliances with Domestic and Overseas Research Institutions

SBI Pharmaceuticals has been proactively cooperating with over 90 domestic and overseas research organizations, and is conducting research and forming business alliances in a broad range of fields including pharmaceuticals, health foods and cosmetics. ALAGLIO®, the first drug launched by SBI Pharmaceuticals, started sales in September 2013 for use in surgery to remove

malignant glioma, a type of brain tumor. As a drug for these tumors, this product is being sold domestically as Japan's first orally administered intraoperative diagnostic agent. Also, photonamic GmbH & Co. KG of Germany, a wholly owned subsidiary of the SBI Group, obtained approval for a similar product in 2007 from the European Medicines Agency (EMA). Through its sales partner, medac GmbH (also of Germany), the company is selling the product under the name of Gliolan in over 25 countries in Europe, including Germany and the U.K. In line with its future goal of selling in the U.S., photonamic is preparing to submit an application for approval to marketing this drug there.

New drug development continues on the heels of ALA-GLIO®. One prospective drug in the R&D pipeline is an intraoperative diagnostic agent for use during surgery for carcinoma vesicae. Following investigator-led clinical trials at Kochi University and four other universities, SBI Pharmaceuticals also completed company-led Phase III clinical trials and plans to apply for approval during FY2016. Moreover, investigator-led trials at Saitama Medical University for a drug to treat cancer chemotherapy-induced anemia have been completed, and it will now enter company-led Phase II clinical trials. In other areas, the company is getting favorable results with investigator-led trials regarding an intraoperative diagnostic agent for peritoneal dissemination of gastric cancer at Osaka University and other medical institutions, and also a drug to treat mitochondrial diseases at Saitama Medical University. Furthermore, SBI Pharmaceuticals is preparing for Phase II clinical trials regarding preventive agent for cardiac ischemia-reperfusion injury at Oxford University of the U.K.

Strengthening the Business Foundation with an Eye on the Future

SBI Pharmaceuticals has obtained numerous Japanese patents in a range of fields including anti-malaria drugs and prophylactic/therapeutic agent for influenza virus infection. The current count comes to 36 patents. The number of obtained patents increased in FY2015 in particular with 11 patents registered, including an immune tolerance inducer, a prophylactic/therapeutic agent for veisalgia, and an agent for treating and preventing cancer anemia. Of the patents granted in Japan, 16 have also received approval in foreign countries. The company is continuously moving ahead with a global vision of patent strategy, while also endeavoring to determine development areas that will carry into the future.

SBI Pharmaceuticals has broadened its alliances with foreign research institutions and corporations from the aspects of R&D and business expansion. At foreign universities and national hospitals, it has confirmed the safety and effectiveness of 5-ALA through conducting and collecting clinical data in 5-ALA food intervention trials of a several dozen research participants that mainly cover metabolic diseases. In January 2016, the SBI Group incorporated photonamic, a former member of medac GmbH of Germany, as a wholly owned subsidiary. Accordingly it enables the Group to establish an exclusive global R&D system, as well as to strengthen the overseas pharmaceuticals sales structure leveraged by the global sales channel of photonamic.

R&D Pipelines Sponsored by SBI Pharmaceuticals

	Phase I	Phase II	Phase III	
① Diagnostic agent for cancer treatment (Brain tumor) *Designated as an orphan drug				ALAGLIO® (Launched in Sept. 2013)
② Diagnostic agent for cancer treatment (Carcinoma vesicae) *Designated as an orphan drug			Completion of an SBI corporate trial at the same five universities conducting the investigator-led trial	Planning to submit for approval in FY2016
③ Diagnostic agent for cancer treatment (Peritoneal dissemination of gastric cancer)		Investigator-led trial by Osaka Univ. (Providing drugs and funds) (from Nov. 2015)		Scheduled to conduct corporate trial
④ Drug to treat cancer chemotherapy-induced anemia (Saitama Medical Univ.) ARO: Kitasato Academic Research Organization		Investigator-led trial by Saitama Medical Univ., as the medical institution completed the clinical trial (Providing drugs and funds)		
⑤ Preventive agent for cardiac ischemia-reperfusion injury (The Univ. of Oxford in the U.K.) Planning to jointly submit a test plan to the Medicines and Healthcare Products Regulatory Agency ("MHRA") soon		Investigator-led trial by Professor Houman, the Univ. of Oxford (Providing drugs and funds) (Phase II clinical trial will be jointly implemented in University Hospitals Birmingham in the U.K.)		
⑥ Drug to treat mitochondrial diseases *Planning to file for grant as an orphan drug (Saitama Medical Univ.)		Investigator-led trial by Saitama Medical Univ. (Providing drugs)		Phase II is in progress, and the explorative trial result is in the process of being analyzed