

Innovation

Accelerating Overseas Development for the 5-ALA Related Business

5-ALA is attracting attention at academic conferences

SBI Pharmaceuticals engages in the development of pharmaceuticals, health foods and other products utilizing the amino acid, 5-aminolevulinic acid (5-ALA). Various research projects concerning 5-ALA are being conducted at more than 90 universities and hospitals in Japan and abroad, and the company plans to continue expanding this research network.

Examples of research and development involving 5-ALA include research on malaria at the University of Tokyo and the U.K.'s National Institute for Medical Research, research on metabolism improvers and diabetes at Kyoto Prefectural University and the University of Hawaii, and research on cancer diagnosis at the Tokyo Institute of Technology.

5-ALA is also attracting attention at academic conferences. The 5-ALA and Porphyrin Research Society, an organization founded in May 2011 by researchers of porphyrin and 5-ALA, whose chairman is Professor Emeritus Ichiro Okura of the Tokyo Institute of Technology, has already held three symposiums.

In addition, a session concerning 5-ALA was held at the 7th World Congress on Prevention of Diabetes and Its Complications, held in November 2012 in Madrid, Spain.

In the Middle East, SBI Pharmaceuticals has made Bahrain its base of operations and plans sequential development of 5-ALA related businesses, such as drug creation, clinical research, manufacturing, and exporting. The reason for the emphasis on the Middle East is that Bahrain and other countries in the Middle East have an extremely high prevalence of diabetes patients, of three to four times that of Japan.

For this reason, diabetes treatment is a pressing issue, and in clinical research into diabetes involving 5-ALA, SBI Pharmaceuticals plans to begin multiple clinical research projects in collaboration with medical and research institutions, including the Bahrain Defense Force Royal Medical Service Hospital and Arabian Gulf University. The company is also cooperating with the Royal College of Surgeons in Ireland - Medical University of Bahrain and KING HAMAD UNIVERSITY HOSPITAL, concerning clinical research into photodynamic diagnosis of colorectal cancer using 5-ALA.

Projects in the pharmaceutical sector are underway in countries around the world

A number of projects are underway in the pharmaceutical sector in countries outside the Middle East as well, including development of a therapeutic agent for anemia in the U.K. and the U.S., contracted out to a contract research organization (CRO). In Phase I clinical testing (a safety trial) in the U.K., an administration trial has been completed and a report is being prepared. In Phase II clinical testing, scheduled to begin in the third quarter of FY2013, the company is considering applications for clinical trials for development as a pharmaceutical agent in multiple fields, including as a therapeutic agent for

anemia. Once Phase II testing begins in the U.K., the company plans to begin clinical testing in the U.S., starting with a Phase II trial.

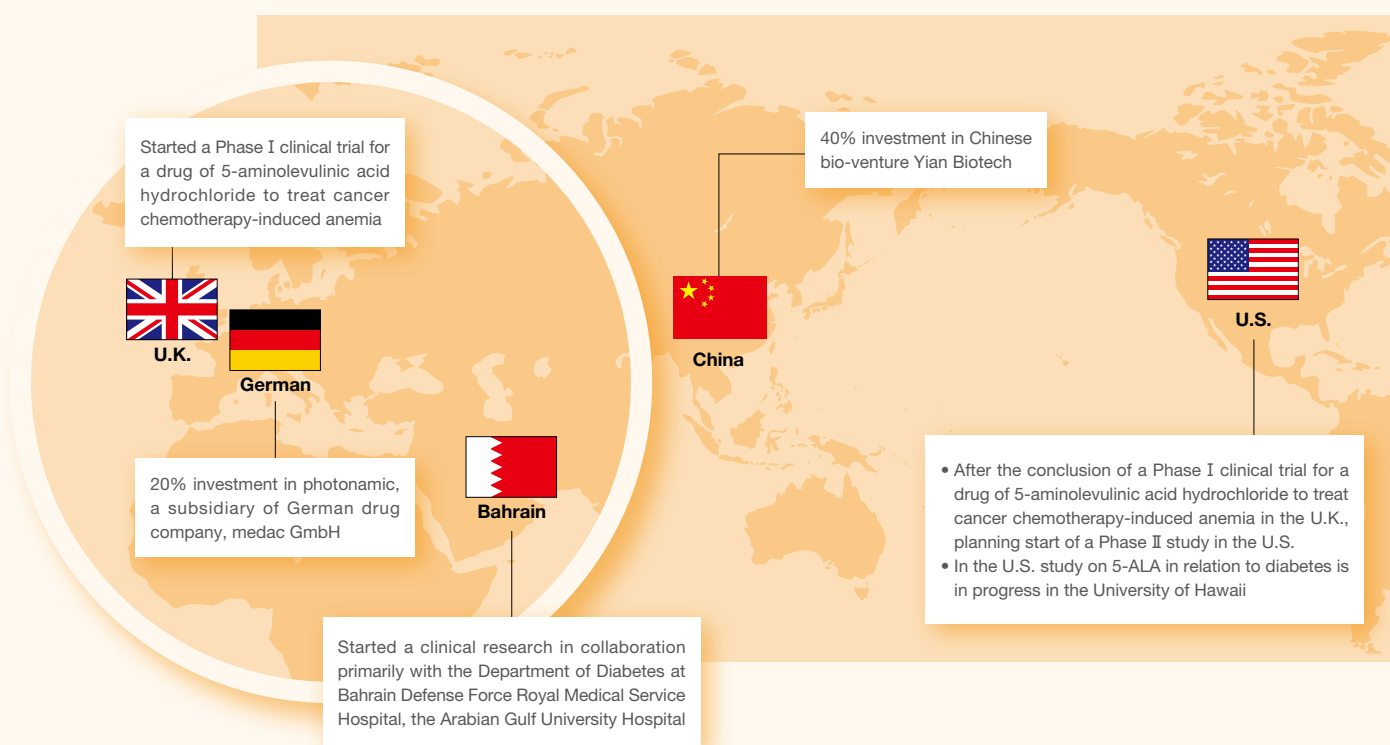
SBI Pharmaceuticals is also making steady progress in obtaining approval from the regulatory authorities in a number of countries for health foods containing 5-ALA, in preparation for sales channel expansion.

Approval has been obtained for the sale of the health food NatuALA ONE from the local authorities in Bahrain and the UAE. Preparations are underway for the establishment of a joint venture company to sell 5-ALA products with Dawani Group Holdings, a major local distributor in Bahrain, as well as developing a sales structure in the UAE.

SBI Pharmaceuticals plans to accelerate business development in Asia as well as the Middle East. In the Philippines, it has obtained a certificate of product registration for NatuALA ONE from the local authorities with plans to begin sales within 2013, with a local partner that has a network of physicians. Preparations are proceeding to establish a joint

venture company to sell 5-ALA products in China, and discussions are underway for the development of the 5-ALA business with major local pharmaceutical companies in South Korea, Malaysia, India and Indonesia.

Worldwide Status of Pharmaceutical Projects and Activities



VOICE



Yusuke Asama

SBI Pharmaceuticals
Bahrain Representative Office

SBI Pharmaceuticals' Bahrain Representative Office was established in October 2012 to develop the sales of 5-ALA related products in the Middle East, conduct clinical trials in cooperation with universities, and eventually establish a 5-ALA production base. Although merely leading an ordinary life in an Islamic country, where the culture and lifestyle is completely different from Japan, can be challenging, in the office, which consists of local employees with different work experiences and expatriate Japanese, all work together with the shared aspiration of popularizing 5-ALA in the Middle East, and this is highly stimulating. In such an environment, I hope to make some small individual contribution to the entire effort.