

Comprehensive centers providing one-stop services to Japanese and foreign companies wishing to start businesses in Hyogo-Kobe

Hyogo-Kobe Investment Support Center Hyogo Economic Development Center  
Kobe Commerce, Industry and Trade Center Bldg 4F  
5-1-14, Hamabe-dori, Chuo-ku, Kobe, 651-0083  
TEL: +81-78-271-8401 FAX: +81-78-271-8403 hkisc@staff.hyogo-iic.ne.jp

Hyogo-Kobe Business Support Center in Tokyo  
Todofuken Kaikan Building 13F  
2-6-3 Hirakawa-chou, Chiyoda-ku, Tokyo 102-0093  
TEL: +81-3-3230-2721 FAX: +81-3-3230-2722

## Practical Application of Regenerative Medicine Using iPS Cells from Kobe Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is making sustained efforts to create and provide innovative and effective new drugs. In April, 2014, the company established a new research base in Kobe to actively promote the business applying the most advanced science such as iPS cells to drug discovery. We invited Mr. Toru Kimura, Ph.D., Executive Officer, Director, Head of Regenerative & Cellular Medicine Office to deliver a lecture on the vision of new business (at the 'Foreign Investment Promotion Seminar to KOBE Biomedical Innovation Cluster (KBIC)' held in Oct. 2015, in Tokyo). Sumitomo Dainippon Pharma is focused on regenerative and cellular medicine business that is promising as a therapy for refractory rare diseases.



### Circumstances surrounding the regenerative and cellular medicine business

We are actively involved in the regenerative and cellular medicine business in which we discover cellular medicines derived from iPS cells and regenerate patients' tissues by using cells as medicines. Organ or bone-marrow transplantation already in practical application has been suffering an insufficiency of donors, and use of ES cells (embryonic stem cells) faces ethical objections as ES cells are created by destructing embryonic cells that may grow to human beings. In 2006, however, iPS cells (induced pluripotent stem cells) created from human body cells were developed, showing a possibility of materialization of the regenerative and cellular medicine business. The market volume is anticipated to be around 2.5 trillion yen in Japan and 38 trillion yen in worldwide by the year 2050. As we have continued our studies on neurotrophic factors and tissue regeneration since around 1990 and have a foundation in collaboration with our affiliates that conduct cell research, we determined to take on the challenge of this new field in 2013.

### Challenge to new drug discovery and drug fields

Transplantation of cells derived from iPS cells can be divided to two types: 'Autologous transplantation' in which patients receive cells derived from his/her own cells; and 'allogeneic transplantation'

in which patients receive cells derived from donors. Since the 'autologous transplantation' that has already been put in clinical application requires a long period and enormous cost, we are currently engaged in treatment by creating and managing a large quantity of cells by a new field, 'allogeneic transplantation,' using them as cell medicines, and transplanting them into patients. Once put in clinical application, stored cells can immediately be administered to patients in emergency, can be sent all over the world, and allow cost reduction. However, we are currently facing many problems in the processes from research & development to market formation. We therefore cooperate with our affiliates, other pharmaceutical companies, bio-venture companies with strong driving force and rich R&D experience, and academia well-versed in developmental biology that directly leads to seeds for practical application, in working on these problems.

### Based in 'KOBE' and expanding to the world

In April, 2014, we established our research center 'Kobe Regenerative & Cellular Medicine Center' in front of the Iryo Center Station. This area is the core of KBIC including 'Riken Center for Developmental Biology (CDB),' and various research centers of medical institutions. We place our emphasis on age-related macular degeneration and retinitis pigmentosa in ophthalmology, and chronic stroke, Parkinson's disease, and spinal cord injury in the brain field. In addition, we are planning to construct an iPS cell culture plant near our center. In Kobe, related organizations

such as Pharmaceuticals and Medical Devices Agency (PMDA) and institutions of the Ministry of Health, Labour and Welfare are located close to our center, and hospitals that can conduct clinical research and clinical trials, medical institutions, and laboratories are concentrated. With such characteristics, Kobe is the optimum place for us to take on a new business that would be very difficult for us to engage in alone. By taking advantage of multilateral supporting environment provided by the city of Kobe, we will cooperate with the municipal government and other companies and make our best efforts to address practical application of iPS regenerative and cellular medicines.



### Sumitomo Dainippon Pharma Co., Ltd.

**Address:**  
(Osaka Head Office)  
6-8, Doshomachi 2-chome, Chuo-ku, Osaka  
(Tokyo Head Office)  
13-1, Kyobashi 1-chome, Chuo-ku, Tokyo  
(Kobe Regenerative & Cellular Medicine Center)  
Kobe KIMEC Center Building 5th Fl. 5-2,  
Minatojiminamimachi 1-chome, Chuo-ku,  
Kobe, Hyogo  
**President and CEO:** Masayo Tada  
**Business:** Manufacturing and sales of pharmaceuticals  
**URL:** <http://www.ds-pharma.com/>

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## Kobe, home of flourishing life-science studies, is optimum for pharmaceutical research

### Eli Lilly Japan K.K.

In 1876, Eli Lilly and Company was established in Indianapolis, US, and has become a global pharmaceutical company that supplies pharmaceutical products in as many as 125 countries. Its Japanese subsidiary, Eli Lilly Japan K.K. commenced business in Kobe and is continuing to develop innovative new medicines under the inherited philosophy that "Research is the Heart of the Business, the Soul of the Enterprise." We invited Mr. Akikazu Yoshikawa, Ph.D., Operating Officer, Senior Director, Science & Regulatory Affairs, to deliver a lecture on the advantages of the city of Kobe as a research base by introducing Eli Lilly as a case study (at the 'Foreign Investment Promotion Seminar to KOBE Biomedical Innovation Cluster (KBIC)' held in Oct. 2015, in Tokyo).



#### Philosophy inherited from the R&D-driven pharmaceutical company

As the Japanese subsidiary of Eli Lilly and Company, that has been developing numerous 'world's first' pharmaceutical products in its history of 135 years or more, Eli Lilly Japan K.K. was established in Kobe in 1975. It is the company's second-largest affiliate only after the US and holds a prominent position among Eli Lilly's global affiliates. Our head office is in Chuo-ku and our Seishin Manufacturing Site and Training Center is in Nishi-ku of Kobe City. We spend a huge amount of money on R&D of pharmaceutical products at an industry-leading scale and have achieved higher growth in Japan in recent years. Today, we would like to introduce our business, attractive features of Kobe and opportunities of success in Kobe especially for foreign-affiliated corporations.

#### In Japan, affected by the rapidly aging society

By keeping a cautious eye on Japan's status quo in which unmet medical needs are increasing in the rapidly-aging society, we focus on such therapeutic areas of neuroscience diseases, endocrine diseases, cancers, and cardiovascular diseases. Above all, we place our emphasis on the therapeutic agent of Alzheimer's

disease that we are developing in collaboration with KBIC. We would like to point out this collaboration as a demonstration of the value of Kobe-based business. By taking advantage of the world's renowned thought leaders in KBIC, hospital networks, and good access to state-of-the-art technologies, we help them in promoting clinical trials to verify disease pathogenesis. In this collaboration, we try to contribute to early detection and early treatment of patients and further to the city of Kobe that also faces rapidly-aging society.



Seishin Laboratories

#### Business and living environment optimum for pharmaceutical product researches

Kobe has many other competitive edges: the scale of the pharmaceutical market in Kansai Area, that is larger than India or South Korea and comparable to the country of Russia; its convenience as a place for foreign residents to live, with a comprehensive infrastructure including international schools; and its ideal

environment, where medical and pharmaceutical graduates can live and work over the long term, and thus talented and skilled personnel are available. Above all, one of the greatest features of Kobe is its high quality of life. Kobe enjoys good access, well-maintained public order, and a pleasant climate. We enjoy working in Kobe every day, consuming refreshingly delicious foods such as Kobe beef and confectioneries. Since the opening of Kobe port in 1868, the city has been actively accepting foreign people and new things and creating superior products. The city has an optimum social background for settlement, growth and development of foreign-affiliated corporations.



#### Eli Lilly Japan K.K.

**Address:**  
(Head Office)  
Sannomiya Plaza Building, 1-5, Isogami-dori  
7-chome, Chuo-ku, Kobe, Hyogo  
(Seishin Laboratories)  
3-3, Takatsukadai 4-chome, Nishi-ku,  
Kobe, Hyogo  
**President:** Patrik Jonsson  
**Business:** Manufacturing and sales of  
pharmaceuticals  
**URL (Eli Lilly and Company):** <http://www.lilly.com/>