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Sumitomo Dainippon Pharma Co., Ltd.
In-house Magazine

The Challenge in New Fields—Developing the New Drugs That Patients Eagerly Await

About the cover design of the 2014 editions of the in-house magazine *Green Prism*:

If you fit together the covers from this year's four issues of the in-house magazine *Green Prism*, the principal regions where the DSP Group operates (Japan, United States, China, United Kingdom) join together to make one world!

Contents

Feature

The Challenge in New Fields—Developing the New Drugs That Patients Eagerly Await

In addition to the therapeutic areas of Psychiatry & Neurology and Oncology, Sumitomo Dainippon Pharma (DSP) set the development of new business fields ("new fields") as its strategy for research and development under the third Mid-term Business Plan. In this issue, we will feature the current status of projects related to these new fields, the rationale for working on them and the challenges and aspirations for the success of the people involved in these fields.

What are the "new fields" that DSP is working on?

The idea that forms the base for expansion by DSP into new fields is the challenge of addressing unmet medical needs. In order to fulfil our mission as a pharmaceutical company and create innovative drugs, we are leveraging our cutting-edge technology to promote research and development into intractable diseases for which there have been no treatments in the past. We are particularly concentrating our efforts on the field of Regenerative Medicine/Cell Therapy using induced pluripotent stem cells (iPS cells) and other regenerative medicine technologies to address diseases such as age-related macular degeneration[1] and retinitis pigmentosa,[2] as well as spinal cord injuries. Moreover, we are trying to expand into the field of preventative healthcare, including new tuberculosis vaccines, from the perspective of contributing to global health.[3]

In addition to this, we are concentrating our efforts on the development of products in fields where no approved drugs exist such as mitochondrial diseases, including Leigh syndrome (see page 6), and non-alcoholic steatohepatitis (NASH)[4] through such means as in-licensed products developed by venture companies.

1. Age-related macular degeneration: A disease in which degeneration due to aging occurs to the macula at the center of retina, making it difficult to see. It is the leading cause of blindness among adults in Europe and the U.S. and the fourth leading cause of blindness in Japan.
2. Retinitis pigmentosa: A disease which occurs due to abnormalities in the retina, the light-sensing organ in the eye. Dysfunctions such as night blindness (nyctalopia), visual field constriction and reduced visual acuity are observed. It is the third main cause of visual impairment in adults.
3. Global health: Fields which require cooperation and collaboration across national boundaries to resolve global-level issues that impact people's health.
4. Non-alcoholic steatohepatitis (NASH): Steatohepatitis accompanied by apoptosis, inflammation and fibrosis of liver tissue with no history of alcohol consumption or hepatitis virus infection. Five to twenty-five percent of cases are reported to progress to cirrhosis over 5 – 10 years, and there is currently no approved treatment.

The Present and Future of DSP's Regenerative Medicine/Cell Therapy Business

Shaping new hopes and possibilities for the future with technology that is ahead of the competition

Q. What is the rationale for expanding into the Regenerative Medicine/Cell Therapy business?

A. When we assessed the industry as we considered the third Mid-term Business Plan, it was clear that while low molecular weight drugs will continue to be the core of the market in the future, growth in this area has plateaued. Considering what kind of fields the Company can use to find a way out of this, the Regenerative Medicine/Cell Therapy business was one of the answers that presented itself.

DSP has a substantial record of joint research with academia, and we have been working on research on regenerative medicine, including research on the neurite outgrowth inhibitor semaphorin for about 20 years. In addition, Sumitomo Chemical Co., Ltd. (Sumitomo Chemical), our parent company, has used embryonic stem cells (ES cells) in safety evaluations for products that include agricultural chemicals, and we had a range of technology and expertise as well as networks with academic researchers in the regenerative medicine field, particularly in the area of research on the retina, which includes success in the world's first 3D formation of neural retina from human ES cells. Our subsidiary DS Pharma Biomedical Co., Ltd. also possessed expertise in cell culture techniques. In addition, we had an option agreement for SB623, a cellular medicine for chronic stroke, with SanBio, Inc. It was under this circumstance that Professor Shinya Yamanaka, Director of the Center for iPS Cell Research and Application at Kyoto University, was awarded the Nobel Prize, increasing public interest in regenerative medicine and cell therapy, and the government has also been moving to revise the legal system in this regard. These factors among others meant that the timing was perfect for advancing into this new field.

Dr. Toru Kimura
Director, Regenerative & Cellular Medicine Office

Q. Could you explain DSP's current initiatives in the Regenerative Medicine/Cell Therapy business?

A. Currently, DSP is working on central nervous system regenerative medicine, and we are promoting joint development with RIKEN and Healios K.K. (Healios)[5] in Japan using allogeneic iPS cell-derived retinal pigment epithelial (RPE) cells for patients with age-related macular degeneration and other eye diseases. Prior to this, RIKEN had been pursuing the world's first clinical research using autologous iPS cells derived from patients with age-related macular degeneration.

Our reasons for choosing age-related macular degeneration are that it is an intractable disease, which can lead to blindness in severe cases, with a relatively large number of patients for an eye disease. In addition, in regenerative medicine, it has been suggested that transplanted cells have the potential risk of carcinogenesis, but the probability of this is low for the eye, and risk can be managed through surgical treatment, including lasers in the event that abnormalities do arise. Production is also relatively easy because of the small number of cells to transplant in comparison with other parts of the body.

With the aim of commercializing this product, in February 2014 DSP and Healios established a joint venture company, Sighregen K.K. (Sighregen), which will be in charge of the manufacturing and sales promotion of RPE cell products. This is the first time that DSP has handled cell therapy, and we hope that it will secure a foothold in the business.

Q. What are the future prospects for the Regenerative Medicine/Cell Therapy business?

A. In April this year, we established the Kobe Regenerative & Cellular Medicine Center in the Kobe Biomedical Innovation Cluster as the company's research base for the Regenerative Medicine/Cell Therapy business. In an excellent environment that brings together truly cutting-edge people, technology and information, including RIKEN, which underpins regenerative medicine in Japan, the Regenerative & Cellular Medicine Office is conducting research on a differentiation[6] method for stem cells, including iPS cells, as well as methods for the efficient production of cells differentiated from iPS cells and others. All researchers of the Office, including those on secondment from group companies and hired from universities and other research organizations, have expertise for research on the Regenerative Medicine/Cell Therapy field. I think that our knowledge will extend further at this site through active interaction with specialists belonging to organizations outside of the Company.

Going forward, I hope that we make the clinical benefit in age-related macular degeneration clear so that sales results can be achieved under the next Mid-term Business Plan. The Company is also involved in regenerative medicine in other areas than eye diseases, including research on spinal cord injuries, and it is pursuing various possibilities. I really want to make these research projects a success, and it would be great if we can make dreams come true for patients and their families.

5. Healios K.K.: A RIKEN venture approved as such by RIKEN, an independent administrative agency. It is engaged in the development of new treatment methods for age-related macular degeneration through transplantation of RPE cells that are differentiated from iPS cells. It also seeks to make a successful development of treatment methods using iPS cells for patients with intractable diseases in other fields.
6. Differentiation: The change of undifferentiated cells such as iPS cells into cells with a specific function, such as nerve cells.

Kobe Regenerative & Cellular Medicine Center

DSP has established a research base for its Regenerative Medicine/Cell Therapy business in four of the facilities in the Kobe Biomedical Innovation Cluster, including the Institute of Biomedical Research and Innovation (IBRI). World-leading research institutes in the life science fields as well as a large number of corporations, organizations, research bodies and hospitals are clustered in this area, and the environment also facilitates collaboration with organizations that are associated with DSP, including Healios, RIKEN and Sumika Chemical Analysis Service, Ltd.

IBRI, one of four facilities. The names of the companies and medical facilities housed there are shown on the information board at the entrance.

People involved in the Regenerative Medicine/Cell Therapy business

Age-related macular degeneration project, basic research staff

Achieving a world first at top speed and bringing new possibilities for patients

Dr. Satoshi Ando

Tissue Engineering Group,
Regenerative & Cellular
Medicine Office

Our role in the age-related macular degeneration project

Age-related macular degeneration is a disease in which retinal pigment epithelial (RPE) cells lose function due to aging, causing degeneration of the macula in the center of the retina and a gradual decline in visual acuity, resulting in blindness in severe cases. We are currently developing a method of treatment based on the concept of restoring the function of the retina by transplanting new RPE cells derived from allogeneic iPS cells in the macula.

Under this project, our joint-development partner Healios has been implementing precursory work in the development of technology for producing and evaluating the quality of RPE cells. Production and sales promotion are to be conducted by Sighregen, which was jointly established by DSP and Healios.

In this project, I am principally involved in basic research related to the production of RPE cells. I also draw on the experience and know-how that I have obtained to date in research that forms the foundation for the regenerative medicine field to analyze research data obtained from Healios, identify issues and propose countermeasures. In this way, we are working to lay the groundwork to establish techniques for the stable production of RPE cells for cell therapy. Needless to say, close exchange of information with Healios is vital for us to fulfil our role. We make active efforts to communicate, taking advantage of the fact that both companies are conducting research in the Kobe Biomedical Innovation Cluster.

Linking experience to the present

I joined Sumitomo Chemical in 2006 and was involved in basic research using ES cells with the aim of developing methods for safety assessment of agricultural chemicals and other products. The following year, I was dispatched to RIKEN to study human ES cell-handling technique and advanced technologies as well as acquiring know-how that included applications under the Ministry of Education, Culture, Sports, Science and Technology concerning the use of human ES cells. Following my dispatch, I was engaged in examining methods for safety assessment of chemicals using human ES cell-derived RPE cells at Sumitomo Chemical, and I was also involved in joint research with RIKEN, which succeeded in the world's first 3D formation of neural retina from human ES cells.

In the development of medical treatments using human iPS cells, which DSP is currently working on, I have been able to apply my past experience of inducing RPE cells from human ES cells to my current research since both processes involve inducing the target cells from ES or iPS cells.

Changing "impossible" into "possible" is the driving force of a challenge

This project is the world's first attempt to apply human iPS cells into a medical product. The environment around us, including government regulations, is also changing rapidly. It is essential to obtain the latest information while anticipating change and moving forward, so being able to conduct research at the Kobe Biomedical Innovation Cluster, where we can get hold of the most up-to-date information, is a big advantage.

The difficulties in taking on the challenge of attempting something new are not negligible, but there is the possibility of being able to do something that we could not do in the past and being able to realize it as a treatment. I feel that this is extremely worthwhile. I hope that we will deliver a safe product to patients who are anxiously awaiting a new treatment as soon as possible. In order to accomplish this, first I want to achieve this project at top speed and then use it as the base leading to a whole succession of new possibilities.

Age-related macular degeneration project, manufacturing method researcher

Pioneering the foundations for manufacture of cellular medicine with "my own hands"

Tetsuya Karino

Cell Processing Group,
Regenerative & Cellular Medicine Office

My role is to identify issues that are forecast to arise when manufacturing cells that are differentiated from iPS cells as a product, to share this information with the departments concerned and Healios, to resolve issues at an early stage and to make the know-how obtained in this process available so that it can be applied to DSP's other iPS cell-related projects as well. As the cells themselves are the product, the method of manufacturing is unique and basically involves human intervention. I am being guided by the people around me who have a wealth of experience, and I am working to get directly involved and increase my experience.

The successful commercialization of this world-leading project will set the standards for iPS cell-related products, and not just for DSP, in terms of the approaches and concepts employed. My goal is to determine standards for methods of manufacturing in this context, and I feel that this is really worthwhile in creating the foundations for a new field in which everything is a first. Also, we might be able to help patients through this work, and I am constantly aware of both the happiness and the responsibility that this brings with it.

The Kobe Regenerative & Cellular Medicine Center offers an environment that facilitates collaboration between researchers while they apply their respective specialties. I hope that I will increase my expertise in the future as I play a role in disseminating information from the frontline.

Intellectual property staff in the Regenerative Medicine/Cell Therapy business

Contributing to the accumulation of DSP rights in new fields

Because conventional low molecular weight drugs originate from new compounds that did not exist previously, the main thrust of intellectual property rights is obtaining a substance patent for the compound to protect the product. In contrast to this, cellular medicine aims to regenerate something that is the same as the cells inside the human body. In other words, it is not a new substance. Therefore, we cannot simply apply the existing patent protection strategy to cellular medicine. In addition, since research and development is being conducted in the regenerative and cellular medicine field using a diverse array of biotechnology, and there are patents for each technology, care about intellectual property rights is required across an extensive area.

Nevertheless, the basic approach to intellectual property is the same, and I hope to proceed with my work, applying the experience and knowledge that I have acquired to date. Although I am trying to find my way in a field that still does not have any textbooks, I would like to put together a strategy in partnership with everyone at the Regenerative & Cellular Medicine Office while fine-tuning my abilities. I am making studious efforts in the belief that steadily building up practice will yield results.

Yumiko Kamikawa

Strategy Group, Intellectual Property

The Rationale for Working on Mitochondria-Related Drug Discovery

An undeveloped field with no treatments—That's why our efforts are so meaningful

Teruya Murata

Project Leader
Mitochondria-related Drug Discovery & Development
Drug Development Division

Q. Please give us an overview of mitochondria-related drug discovery.

A. EPI-743, a potential therapeutic agent for mitochondrial disease,[7] is a compound that works by counterbalancing redox stress that arises due to mitochondrial dysfunction. Together with EPI-589, a redox cofactor but differs in pharmacological profile and physical properties, DSP concluded a license agreement with Edison Pharmaceuticals, Inc. (Edison)[8] in March 2013 to acquire exclusive research, development and commercial rights in Japan. The Company subsequently acquired development and commercial rights to EPI-589 for indications in adults in North America. Furthermore, considering that the research know-how that Edison has accumulated to date is not limited to EPI-743 and EPI-589, but can be applied and developed, DSP began joint research with Edison in 2014. The goal for this research is to discover ten novel candidate pharmaceutical compounds over five years targeting the redox system, which plays a critical role in cellular energy metabolism.

Q. What is the status of development for each drug and how is the project organized?

A. At present, Phase II/III clinical studies of EPI-743 for Leigh syndrome[9] are making steady progress in Japan, and we plan to submit an application for approval in the first half of fiscal 2015. Outside Japan, Edison is conducting Phase IIb clinical studies of EPI-743 for Leigh syndrome in the United States, and development is being pursued not only for Leigh syndrome, but also for other mitochondrial diseases, as well as for Parkinson's Disease and other neurodegenerative diseases involving redox stress due to mitochondrial dysfunction. Edison is also conducting Phase I clinical studies for EPI-589 in Europe.

In order to apply the knowledge obtained through the development of EPI-743 and EPI-589 to the discovery of novel pharmaceutical compounds, the project is organized to facilitate close communication not only in the Drug Development Division, but also in the Drug Research Division and other related departments. Moreover, a large number of people are involved, including members of Sunovion Pharmaceuticals, in anticipation of development of EPI-589 in the United States. We hope that this structure will move the project forward while taking advantage of the respective strengths of DSP's many years of research and development experience and Edison's specialist knowledge.

Q. What do you think is the significance of DSP's involvement in mitochondria-related drug discovery?

A. I feel strongly that DSP's drug discovery is meaningful precisely because these are rare diseases for which patients and doctors are eagerly awaiting effective treatments. At the same time as contributing to society as a company, it will also lead to drug discovery focused on DSP's priority therapeutic areas, including neurodegenerative diseases. We definitely hope to discover some ground-breaking new drugs in our aim to be a leading company in the as yet undeveloped mitochondria-related field.

7. Mitochondrial disease

Mitochondria are organelles with functions such as producing energy for cells. The term mitochondrial disease collectively refers to diseases caused by redox stress due to mitochondrial dysfunction. These diseases cause damage to the nerves, muscles and heart, which require a lot of energy, and are designated as intractable.

8. Edison Pharmaceuticals, Inc.

A U.S.-based biotechnology company that excels in research on cellular energy metabolism, including mitochondria, with a business base in drug discovery and development in this area.

9. Leigh syndrome

A type of mitochondrial disease. Onset is during infancy, and symptoms such as psychomotor retardation, cramps, muscular hypotonia and muscle weakness are observed. The cause is considered to be genetic mutation, and it is one of the most serious mitochondrial diseases.

People involved in mitochondria-related drug discovery

Joint research with Edison Pharmaceuticals, pharmacology staff

Making research successful over the next five years to be able to save even more patients

Tatsuya Kamei

Mitochondrial Drug Discovery Group,
Innovative Drug Discovery Laboratories

I am involved in joint research with Edison as part of the Mitochondrial Drug Discovery Group, which was just inaugurated in April this year. As a pharmacology staff member, I am engaged in activities that include investigating potential drug targets and development of assay systems[10] for evaluating compounds.

In the past, I was responsible for other areas such as neuropathic pain medications, and this is my first time to carry out joint research, but I want to try my best to succeed in the goal of discovering ten novel candidate compounds over five years targeting the redox system.

It is also a field that DSP is tackling for the first time, and in the absence of in-house mitochondria experts, we need to achieve the goal quickly in the short space of five years, debating on an equal footing with American researchers as we share our respective knowledge and technology with each other. This comes with a great responsibility as well as some pressure, but it is also worthwhile. Everything in our communication with Edison is new, and it includes how to proceed with drug discovery research and the decision-making process. I hope that we will be able to absorb the beneficial aspects of working as a venture company and put them to good use in the future.

I was really impressed when I visited Edison and saw a large number of photographs and letters received from Leigh syndrome patients and their families pinned on the wall of a hallway. They fully conveyed the joy, surprise and gratitude from improvements made due to participation in clinical studies of EPI-743 for a medical condition that had been thought to have no hope of improvement, and I was able to reaffirm the significance of meeting unmet medical needs.

With rare mitochondrial diseases as a foothold, I hope that through this joint research we will discover candidate compounds that can provide novel treatments for neurodegenerative diseases where there are numerous unmet medical needs as well as a large number of patients.

10. Development of assay systems: Development of evaluation systems that can reproduce in vivo reactions in vitro, etc., in order to investigate the actions of a compound on the target.

Participant in research and development project at Edison Pharmaceuticals

Dr. Tetsuaki Nashida

Mitochondria Drug Discovery Group,
Innovative Drug Discovery Laboratories

Drawing on venture company strengths to drive DSP's drug discovery

I was dispatched to Edison in January this year, and I have been pursuing the possibility of being able to expand the indications of compounds currently undergoing clinical studies to other diseases in my capacity as a pharmacology researcher. Actually, working at Edison, I have become aware of the focus on speed and the strong feelings towards patients. For example, the speed that discoveries in the laboratory are used as biomarkers[11] in actual clinical studies a few months later is one of the advantages of Edison's compact organization. There are also connections with patient groups and frequent communications about progress in clinical studies, so it is possible for researchers to imagine the faces of the patients they want to provide with medicines. This is motivating for researchers and results in the acceleration of drug discovery. In the future, I want to keep on taking up the challenge of making new discoveries in partnership with our high-spirited team at Edison and be able to provide our compounds to patients as new drugs as soon as possible.

11. Biomarker: A biological indicator that marks status and changes in disease and degree of recovery

Welcome to Our Team

API Technology Group, Oita Plant

Improving technical capabilities in the production of active pharmaceutical ingredients to achieve the “3S” policy: safe operations, stable supplies and security in product quality

The API Technology Group at the Oita Plant is a new department inaugurated in October 2012 as the sole technology group in the Manufacturing Division with responsibility for the production of active pharmaceutical ingredients. The group is composed of a total of 11 members, with nine members, including the group’s manager, from the Oita Plant and two members from the Suzuka Plant. It brings together a unique team with diverse backgrounds, including people with experience on the manufacturing frontline, people transferred from other divisions and people on secondment from Sumitomo Chemical Co., Ltd.

The group’s tasks are wide-ranging and cover investigating industrial-scale production* for new products, examining rationalization for existing products, addressing manufacturing difficulties inside and outside the Company, responding to regulations in each country, and other tasks. It maintains close communication with the departments concerned while working as a cross-departmental unit. As the core of DSP’s technology for the production of active pharmaceutical ingredients, the group brings together the wisdom of 11 unique individuals, and it will continue rising to the challenge in realizing the “3S” policy: safe operations, stable supplies and security in product quality on the manufacturing frontline into the future.

*Industrial-scale production: Investigation concerning production for market launch and manufacturing

▲FU33 Office housing the group’s office and laboratory

Dr. Hisakazu Kishimoto
Group Manager, API Technology Group, Oita Plant

The challenge for our team

Striving to ensure the “3S” policy: safe operations, stable supplies and security in product quality at all manufacturing sites

Introducing Oita

Tsurusaki, the site of the Oita Plant, is located in the center of Oita City in Oita Prefecture. Historically, it was an enclave of the Higo Kumamoto Domain, and the ruins of the port of arrival and departure for the ships used for the system of alternate attendance in Edo (present day Tokyo) by the feudal lords still remain inside the plant’s grounds. The Tsurusaki Odori Festival is held in August, and the gorgeously costumed figures of the dancers are a summer tradition in Oita. Going a bit further afield, there is Saganoseki, which is famous for *seki aji* (horse mackerel) and *seki saba* (common mackerel), and the Beppu Onsen hot springs, Japan’s number-one hot springs both in terms of the volume of hot spring water discharged and the number of springs. Be sure to experience them when you visit history- and nature-rich Oita.

❶❷ Tsurusaki Odori, which has been handed down for at least 450 years, is a designated national intangible folklore cultural asset and is a traditional and elegant festival held in Tsurusaki Koen park in the evenings of the last Saturday and Sunday of August. The flamboyant figures of over 1,000 gorgeously costumed dancers assemble in front of the large stage and dance in rings. (Photo courtesy of Oita City Tourist Association)

❸ Beppu Onsen is the hot spring district in the center of Beppu City, Oita Prefecture. The Beppu Jigoku Meguri (Beppu Hell Tour), taking in the tourist hot spring water outlets that are known as *jigoku* or “hell,” offers up a variety of spectacles and is on the standard tourist itinerary. Beppu Onsen is rich in this and other tourist highlights, attracting more than eight million visitors a year.

Welcome to Our Team

Clinical Operations

Serving as a key driver for global clinical development

Clinical Operations oversees all clinical trials, from Phase I to Phase IV, across all therapeutic areas for the Global Clinical Development (GCD) organization. It strives to provide the highest global standards of data integrity and to adopt innovative technologies and practices to continually increase productivity and clinical trial efficiency.

The group manages relationships with Contract Research Organizations (CROs), third-party vendors and investigators to facilitate high-quality execution of Sunovion clinical trials. It also provides documents to support all trials and regulatory submissions worldwide.

The 50-person department is divided into four teams: Clinical Trial Management, Clinical Operations Administration, Medical Writing and Project Management. Team members are located in Marlborough, MA, U.S. and Fort Lee, NJ, U.S. where they oversee both regional and global trials.

As an "engine of innovation," Clinical Operations is a key driver of integration and globalization for GCD, collaborating on many key initiatives between the U.S. and Japan. It is currently working with DSP with the goal of delivering all clinical studies —as one department—for the entire organization.

Dr. Josephine Cucchiaro
Vice President of Clinical Operations

▲Josephine Cucchiaro giving the 2011 Encore Award to Maura Maria at an off-site luncheon. The Encore Award is an annual award given to recognize Sunovion employees who have done an exemplary job of displaying the company's values.

▲Some members of Clinical Operations with Team Tokyo, the team working on lurasidone studies in Japan, in 2013

The challenge for our team

Ensuring delivery of timely, efficient, best-in-class clinical trials to the Global Clinical Development (GCD) organization.

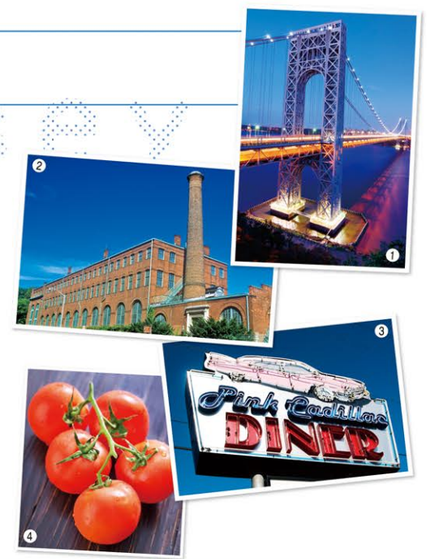
▲Clinical Operations Team Fort Lee

◀Clinical Operations Team Marlborough

Introducing New Jersey

Josephine Cucchiaro, PhD, VP Clinical Operations, leads the team and is based in the Fort Lee, NJ, U.S. office. Fort Lee is connected to Manhattan via the George Washington Bridge (❶), which spans the Hudson River. Although New Jersey is the 4th smallest state in the U.S., it is home to over 3,000 biotech companies and 14 of the world's largest pharmaceutical companies. New Jersey ranks first in the number of chemists and second in the number of biochemists and biophysicists in the U.S.

❷ Thomas Edison Labs at the Edison National Historic Site in West Orange, NJ. Thomas Edison invented the light bulb, phonograph and motion picture projector in his laboratory in Menlo Park, NJ.
❸ Sign for the Pink Cadillac Diner on the New Jersey shore. New Jersey has more diners than any other state—over 600—and is called "the diner capital of the world." Many 1950s-era diners dot the roadways in New Jersey
❹ Tomatoes are the state vegetable of New Jersey. The Jersey tomato is considered to be one of the world's best tasting!



PRISM TIMES+

10 October

USA **May 3–7, 2014**

Sunovion Showcases LATUDA® at American Psychiatric Association Annual Meeting

Sunovion Pharmaceuticals Inc. had a strong presence at the American Psychiatric Association's (APA) 167th Annual Meeting, held in New York, NY from May 3 to May 7, 2014, helping to raise awareness of LATUDA® (lurasidone HCl) in the psychiatric community. LATUDA® advertisements were placed strategically in locations throughout New York City, directing more than 1,300 healthcare professionals to the LATUDA exhibition booth. The LATUDA sales team used innovative tools, including a 3D video and interactive visual aids, to demonstrate the drug's benefits.

LATUDA advertisement

Sunovion presented 20 new research posters at the meeting. It also hosted a LATUDA product theater, attended by 275 people; a therapeutic update dinner, attended by 300 people; and its third annual mental health advocacy partner reception.

Exhibition booth

USA **May 30, 2014**

LATUDA® Named One of IMS Top 100 Selling Drugs in U.S.

LATUDA® was listed among the top 100 drugs by total sales in the U.S., according to IMS Health (April 2013–March 2014). The product has seen record success since receiving an indication for the treatment of bipolar I depression. In less than a year, the volume of weekly prescriptions for LATUDA® has nearly doubled—to more than 30,000.

In addition, psychiatrists recognized the LATUDA sales team for outstanding work in a recent IMS Pharmaceutical Sales Force Structures and Strategies (SFSS) survey. The LATUDA® brand, sales and cross-functional teams have all achieved significant milestones for the brand—and ultimately for patients.

USA **June 4, 2014**

Sunovion June 2014 All-Company Meeting

On June 4, 2014 approximately 700 Sunovion employees participated in an All-Company Meeting (ACM) to hear updates on Sunovion's Performance, to meet the Company's new Chief Financial Officer, Steve Freeman, and to celebrate the achievement of colleagues who had earned annual awards for demonstrating company values in their work. The 90-minute meeting was hosted in Marlborough, MA with employees from Fort Lee, NJ and field-based employees joining via Web Stream. Sunovion holds quarterly ACMs to update employees on business performance, R&D and DSP milestones and to recognize teams. In the post-meeting survey, 89% of respondents found the meeting valuable, 94% found the topics interesting, and 95% gained a greater understanding of Sunovion's FY13 performance.

USA **June 5, 2014**

Pop Music Star Collaborates with Sunovion on Mental Health Advocacy Tour

Sunovion has embarked on a new initiative with Demi Lovato, a platinum-selling American recording artist living with bipolar disorder. Called the Mental Health Listening & Engagement Tour, this program will connect the 21-year-old singer with the mental health advocacy community and allow her to reach out to those impacted by mental illness and share her personal story of living with mental illness.

On June 5th, the tour held its first event in New York City at The Jed Foundation, an organization founded to promote emotional health and prevent suicide among college and university students. That night, Ms. Lovato spoke at its annual gala, addressing more than 600 members of the mental health community.

USA **June 23, 2014**

Sunovion Employees Explore Global Cultures for Innovation—First Stop: Sushi!

A creative new program called The Cultural Voyage was launched this summer by Hiroyuki Baba, Executive Vice President (EVP), Corporate Strategy at Sunovion. It is designed to promote cultural appreciation, foster innovation and harness the best of Japanese, American and global thinking and business practices.

On June 23, employees gathered in the Marlborough and Fort Lee offices for the first event: a celebration of sushi! Highlights included clips from the film Jiro Dreams of Sushi, talks by Baba and the executive director of the Japan Society of Boston, and demonstrations by knowledgeable local sushi chefs. All enjoyed sampling sushi at the end.

EVP Hiroyuki Baba welcomes the audience

EUROPE **June 27, 2014**

Sunovion Europe Mental Health Pharmacist Advisory Board

Sunovion Pharmaceuticals Europe Ltd. held a Mental Health Pharmacist Advisory Board at the Royal College of Physicians on June 27 to review the latest data on lurasidone as a treatment for schizophrenia and gain insight on new compound introduction to the NHS. The advisors were Chief Mental Health Pharmacists from the London area. They concluded that lurasidone was significantly more effective than a placebo and as effective as olanzapine (15mg). The advisors were also generally impressed with safety evidence in regard to weight gain and the negligible effect on cardio-metabolic parameters; and were positive about the effects on cognition. The conclusion from the board was that most advisors thought LATUDA® would achieve formulary approval on a restricted basis.

JAPAN **July 1, 2014**

Transfer of marketing rights for INTEBAN®, CATLEP®, and DRENISON®

On July 1, Sumitomo Dainippon Pharma Co., Ltd. (DSP) transferred the marketing rights for INTEBAN®, CATLEP®, and DRENISON® to Teikoku Seiyaku Co., Ltd. ("Teikoku Seiyaku"). In conjunction with the transfer, DSP's manufacturing and marketing approval for INTEBAN® in Japan was succeeded by Teikoku Seiyaku as of the same date.

Even after July 1, 2014, DSP will be responsible, as the contractor of Teikoku Seiyaku, for the receipt of orders and the physical distribution of the three products to pharmaceuticals wholesalers.

CHINA **July 5–12, 2014**

DSPC's top MRs of fiscal 2013 visit Japan

From July 5 to 12, the twelve highest-achieving medical representatives (MRs) of fiscal 2013 from Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (DSPC) visited Japan. Following a meeting with President Tada and Senior Executive Officer Hiroshi Nomura at the Tokyo Head Office, they were each presented with a certificate and were congratulated by President Tada. At a meeting with the Global Corporate Management, they discussed the development and expectations of the Chinese operations going forward, as well as their hopes and dreams for the future of DSPC. All of the MRs are proud to be part of the DSP group and vowed to work even harder in the future to contribute to the company.

OTHER **July 8, 2014**

Antiepileptic drug APTIOM™ obtains approval in Canada

On July 8, Sunovion Pharmaceuticals Canada Inc. obtained approval from Health Canada of the antiepileptic drug APTIOM™ (eslicarbazepine acetate) for use as a once-daily adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy who are 18 or older.

EUROPE **July 21, 2014**

Sunovion Europe Satellite Symposium

Sunovion Europe sponsored a Satellite on the Latest Advances in the Treatment of Schizophrenia at the British Association for Psychopharmacology (BAP) 40th Anniversary Annual Meeting on July 21 at Robinson College, Cambridge. The BAP is a society that brings together groups from pre-clinical neuroscience, clinical psychiatry and industry to improve the understanding of treatments and generate innovation in the commercial sphere. The Satellite reviewed lurasidone as a new treatment option for schizophrenia as well as the journey from laboratory research to patient

outcomes. The Sunovion Europe team used the meeting as a launch platform for LATUDA® in the UK, and 60% of the delegates attended the Satellite. LATUDA® received positive feedback from the delegates.

Exhibition booth

Presentation by Dr. Antony Loebel

JAPAN **July 23, 2014**

Investment in a new venture capital fund

DSP entered into an agreement with Remiges Ventures, a venture capital firm with offices in Tokyo, Japan and Massachusetts, U.S., under which it will invest up to a cumulative total of US$30 million in Remiges BioPharma Fund, LP, a new venture capital fund created by Remiges Ventures.

Created in June 2014, the fund is focused on investments in venture firms principally in the U.S. and Europe that are actively engaged in the development of life science innovations. DSP hopes that the investment in the fund will allow efficient access to the most up-to-date information on venture firms with new drug discovery potentials and cutting-edge technologies, thus leading to the enrichment of its development pipeline and helping ensure seamless discovery of innovative new drugs.

EUROPE **August 4, 2014**

LATUDA® now available in the UK

On August 4, Sunovion Europe launched in the UK the atypical antipsychotic agent LATUDA®, a once-daily oral treatment for schizophrenia in adults. Sunovion Europe also restructured its organization to specialize in the sales and marketing of LATUDA®, and from July 1, it became a wholly owned subsidiary of Sunovion Pharmaceuticals Inc. This structural change will enable it to develop in the UK the marketing strategies that were cultivated in the U.S. and maximize the sales of LATUDA®, a global strategic product that is the first product launched by Sunovion in Europe.

JAPAN **August 19, 2014**

President's Awards held

On August 19, the award ceremony for the 7th President's Awards was held at the Osaka Head Office. There were two winners of the President's Encouragement Award: "Obtaining approval for partial change of AD-810N (TRERIEF®)" (six recipients), and "LATUDA® European Application and Response to Inquiries" (10 recipients), and one winner of the President's Special Award: "Reducing Economic Risk to DSP in the Tuberculosis Vaccine Business" (six recipients).

JAPAN **August 29, 2014**

Approval of additional dosage and administration for biguanide oral hypoglycemic drug METGLUCO® for pediatric patients with type 2 diabetes

On August 29, DSP obtained approval for partial changes to the approval of METGLUCO® Tablet 250 mg and METGLUCO® Tablet 500 mg (generic name: metformin hydrochloride), a biguanide oral hypoglycemic, for the additional dosage and administration of the drug for type 2 diabetes in pediatric patients. DSP submitted this application in October 2013 after receiving a request from Japan's Ministry of Health, Labour and Welfare for the additional dosage and administration based on the results of consultation at the Study Group on Unapproved and Off-label Drugs of High Medical Need, and carrying out clinical studies. The recent approval is expected to help improve the blood sugar control of children with type 2 diabetes in Japan and contribute to preventing incidence of serious complications.

Other news in Japan

May 24 and 31, 2014	DSP supports Sports Day of two elementary schools in Ofunato, Iwate Prefecture
May 26–July 24, 2014	DSP carries out school visits by employees to give classes on genetic diagnosis at four high schools in Osaka Prefecture and a junior high school in Shiga Prefecture
June 16, 2014	DSP announces effects on current term business results of the closure to further accrual of patients in the Phase III global colorectal carcinoma monotherapy trial using anticancer drug BBI608
June 19, 2014	DSP implements change of the Company's English trade name and partial amendments to its Articles of Incorporation
July 7–18, 2014	DSP Opinion 2014 (companywide employee surrey) carried out
July 30, 2014	Financial results for the three-month period ended June 30, 2014 announced; conference call conducted in Tokyo
August 7, 2014	Press conference with the president and informal gathering with the press held in Tokyo
August 29, 2014	DSP announces transfer of some fixed assets (idle assets) (Horikawa Building, Nishinomiya Dormitory, Takatsuki Apartment)