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Dainippon Sumitomo Pharma Co., Ltd

# Dainippon Sumitomo Pharma Deepens Cooperation with Edison Pharmaceuticals for Therapeutic Agents for Mitochondria Disease --- Amends the License Agreement and Concludes a Joint Research Agreement and a Stock Purchase Agreement ---

Osaka, Japan, January 31, 2014 — Dainippon Sumitomo Pharma Co., Ltd (Head Office: Osaka, Japan; President: Masayo Tada) ("DSP") announced that today it has entered into an agreement with Edison Pharmaceuticals, Inc. (Head Office: Mountain View, California, U.S.A.) ("Edison") that amends the license agreement between the two companies relating to EPI-743 and EPI-589, therapeutic agents under development for mitochondrial disease ("License Agreement"). As of the same date, in addition, a joint research agreement for discovery of novel candidate pharmaceutical compounds targeting cellular energy metabolism ("Joint Research Agreement") and a stock purchase agreement for DSP's purchase of an equity in Edison ("Stock Purchase Agreement") have been concluded.

1. Amendment of the License Agreement

The License Agreement, which was entered into on March 28, 2013, grants DSP exclusive research, development and commercial rights in Japan for EPI-743 and EPI-589. The amendment agreement concluded today additionally grants DSP exclusive development and commercial rights of EPI-589 in North America for agreed-upon indications in adults. DSP will pay in total between US\$30 – 105 million in development milestone payments per indication associated with successful development of EPI-589 in North America. After launch, Edison will receive double-digit royalties based on sales amounts and sales milestone payments\* in accordance with sales goals achieved.

2. Joint Research Agreement

Edison is a world leading company in the research on mitochondrial and other cellular energy metabolism. Alteration in cellular energy metabolism is known to cause cancer, neuropsychiatric disorder, metabolic disorder and other diseases. Both companies aim to lead to therapy of intractable diseases including Mitochondrial disease and reactive oxygen species-induced neuropsychiatric disorder through studying redox system a critical role in the regulation of energy metabolism. DSP will work to discover 10 novel candidate pharmaceutical compounds over the next five years through the joint research with Edison which has a solid drug discovery platform for Mitochondrial disease research. Under the terms of the Joint Research Agreement, non-clinical studies required for the Investigational New Drug application of such novel candidate compounds will be conducted, with DSP paying to Edison US\$10 million as upfront payment and up to US\$40 million to cover a part of the joint research expenditures over the four years starting with the first anniversary of the coming-into-force of the Joint Research Agreement. DSP will have exclusive development and commercial rights in Japan and in North America on three novel compounds of DSP's choice from among those resulting from the joint research. DSP will pay in total between US\$10 - 30 million per indication for Japan and North America in development milestone payments associated with successful development. After launch, Edison will receive double-digit royalties based on sales amounts and sales milestone payments\* in accordance with sales goals achieved. On novel candidate pharmaceutical compounds of Edison, DSP will receive single-digit royalties based on sales amounts.

3. Stock Purchase Agreement

Upon coming-into-force of the above two Agreements, DSP will purchase US\$50 million-worth of preferred stocks in Edison and, upon request of Edison, additional preferred stocks worth up to US\$50 million during the period between the first and the fifth anniversaries of the initial equity closing.

Through the joint research with Edison which has a very strong position in the development of EPI-589 in North America and the research and development of therapeutic agents for Mitochondrial disease and related diseases, DSP aims to become an established leading company in this domain and offer innovative therapeutic agents to as many patients as possible. It should be added that implementation of the three Agreements mentioned above is subject to fulfillment of the conditions of and completion of statutory procedures based on the US Antitrust Law.

\* DSP will make sales milestone payments for EPI-589 and three novel compounds up to US\$3.86 billion in total.

## <Reference>

### <u>EPI-743</u>

EPI-743's mode of action is to synchronize energy generation in the mitochondria with the counterbalancing of redox stress. Edison is currently conducting a Phase IIB clinical trial of EPI-743 in the U.S. and Europe for Leigh syndrome, a mitochondrial disease. In Japan DSP is conducting a Phase II/III clinical trial for Leigh syndrome. EPI-743 is expected to be a world first treatment for Leigh syndrome and other mitochondrial diseases for which no therapeutic agents are available today.

### EPI-589

EPI-589 is a next-generation redox cofactor modeled after EPI-743. Edison is conducting a Phase I clinical trial on EPI-589 and intends to advance its development for neuropsychiatric indications that share as a common etiology disorders of redox biochemistry.

## Mitochondrial disease

Mitochondria are organelles with functions such as producing energy for cells. Diseases caused by mitochondrial dysfunction are collectively referred to as "Mitochondrial disease." Although a variety of symptoms appear, functions that require a lot of energy such as nerves, muscles, the heart, etc. are seen affected most often and Mitochondrial disease is classified into various diseases by the symptoms. It is a disease designated as intractable in the Specified Disease Treatment Research Program of the Japanese government.

#### Edison Pharmaceuticals

Edison Pharmaceuticals (Chairman and CEO: Guy Miller, MD, PhD) is a biotechnology company based on the discovery and development of low-molecular therapeutic drugs for the treatment of Mitochondrial disease. Founded in 2006, it is headquartered in Mountain View, California, USA.

Contact:

Corporate Communications Dainippon Sumitomo Pharma TEL: +81-6-6203-1407 (Osaka) +81-3-5159-3300 (Tokyo)