



Press Release

September 16, 2015

To the Press

Eli Lilly Japan K.K.
Sumitomo Dainippon Pharma Co., Ltd.

Market Release of “Trulicity® Subcutaneous Injection 0.75mg Ateos®” Once-Weekly Type 2 Diabetes Treatment : GLP-1 Receptor Agonist

~To Be Provided with Unique Auto-Injector-Type Device~

Eli Lilly Japan K.K. (Head Office: Kobe City, Hyogo, President and Representative Director: Patrik Jonsson, hereinafter called “Eli Lilly Japan”) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka City, Osaka, Representative Director, President and CEO: Masayo Tada, hereinafter called “Sumitomo Dainippon Pharma”) have launched today on Sep. 16, a once-weekly GLP-1 receptor agonist “Trulicity® Subcutaneous Injection 0.75 mg Ateos®”(Generic name: Dulaglutide [Genetical Recombination], hereinafter called “Trulicity”) which gained approval for the treatment of “type 2 diabetes”.

Trulicity is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist. Trulicity stimulates insulin secretion when the blood sugar level rises after meal, depending on the blood sugar level in the body. Not only accompanying its proven effect of lowering blood sugar level with only once-weekly administration, but Trulicity comes in a unique disposable, pen-type auto-injector with a pre-attached needle.

Trulicity has gained marketing approval in 45 countries and areas to date; 10 countries out of which including Japan, the U.S., and the EU have initiated selling this product (as of Sep. 16, 2015).

“Trulicity is a promising new product with its proven efficacy in glycemic control. In addition to its largest features of once-weekly administration and highly convenient usage, Trulicity is to be provided with an unprecedentedly innovative device called Ateos and a disposable automatic injector.” said Kadir Tepebasi, Senior Director, Diabetes/GHD Business Unit of Eli Lilly Japan, as a statement regarding this launch. “I hope Trulicity will help more people with type 2 diabetes achieve their treatment goals and improve their outcomes”

“We are pleased to add Trulicity which has proven efficacy along with convenience into our product lineup in the diabetes area, one of our domestic important sales areas,” said Susumu Nakajima, Sumitomo Dainippon Pharma’s Senior Executive Officer, Executive Director, Sales & Marketing. “In collaboration with Eli Lilly Japan, we will promote Trulicity’s appropriate use by ensuring the proper delivery of Trulicity information for healthcare providers. We will do our best so that we can contribute to treat more and more patients who need this drug.”

Eli Lilly Japan retains the manufacturing/marketing license for Trulicity and Sumitomo Dainippon Pharma takes responsibility for sales/distribution of the drug. Both companies engage in the information provision of Trulicity for healthcare providers. Using synergy between the both companies’ experience which have been built up to date, to sell as a team Trulicity, a promising new option of type 2 diabetes treatment, Eli Lilly Japan and Sumitomo Dainippon Pharma hope to contribute more to the treatment of type 2 diabetes in Japan.

*** Reference Information ***

<Commercial name>

Trulicity® Subcutaneous Injection 0.75 mg Ateos®

<Generic name>

Dulaglutide [recombinant](JAN)

<Indication>

Type 2 diabetes

<Administration/dosage>

Normally for an adult, 0.75 mg as dulaglutide [recombinant] should subcutaneously be injected once a week.

<Drug price>

“Trulicity® Subcutaneous Injection 0.75 mg Ateos®” 1 Kit 3,586 yen

<Date of manufacturing/marketing approval>

July 3, 2015

<Date of the listing in the National Health Insurance drug price list>

August 31, 2015

<Date of launch>

September 16, 2015

<Manufacturer & Distributor>

- Manufacturing and marketing by: Eli Lilly Japan K.K.
- Sales and distribution by: Sumitomo Dainippon Pharma Co. , Ltd.

About “Trulicity® Subcutaneous Injection 0.75 mg Ateos®”

Trulicity is a once-weekly glucagon-like peptide-1 receptor agonist. The product therefore facilitates insulin secretion when the blood sugar level increases after meal, depending on the blood sugar level in the body.

Trulicity is provided as a disposable, pen-type auto-injector. Its needle is attached to the device beforehand, and pressing the injection button triggers automatic insertion of the needle under the skin to deliver a dose of the prefilled drug solution. Once the delivery is completed, the needle automatically goes back inside the device.

The efficacy and safety of Trulicity have been investigated in 3 Phase III clinical studies conducted in Japan. In the study of Trulicity monotherapy, Trulicity 0.75 mg showed superiority over placebo as well as non-inferiority to liraglutide in HbA1c reduction. Also, in the study of a combined therapy with a sulfonylurea medicine and/or a biguanide medicine, Trulicity 0.75 mg showed non-inferiority, and as a secondary endpoint, superiority to insulin glargine in HbA1c reduction. In addition, the safety of Trulicity treatment up to 52 weeks was shown in the long-term administration study of an open-label combined therapy.

About Eli Lilly and Company’s diabetes business

Eli Lilly and Company has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we work to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and a continued commitment to providing real solutions—from medicines to support programs and more—to make lives better. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>.

About Eli Lilly Japan

Eli Lilly Japan K.K. is a subsidiary of Eli Lilly and Company and celebrating the 40th anniversary of its foundation this year. It contributes to medical treatment in Japan through the development, manufacture, import and sale of innovative pharmaceutical products that allow people to live longer, healthier, and more fulfilling lives. Lilly provides therapeutic agents for schizophrenia, depression, bipolar disorder, attention deficit disorder / hyperactivity disorder (AD/HD), cancer (non-small cell lung cancer, pancreatic cancer, biliary tract cancer, malignant pleural mesothelioma, urothelial carcinoma, breast cancer, ovarian cancer, malignant lymphoma and gastric cancer), diabetes mellitus, failure to thrive, osteoporosis, etc. Lilly is also developing diagnostic agents and therapeutic agents for Alzheimer-type dementia, rheumatoid arthritis, psoriasis, hypercholesterolemia, etc. For more detail, please visit our website. (URL: <http://www.lilly.co.jp>)

About Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma defines its corporate mission as “to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide”. By pouring all our efforts into the research and development of new drugs, we aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world in order to realize our corporate mission. We have positioned Cardiovascular/Diabetes, Psychiatry & Neurology, and Speciality areas as our focus marketing areas in Japan. For more detail, please visit our website. (URL: <http://www.ds-pharma.com>)