



## Press Release

November 21, 2016

For immediate release

Eli Lilly Japan K.K.  
Torii Pharmaceutical Co., Ltd.

### **Eli Lilly Japan and Torii Pharmaceutical launch “Taltz<sup>®</sup> Subcutaneous Injection 80mg Auto-injector” and “Taltz<sup>®</sup> Subcutaneous Injection 80mg Syringe” Humanized anti-human IL-17A monoclonal antibody product**

Eli Lilly Japan (head office: Kobe City, Hyogo Prefecture, President and Representative Director: Patrick Johnson) and Torii Pharmaceutical Co., Ltd. (head office: Chuo-ku, Tokyo, President and Representative Director: Shoichiro Takagi) today launch humanized anti-human IL-17A monoclonal antibody product “Taltz<sup>®</sup> Subcutaneous Injection 80mg Auto-injector” and “Taltz<sup>®</sup> Subcutaneous Injection 80mg Syringe” (generic name: ixekizumab [recombinant] hereinafter called “Taltz”) indicated for psoriasis vulgaris, arthropathic psoriasis, pustular psoriasis, and psoriatic erythroderma.

Taltz is a monoclonal antibody (biological drug) that binds to interleukin-17A (IL-17A) with high affinity, which is deeply associated with pathology of psoriasis and arthropathic psoriasis, and neutralize its activity. The product won its manufacturing/marketing approval on July 4 of this year.

As a result of domestic and overseas clinical trials on which the manufacturing/marketing approval was based, among patients with psoriasis vulgaris that did not fully respond to existing treatment, 89.1% achieved PASI\*<sup>1</sup> 75, 70.9% PASI 90, 35.3% PASI 100 at Week 12 of Taltz administration<sup>i</sup>. The PASI 75/90/100 achieved at Week 12 of Taltz administration were long maintained until Week 52<sup>ii</sup>. Furthermore, among patients with psoriasis vulgaris that did not fully respond to existing treatment, 62.1% achieved ACR20\*<sup>2</sup>, 46.6% ACR50\*<sup>2</sup>, 34.0% ACR70\*<sup>2</sup> at Week 24 of Taltz administration. These improvement rates show that the drug significantly inhibited progress in joint destruction (mTSS)<sup>\*3 iii</sup>. From these results, Taltz is expected to become a new treatment option for patients who did not fully respond to existing treatment. The product is available in a conventional syringe type injector and an auto-injector type injector approved for the first time in Japan\*<sup>4</sup>, making it possible to choose depending on patient needs.

Commenting on the product launch of this time, Barret B. Madrigal, Senior Director of Eli Lilly Japan’s Musculoskeletal Business Unit and Autoimmune, says, “With the launch of Taltz, Eli Lilly Japan entered the area of autoimmune diseases which is one of our focused areas. For arthropathic psoriasis, the Japanese launch is the world’s first launch ahead of other countries. From now on, our mission is to ensure the delivery of this innovative therapy to psoriasis patients who need it. We are committed to seriously making all-out efforts so as to improve psoriasis care”.

Akihiko Tamura, Executive Managing Director and Pharmaceutical Sales Group Leader of Torii Pharmaceutical, says, “We are very pleased that, with the launch of Taltz, we can provide actual medical sites with a new value and option. In the area of the skin disease, an

important area for Torii Pharma, we will make more contributions to medicine in the skin disease area by speedily and appropriately delivering Taltz, a new treatment option in psoriasis, to actual medical sites”.

For Taltz, Eli Lilly Japan and Torii Pharmaceutical have signed a strategic sales collaboration agreement in the skin disease area in Japan, and the two companies are co-promoting products to healthcare professionals in the skin disease area. On the other hand, for arthropathic psoriasis, diagnosis and treatment are often provided by rheumatism / connective tissue disease department or orthopedics department. For healthcare professionals in these rheumatism disease areas, Eli Lilly Japan will therefore provide information speedily and appropriately.

\*<sup>1</sup>PASI: Index for psoriasis size and severity. Each of PASI75/90/100 means an improvement filling over 75/90% or 100% from baseline.

\*<sup>2</sup> ACR20/50/70: Improvement standard of American College of Rheumatology

\*<sup>3</sup>Results of trials in arthropathic psoriasis were evaluated in comparison with placebo arm patients in terms of safety and efficacy of Taltz 80 mg administered once in every 2 or 4 weeks after administering 160 mg as initial dosage. It is different from the approved administration / dosage.

\*<sup>4</sup> Source: Eli Lilly Japan’s internal materials

### <Reference information>

#### Product photos:



## Product Outline

<Brand name>

Taltz<sup>®</sup> Subcutaneous Injection 80mg Auto-injector

Taltz<sup>®</sup> Subcutaneous Injection 80mg Syringe

<Generic name>

ixekizumab [recombinant](JAN)

<Effect / efficacy>

The following diseases that do not fully respond to existing treatment:

Psoriasis vulgaris, arthropathic psoriasis, pustular psoriasis, and psoriatic erythroderma.

<Administration / dosage>

Normally, for an adult, as ixekizumab [recombinant], 160 mg is subcutaneously administered initially. From Week 2 to Week 12, 80 mg is subcutaneously administered once in every 2 weeks. After this period, 80 mg is subcutaneously administered once in every 4 weeks.

<Date of approval>

July 4, 2016

<Date of NHS price listing>

November 18, 2016

<Drug price>

Taltz<sup>®</sup> Subcutaneous Injection 80mg Auto-injector: 146,244 yen

Taltz<sup>®</sup> Subcutaneous Injection 80mg Syringe: 146,244 yen

<Manufactured and marketed by>

Eli Lilly Japan K.K.

<Sales partner>

Torii Pharmaceutical Co., Ltd.

<Date of launch>

November 21, 2016

## What is Psoriasis?

Psoriasis is a chronic non-infectious auto-immune disease that presents on the skin. The disease expresses itself due to the immune system sending out the wrong signal, accelerating the growth cycle of skin cells<sup>iv</sup>. It is the most common inflammatory disease, with 7.5 million sufferers in the United States and a total of 125 million affected individuals across the entire world<sup>iv</sup>. An estimated 430,000 people in Japan have the disease<sup>v</sup>. A recent report<sup>vi</sup> estimates that 60,000 people are affected by psoriatic arthritis in Japan. Psoriasis appears in all parts of the body and is linked to other serious diseases such as diabetes and heart disease<sup>vii, viii</sup>.

The most common form of psoriasis is called psoriasis vulgaris. It presents with well-defined red raised patches together with silvery white scales. About 17% of psoriasis vulgaris is said to be moderate to severe<sup>ix</sup>.

## About Eli Lilly Japan K.K.

Eli Lilly Japan K.K. is a subsidiary of Eli Lilly and Company and it contributes to medical treatment in Japan through the import, development, manufacture, 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), pain, cancer (non-small-cell lung cancer, pancreatic cancer, biliary tract cancer, malignant pleural mesothelioma, urothelial carcinoma, breast cancer, ovarian cancer, malignant lymphoma, gastric cancer and colorectal cancer), diabetes mellitus, failure to thrive, osteoporosis, psoriasis, etc. Lilly is also developing diagnostic agents and therapeutic agents for Alzheimer-type dementia, rheumatoid arthritis, etc. For more information, please visit us at <http://www.lilly.co.jp>

## About Torii Pharmaceutical Co., Ltd.

With its corporate mission "Torii Pharmaceutical Co., Ltd. aims to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products.", Torii Pharma positions "Renal diseases and Hemodialysis area", "HIV infection area", "Allergens area" and "Skin disease area" as its areas of importance.

Torii is a member of the Japan Tobacco Inc. (JT) group. Collaboration with JT takes the form of functional focus, with JT undertaking R&D on new compounds and Torii integrating manufacture and marketing. In addition to Torii's independent activities, Torii's partnership with JT is leading to the in-licensing of excellent pharmaceuticals. More details can be found on the corporate website <http://www.torii.co.jp/>

## Contact Information

Miori Kusama, Communications & CSR, Eli Lilly Japan K.K. Tel. 080-8017-2629

Email: [kusama\\_miori@elanco.com](mailto:kusama_miori@elanco.com)

- 
- i. Gordon K. B et al.: *New Engl J Med*. DOI:10.1056/NEJMoa1512711 (2016).
  - ii. Saeki H. et al. *J Eur Acad Dermatol Venereol*. 29(6):1148-1155(2015).
  - iii. Philip J Mease et al.: *Ann Rheum Dis* doi:10.1136/annrheumdis-2016-209709
  - iv. National Psoriasis Foundation®, File, Communications, Psoriasis, <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf> (Accessed August 20, 2014)
  - v. Kubota K. et al. *BMJ Open*. 2015 Jan 14;5(1):e006450.
  - vi. Ohara Y. Et al. *J Rheumatol*. 2015; 42:8;1439-1442.
  - vii. Rapp SR. et al. *J Am Acad Dermatol*. 1999;41:401-407.
  - viii. Kurd SK. et al. *Arch Dermatol*. 2010;146(8):891-895.
  - ix. About psoriasis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriasis>. Accessed March 22, 2016.