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## NHI Drug Price Listing for Bipresso® Extended Release Tablets for the Improvement of Depressive Symptoms Associated with Bipolar Disorder Announced

**Mumbai, August 30, 2017:** Pharma Major Lupin Limited (Lupin) announced that its Japanese subsidiary Kyowa Pharmaceutical Industry Co., Ltd. (headquarters: Yodogawa-ku, Osaka; President and Representative Director: Ray Tsunoda; hereinafter Kyowa) announced the listing of the NHI (National Health Insurance) drug price for Bipresso® (generic name: Quetiapine Fumarate) extended release 50mg and 150 mg tablets for the treatment of depressive symptoms associated with bipolar disorder.

NHI drug price:

71.00 Yen per 50mg tablet

188.60 Yen per 150mg tablet

Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka; hereinafter Astellas) obtained approval for Bipresso® Extended Release Tablets on July 3, 2017. Bipresso® Extended Release Tablets contains the active ingredient quetiapine fumarate and is an extended-release tablet to be taken orally once a day. Earlier, Astellas had submitted an application to manufacture and sell Bipresso® extended-release 50mg and 150 mg tablets for the improvement of depressive symptoms associated with bipolar disorder following a development request from the Ministry of Health, Labour and Welfare's Evaluation Committee of Unapproved or Off-Labelled Drugs with High Medical Need.

Based on the agreement between Astellas and Kyowa made in February 2017, Kyowa will distribute, sell and promote Bipresso® Extended-Release Tablets exclusively in Japan.

Dr. Fabrice Egros, chairman and representative director of Kyowa, remarked, *"Today Kyowa is entering the CNS specialty field to serve high medical needs for patients suffering from severe diseases. Bipresso® Extended Release Tablets received its NHI price listing following PMDA approval last July based on a governmental advisory body request for its high medical need. It is estimated that hundreds of thousands patients are suffering from bipolar disorder in Japan."*

(\*from Ministry of Health, Labour and Welfare's homepage on bipolar disorder:  
[http://www.mhlw.go.jp/kokoro/specialty/detail\\_bipolar.html](http://www.mhlw.go.jp/kokoro/specialty/detail_bipolar.html))

Ray Tsunoda, president and representative director of Kyowa, added, *"Up till now Kyowa primarily expanded its business in generics and enhanced branded AMEL CNS generics, covering 94% of the Psychiatric Institution nationwide. Last year, Kyowa reached an agreement with Shionogi & Co., Ltd. to transfer 21 long-listed drugs, with a large part of them being essential medicines. Now with this transaction with Astellas, Kyowa will be able to provide Bipresso® Extended Release Tablets, a new product that meets a high medical need. While continuing to offer a wide variety of generic drugs under the Kyowa AMEL brand, Kyowa is reinforcing its operations by emphasizing its expertise and speciality in CNS to provide generic, long-listed and new drugs in the CNS therapeutic area. Kyowa is working to bring Bipresso® Extended Release Tablets to market as soon as possible and promote its appropriate use effectively."*

### Product Description of Bipresso® Extended Release Tablets, 50mg, 150mg

- Product name: Bipresso® Extended Release Tablets, 50mg, 150mg
- Generic name: Quetiapine Fumarate
- Indication: Improvement of depressive symptoms associated with bipolar disorder
- Dosage/Administration: Typically for adults, dosage is started at 50mg quetiapine a day, then after an interval of at least two days, dosage is increased to 150mg a day. After another interval of at least two days, dosage is increased to the recommended 300mg a day. In all cases, the drug is to be taken orally once a day before bedtime and at least two hours after a meal.
- Manufacturer: Astellas Pharma Inc.
- Manufacturing and marketing approval date: July 3rd, 2017
- Date of NHI drug price listing: August 29th, 2017
- NHI drug price: 71.00 Yen per 50mg tablet  
188.60 Yen per 150mg tablet
- Planned launch date: Around Late October

#### **About Kyowa Pharma**

Founded in 1954, Kyowa Pharmaceutical Industry Co., Ltd. (<http://www.kyowayakuhin.co.jp/>) develops, manufactures and sells branded and generic pharmaceutical products for patients in the Japanese market. With sales of 28.8 billion yen for the fiscal year ended March 2017, Kyowa is one of the fastest growing pharmaceutical companies in Japan. With a diverse product lineup that covers cardiovascular, gastroenterology and a wide variety of other segments, Kyowa has a particularly strong presence in the central nervous system/neurology space and covers 94% of the 1,400 psychiatric hospitals in Japan. In addition to its Kyowa AMEL brand franchise of high-quality generic drugs, Kyowa is reinforcing its operations by emphasizing its expertise and speciality in CNS to provide generic, long-listed and new drugs in the CNS therapeutic area.

Kyowa is a Japanese subsidiary of Lupin Limited.

#### **About Lupin Limited**

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 7<sup>th</sup> and 6<sup>th</sup> largest generics pharmaceutical company by market capitalization (June 30<sup>th</sup>, 2017, Bloomberg) and revenues (March 31<sup>st</sup>, 2017, Bloomberg) respectively. The Company is the 4<sup>th</sup> largest pharmaceutical player in the US by prescriptions (Quintiles IMS MAT March 2017); 2<sup>nd</sup> largest Indian pharmaceutical company by global revenues (March 31<sup>st</sup>, 2017, Bloomberg); 6<sup>th</sup> largest generic pharmaceutical player in Japan and 6<sup>th</sup> largest company in Indian Pharmaceutical Market (Quintiles IMS MAT June 2017).



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For the financial year ended 31<sup>st</sup> March, 2017, Lupin's Consolidated sales and Net profit stood at Rs. 171,198 million (USD 2.55 billion) and Rs. 25,575 million (USD 381 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter - [www.twitter.com/lupinlimited](http://www.twitter.com/lupinlimited)

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