

# Press Release

August 30, 2017  
Kyowa Pharmaceutical Industry Co., Ltd.

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

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.

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-Labeled 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/speciality/detail\\_bipolar.html](http://www.mhlw.go.jp/kokoro/speciality/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.”

#### 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.

For further information, please contact:

President's Office, Kyowa Pharmaceutical Industry Co., Ltd.

[kyowa-info@kyowayakuhin.co.jp](mailto:kyowa-info@kyowayakuhin.co.jp)