Kowa Company, Ltd. Mitsubishi Tanabe Pharma Corporation

## Launch of Pitavastatin Calcium, a Hypercholesterolemia Treatment Agent, in Taiwan

Kowa Company, Ltd. (Nagoya, President & CEO: Yoshihiro Miwa, hereinafter "Kowa") and Mitsubishi Tanabe Pharma Corporation (Osaka, President: Michihiro Tsuchiya, hereinafter "Mitsubishi Tanabe Pharma") announced today that a consolidated subsidiary of Mitsubishi Tanabe Pharma, Tai Tien Pharmaceuticals Co., Ltd. (Taipei, Taiwan), started marketing pitavastatin calcium (generic name, brand name in Japan: Livalo Tablets), a hypercholesterolemia treatment agent, in Taiwan on June 1, 2012, according to the agreements on exclusive development and commercialization licenses for the drug between Kowa and Tai Tien Pharmaceuticals Co., Ltd.

Pitavastatin, whose raw material is created and manufactured by Nissan Chemical Industries, Ltd., is commercialized (development, manufacture, marketing and alliance) globally and exclusively by Kowa. As a new HMG-CoA reductase inhibitor that exhibits strong LDL cholesterol lowering action. Pitavastatin is positioned as a strong statin, and due to many findings, apart from that excellent effect of dyslipidemia improvement, other characteristics such as safety in long-term use, decreases in the occurrence of drug-drug interactions and usefulness when patients have diabetes complication have also been confirmed. Kowa obtained manufacturing approval in Japan in July, 2003 and sales of the drug started in September of the same year. Sales of Livalo Tablets in 2010 in Japan reached \(\frac{4}{2}\)5 billion.

Kowa is proactively promoting the overseas development and commercialization of drugs, aiming at the global expansion of its pharmaceutical business centered on pitavastatin. So far, Kowa has commenced sales of the drug in many countries including the U.S. and China through other business partners, and commenced sales in Spain, as the first launch in Europe, in May 2011, and in Mexico, as the first launch in the Central & South America, in February of this year. Pitavastatin is marketed in 11 overseas countries including Taiwan. Kowa will promote the global expansion of pitavastatin covering 5 continents within this year.

Meanwhile, Mitsubishi Tanabe Pharma is currently working on the promotion of overseas business expansion. In the U.S. and Europe, Mitsubishi Tanabe Pharma is conducting in-house promotion such as premarketing and establishing sales system for kidney disease treatment, while in Asian countries; it works to rapidly launch new products and to strengthen operating basis through its subsidiaries in each country. Mitsubishi Tanabe Pharma expects early penetration of pitavastatin in Taiwanese market and maximization of the sales through the excellent marketing capabilities of Tai Tien Pharmaceuticals Co., Ltd. and the strong synergies with their good performance, experience of existing drugs in the cardiovascular area.

Through this alliance, the companies will continue to work for maximization of the pitavastatin business as well as strengthening their business expansions in Asia, a promising market in the world.

## [Reference] Pitavastatin global development

Country or region name	Status	Launch (schedule)	Marketing partner
Japan	Launched	September 2003	Kowa Pharmaceutical Co. Ltd. Daiichi Sankyo Company, Limited
Korea	Launched	July 2005	Choongwae Pharma Corporation
Thailand	Launched	January 2008	Biopharm Chemical Co., Ltd.
China	Launched	July 2009	*1
USA	Launched	June 2010	*2
Spain	Launched	May 2011	Recordati, Esteve
Portugal	Launched	June 2011	Recordati, Delta
Europe	*3	2012	KPE, Recordati
Lebanon	Launched	March 2011	Algorithm
Middle East	Preparing the application	2013	Algorithm
Mexico	Launched	February 2012	Eli Lilly & Co.
Indonesia	Launched	May 2012	P.T. Tanabe Indonesia
Taiwan	Launched	June 2012	Tai Tien Pharmaceuticals Co., Ltd.
Central & South America	Application filed	2012	Eli Lilly & Co.
Australia	Approved	2012	Abbott

- \*1 In China, Kowa is advancing the provision of information to medical institutions and doctors on the appropriate use of pitavastatin and conducting information gathering activities through Kowa (Shanghai) Pharma Consulting Co., Ltd., a wholly-owned subsidiary of Kowa.
- \*2 In the United States, Kowa Pharmaceuticals America, Inc. (Alabama, USA), a wholly-owned subsidiary of Kowa, sells and markets pitavastatin with a co-promotion partner, Eli Lilly (Indiana, USA).
- \*3 Development in Europe

Approved

Ireland, U.K., Netherlands, Sweden, Norway, Finland, France, Belgium, Germany, Greece, Cyprus, Austria, Poland

Application filed

Italy

Media inquiry			
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