Livazo® (pitavastatin), a new potent statin with beneficial effects on lipid fractions associated with heart disease, launches in Spain

Wokingham, UK, 3 May 2011: Kowa Pharmaceutical Europe welcomes the first European launch of its statin, pitavastatin in Spain, where it will be marketed and distributed as Livazo® by Recordati, and as Alipza® by Recordati’s partner distributor, Esteve.

Spain is the first European market for Livazo, which is indicated for patients with primary hypercholesterolaemia and / or mixed dyslipidemia.¹ Kowa Pharmaceutical Europe Co. Ltd., with Recordati, intends to launch Livazo in further European markets later this year and into 2012.

Livazo is a potent statin that combines effective control of low density lipoprotein-cholesterol (LDL-C) and triglycerides (TG), with long-term incremental high density lipoprotein-cholesterol (HDL-C) increase and, due to its novel structure, is less likely to have drug-to-drug interactions.² Its effectiveness has been demonstrated in several Phase III clinical studies:

- Livazo safely and effectively reduced LDL-C and achieved European Atherosclerosis Society (EAS) guideline targets in the majority of patients with primary hypercholesterolaemia or mixed dyslipidemia, similar to reductions seen with atorvastatin³ and simvastatin⁴
- Livazo 2 mg and 4 mg demonstrated comparable efficacy to commonly prescribed statins, with 2 mg Livazo demonstrating statistically significant superior efficacy compared with simvastatin 20 mg in lowering LDL-C, non high-density lipoprotein cholesterol (non-HDL-C) and total cholesterol (TC)⁴
- Livazo effectively reduced LDL-C in the elderly⁵ and also improved LDL-C and other parameters of lipid metabolism in patients at higher cardiovascular risk²
- Livazo was superior to pravastatin in improving LDL-C in elderly patients ( aged 65 years and older)⁵
- Livazo demonstrated a gradual and sustained increase in HDL-C over the long-term, supported by data from a 52 week extension study.⁶

“Pitavastatin is an attractive treatment option for clinically complex patients in Europe on multiple medications, due to its distinct pharmacological characteristics, among which the low drug-drug interaction seen in clinical trials is particularly relevant. It has also shown strong efficacy in metabolic syndrome patients without effect on HbA1C levels, as well as in elderly patients,” said Professor John Chapman, Director, Dyslipidemia and Atherosclerosis Research Unit, National Institute of Health and Medical Research, Hôpital de la Pitié-Salpêtrière Université Pierre et Marie Curie Paris, France.

“Innovative treatments such as Livazo are key to advancing disease management as it has shown this innovative statin not only lowers LDL-C effectively but also addresses low residual risk, meaning associated with low HDL-C, clearly suggesting that it has the potential to increase the proportion of patients achieving treatment targets,” added Prof Chapman.
High cholesterol levels are a major risk factor for heart disease (cardiovascular disease), the number one cause of death globally\(^7\) and accounts for 33% of all deaths in Spain.\(^8\)

The overall safety and tolerability of pitavastatin are consistent with other commonly prescribed statins. In Phase III studies comparing pitavastatin with atorvastatin,\(^3\) simvastatin\(^4\) and pravastatin,\(^5\) the overall safety profile of pitavastatin was demonstrated, with low incidences of adverse events. All three doses of pitavastatin (1, 2 and 4 mg) demonstrated a comparable safety profile to 10, 20 and 40 mg of pravastatin,\(^5\) which is considered to be the statin least likely to cause adverse drug reactions or drug–drug interactions. Additionally, pitavastatin has demonstrated a long-term safety profile (to 52 weeks),\(^6\) comparable to that of simvastatin\(^9\) or atorvastatin.\(^10\)

Drummond Paris, President of Kowa Research Europe, said: “The launch of Livazo in Spain represents a great milestone for Kowa as our first European launch. It will be the first of many launches in Europe, the Middle East and North Africa during 2011. We are keen to offer patients across the globe improved treatment choice and access to Livazo.”

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References
1. Livazo Summary of Product Characteristics
5. Stender S, Hounslow N. Robust efficacy of pitavastatin and comparable safety to pravastatin. Atherosclerosis Suppl. 2009;10:e945
6. Ose L, Budinski D, Hounslow N, et al. Long-term treatment with pitavastatin is effective and well tolerated by patients with primary hypercholesterolemia or combined dyslipidemia. Atherosclerosis 2010; 202-208
9. Data on file (study 309)
10. Data on file (study 310)

About Livazo®

Pitavastatin (a statin) is a fully synthetic and highly potent inhibitor of HMG-CoA reductase used for primary hypercholesterolemia and combined dyslipidemia. Pitavastatin has a novel cyclopropyl
group on the base structure common to the statin class. Since its 2003 launch in Japan, pitavastatin has accumulated millions of patient-years of exposure. Many of these patients have co-morbidities and are taking multiple medications. Kowa received FDA approval of pitavastatin (Livalo®) for the treatment of primary hyperlipidemia or mixed dyslipidemia in August 2009 and it was launched in the U.S. in June 2010. Additionally, Kowa filed in Europe in August 2008 using the decentralised authorisation procedure and received regulatory approval in mid 2010. In much of Europe, pitavastatin will be marketed by Recordati as Livazo. Pitavastatin will be available in three dosage strengths (1 mg, 2 mg and 4 mg).

<table>
<thead>
<tr>
<th>Country/area</th>
<th>Current status</th>
<th>Launched (or expected)</th>
<th>Distributors</th>
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<tbody>
<tr>
<td>Japan</td>
<td>Launched</td>
<td>September 2003</td>
<td>Kowa Soyaku Co., Ltd, Dalichi Sankyo Co., Ltd.*1</td>
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<tr>
<td>Korea</td>
<td>Launched</td>
<td>July 2005</td>
<td>Choongwae Pharma Corporation</td>
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<tr>
<td>Thailand</td>
<td>Launched</td>
<td>January 2008</td>
<td>BioPharma Chemical</td>
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<td>China</td>
<td>Launched</td>
<td>July 2009</td>
<td>*2</td>
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<tr>
<td>USA</td>
<td>Launched</td>
<td>June 2010</td>
<td>*3</td>
</tr>
<tr>
<td>EU</td>
<td>Launched in Spain; approved in some EU countries, undergoing national phase in others</td>
<td>2011</td>
<td>*4</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Submitted</td>
<td>2011</td>
<td>Tai Tien Pharmaceuticals Co., Ltd.*</td>
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<tr>
<td>Middle East/ North Africa</td>
<td>Launched in Lebanon; preparing for other launches in 2012-2015</td>
<td>2011</td>
<td>Algorithm SAL</td>
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<td>Latin America</td>
<td>Submitted in part</td>
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<tr>
<td>Australia/ New Zealand</td>
<td>Submitted in part</td>
<td>2012</td>
<td>Abbott</td>
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*1 Co-marketing by the two companies under one brand name, Livalo. The annual sales of Livalo tablets in Japan reached $520 million in 2010.

*2 Kowa (Shanghai) Pharma Consulting Co. Ltd., a wholly-owned subsidiary of Kowa, is obtaining and providing information to physicians and hospitals in China to ensure proper use of pitavastatin.

*3 In the United States, Kowa Pharmaceuticals America, Inc. (Headquarters in Alabama, US), a wholly-owned subsidiary of Kowa, sell and market pitavastatin with a co-promotion partner, Eli Lilly (Headquarters in Indiana, US).
*4 In Europe, pitavastatin will be distributed by Kowa Pharmaceutical Europe Co. Ltd. (Headquarters in Wokingham, UK), a wholly-owned subsidiary of Kowa, and Recordati (Headquarters in Milan, Italy), a partner distributor.

About Kowa

Kowa Company, Ltd. (KCL) is a privately held multinational company headquartered in Nagoya, Japan. Established in 1894, KCL is actively engaged in various manufacturing and commercial activities in the fields of pharmaceutical, life science, information technology, textiles, machinery and various consumer products. KCL’s pharmaceutical division was founded in 1947, and is focused on cardiovascular therapeutics, with sales of the company’s flagship product, Livalo, totalling $520 million (14.3% market share) in Japan during 2010 and expected to exceed $700 million in the near future.

Kowa Research Europe Ltd. (KRE), established in 1999 in the United Kingdom, is responsible for European clinical trials for Kowa’s strategic global pharmaceutical development.

Kowa Pharmaceutical Europe Co. Ltd, established in 2000, is a specialty pharmaceutical company located in Wokingham, UK, focused primarily on cardiometabolic therapeutics. Working in harmony with KRE, these European pharmaceutical divisions of Japanese Kowa Company, Ltd. are committed to ground-breaking research, development and marketing to ensure quality products are made available to people around the world, enabling them to enjoy a better standard of health and a more comfortable life.

About Recordati

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of over 2,800, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. It has headquarters in Milan, Italy, operations in the main European countries, and a growing presence in the new markets of Central and Eastern Europe. A European field force of around 1,400 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati’s current and growing coverage of the European pharmaceutical market makes it a partner of choice for new product licenses from companies which do not have European marketing organizations.

Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2010 was € 728.1 million, operating income was € 154.8 million and net income was € 108.6 million.

For more information about Recordati please visit www.recordati.com

About Esteve

Esteve is a private family-owned group of businesses headquartered in Barcelona, Spain. Founded in 1929, Esteve has since grown into a fully integrated pharmaceutical company with nearly 3000 employees and over $ 1B in annual sales. The pursuit of excellence in discovery, development,
manufacturing, and marketing of innovative pharmaceuticals is Esteve’s top priority. Its international business activities extend to the animal health, OTC, generic, and API sectors.

To find out more please visit Esteve’s website at www.esteve.es