

## News Release

September 16, 2009

### **Merck Serono Growth Hormone Injection Device easypod<sup>®</sup> Approved in Japan**

Geneva, Switzerland, September 16, 2009 – Merck Serono, a division of Merck KGaA Darmstadt, Germany, today announced that the Japanese health authorities, the Pharmaceutical and Medical Devices Agency (PMDA), have granted a marketing authorization for easypod<sup>®</sup> in Japan. Easypod<sup>®</sup> was developed for exclusive use with cartridges of Saizen<sup>®</sup> (somatropin), Merck Serono's human recombinant growth hormone for the treatment of growth hormone deficiency.

Easypod<sup>®</sup> is an innovative electronic auto injection device designed to improve ease of usage, reliability and convenience for patients who need daily subcutaneous injections of Saizen<sup>®</sup>. It allows patients to self-inject in just three simple key steps. Additionally, a built-in dose memory automatically records the number of doses administered, allowing physicians and caregivers to accurately monitor patient adherence to therapy.

“Easypod is both an easy to use and intelligent device enabling physicians to track patients' adherence to Saizen therapy, which is an essential component for optimal treatment outcomes,” said Franck Latrille, Executive Vice President, Head of Commercial International at Merck Serono. “We are pleased to offer this innovative and successful device today to patients in Japan.”

Easypod<sup>®</sup> is registered in 39 other countries worldwide including European countries and the United States. In Japan, easypod<sup>®</sup> will be launched in the course of 2009.

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### About Growth Hormone Deficiency

Growth hormone (GH) plays a central role in the growth process and maturation from child- to adulthood and regulates a number of metabolic and physiologic processes during the whole life. In children lack of GH will result in delayed maturation and short stature, whilst in adults the signs are more subtle, and include several psychological features, such as depression, anxiety, poor memory, and social isolation, as well as the physiological problems of weakness, poor vitality, easy fatigue, and weight gain. The current prevalence of pediatric GH disorder is estimated globally to be 100,000 children<sup>1</sup> and in Europe 50,000 adults suffer from the condition<sup>2</sup>.

<sup>1</sup> Journal of Clinical Endocrinology and Metabolism 1997;V.82 No.2:349

<sup>2</sup> GH and IGF Research 2001; 11: 137-165

### About Saizen®

Saizen® (somatropin) is a recombinant human growth hormone (GH) and is therapeutically equivalent to the natural GH produced by the body.

Saizen® is currently registered in 78 countries for the treatment of:

- GH deficiency in children
- GH deficiency in adult patients
- Children born Small for Gestational Age
- Turner's syndrome
- GH deficiency in children associated with chronic renal failure

The registered indications vary slightly from one country to another.

### About Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alpha), endocrine and metabolic disorders (Saizen® and Serostim®, somatropin), (Kuvan®, sapropterin dihydrochloride) as well as cardiometabolic diseases (Glucophage®, metformin), (Concor®, bisoprolol), (Euthyrox®, levothyroxine). Not all products are available in all markets.

With an annual R&D expenditure of around € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

### About Merck

Merck is a global pharmaceutical and chemical company with total revenues of € 7.6 billion in 2008, a history that began in 1668, and a future shaped by 33,000 employees in 60 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit [www.merckserono.com](http://www.merckserono.com) or [www.merck.de](http://www.merck.de)