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Merck Serono Launches New Website On Phenylketonuria

Geneva, Switzerland, November 25, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today the launch of a website dedicated to phenylketonuria (PKU), a rare inborn metabolic disorder. Developed in collaboration with healthcare professionals and dieticians, the website aims to provide patients living outside of the United States¹, with a reliable and extensive source of information on the disease and its management, including practical tips for everyday life.

“After the launch in Europe of Kuvan[®], the first pharmaceutical treatment option for PKU, Merck Serono is pleased to provide further support to patients and their families with a new website”, said Roberto Gradnik, Executive Vice President, Commercial Europe at Merck Serono. “The website provides clear information addressing the different needs of anyone affected by this disease, whether patients, families with children suffering from PKU, or patients seeking to start a family.”

Over time, the website will be enriched with new tools and additional languages. The website is currently available in English and accessible via: <http://www.pku.com/en>. French, German, Italian and Spanish versions are expected to be available by the end of 2009, while versions in other languages are planned for 2010.

PKU is an inherited disorder whereby the body fails to break down an essential amino acid called Phenylalanine (Phe), which can be found in protein-rich food. In patients

¹ The website <http://www.pku.com> is already available to PKU patients and their families living in the US and is managed by BioMarin, Merck Serono's development partner.

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suffering from PKU, a long lasting excess level of Phe in the blood may lead to irreversible neurological disorders in children, and cognitive deficits and psychiatric disorders in adults. At present, the management of PKU consists of lifelong dietary restrictions limiting the Phe intake, often combined with food supplements or substitutes. Used with a restricted Phe diet, Kuvan[®] has been shown to help control blood levels of Phe in patients suffering from PKU.

About phenylketonuria (PKU)

PKU, a genetic disorder affecting approximately 50,000 diagnosed patients in the developed world, is caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH). PAH is required for the metabolism of phenylalanine (Phe), an essential amino acid found in all protein-containing foods. If the active enzyme is not present in sufficient quantities, Phe accumulates to abnormally high levels in the blood and brain, resulting in a variety of complications including severe mental retardation and brain damage, mental illness, seizures and tremors, and cognitive problems. As a result of global newborn screening efforts implemented in the 1960s and early 1970s, virtually all PKU patients in developed countries are diagnosed at birth.

About Kuvan[®]

Developed by Merck Serono and BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN), Kuvan (sapropterin dihydrochloride), is an oral therapeutic and the first treatment indicated in Europe for the treatment of hyperphenylalaninemia (HPA) due to phenylketonuria (PKU) in patients over the age of 4; or due to tetrahydrobiopterin (BH4) deficiency. Kuvan is the synthetic form of 6R-BH4, a naturally occurring enzyme cofactor that works in conjunction with the enzyme phenylalanine hydroxylase (PAH) to metabolize phenylalanine (Phe). Clinical data show that Kuvan produces significant reductions in blood Phe levels in the subset of patients who are BH4-responsive.

Most common side effects reported with the use of Kuvan include headache, runny nose, diarrhea, vomiting, sore throat, cough, abdominal pain, stuffy nose and low levels of phenylalanine in the blood.

Kuvan is approved in 32 countries, including member states of the European Union and the USA. Under the terms of the agreement with BioMarin, Merck Serono has exclusive rights to market Kuvan in all territories outside the USA, Canada and Japan.

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 (Erbix[®], 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



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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 approximately 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 or www.merck.de