

News Release

May 5th, 2009

Merck Serono Launches Glucophage Powder in First European Countries

- **Innovative powder formulation of metformin designed to facilitate adherence by increasing patient choice in the treatment of type 2 diabetes, now available in France and the United Kingdom**

Geneva, Switzerland, May 5th, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, today announced that Glucophage[®] Powder for Oral Solution in Sachets, (metformin hydrochloride in 500mg, 850mg and 1000mg strengths) indicated for the first-line treatment of type 2 diabetes mellitus, is now licensed in France and the United Kingdom¹, the first European countries to launch this new formulation of Glucophage. Launches in other European countries are expected to take place in the coming months, once individual marketing authorizations are granted.

Bioequivalent to the existing Glucophage tablets, the new powder formulation is packaged in individual sachets of 500mg, 850mg and 1000mg.¹ Glucophage powder can be easily dissolved in water to produce a clear to slightly opalescent solution.

“Adherence to therapy is increasingly being recognized by physicians as a key condition to achieve glycaemic control for patients with diabetes,” said Roberto Gradnik, Executive Vice President Commercial Europe at Merck Serono. “We are pleased to provide this innovative powder formulation of Glucophage to patients seeking a convenient alternative to tablets which may facilitate their adherence to treatment.”

The International Diabetes Federation (IDF) estimates that diabetes currently affects 246 million people worldwide, representing roughly 6% of the adult population;

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this number is expected to rise to 380 million by 2025. Type 2 diabetes constitutes about 85% to 95% of all diabetes cases in developed countries and accounts for an even higher percentage in developing countries. The IDF recommends that metformin remains a drug of choice for first-line therapy of type 2 diabetes.²

The American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) advise that metformin therapy should be initiated concurrently with lifestyle intervention at diagnosis of type 2 diabetes.³ However the current therapeutic indication for Glucophage remains the treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control.

References

¹ In the United Kingdom, Glucophage[®] Powder for Oral Solution in Sachets is available in 500mg and 1000mg strengths only.

² International Diabetes Federation, Global Guideline for Type 2 Diabetes, accessed via: <http://www.idf.org/webdata/docs/IDF%20GGT2D.pdf>

³ Nathan DM et al., Medical Management of Hyperglycemia in Type 2 Diabetes: a Consensus Algorithm for the Initiation and Adjustment of Therapy, *Diabetes Care* 2009, 32:193-203

About Glucophage[®] (metformin hydrochloride)

Glucophage[®] has been approved worldwide as a first line treatment of Type 2 diabetes. It belongs to the biguanide class of molecules, which decrease glucose production by the liver. A primary objective of type 2 diabetes treatments is to correct the dual effects of tissue unresponsiveness to insulin (insulin resistance) and insulin deficiency arising from impaired functioning of the beta cells in the pancreas that make insulin. Metformin corrects insulin resistance by making tissues, such as the liver and muscle, responsive to insulin. This way, patients get less "in-house" glucose production in the liver and better glucose uptake into muscle, where it is stored as glycogen or burnt off to produce energy. The net result is restoration of normal glucose levels.

The wealth of evidence documented in some 5,600 scientific publications since 1957, the year of metformin's introduction into clinical practice, led the International Diabetes Federation (IDF) to recommend metformin as the 1st line therapy of choice for the treatment of type 2 diabetes in its global guidelines, issued in 2005. A landmark study, the United Kingdom Prospective Diabetes Study (UKPDS) has shown metformin to be effective at lowering blood glucose and reducing the risk of long term complications (eg heart attacks and strokes).



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Merck Serono is a world market leader in oral diabetes medications. More than six million patients in over 100 countries around the globe currently benefit from various products of the Glucophage® family.

Glucophage® Powder for Oral Solution in Sachet is a new formulation manufactured under license from Dainippon Sumitomo Pharma Co., Ltd. Osaka, Japan.

About Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. Its North American business operates in the United States and Canada as EMD Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alfa), endocrine and cardiometabolic disorders (Glucophage®, metformin); (Concor®, bisoprolol); (Euthyrox®, levothyroxine); (Saizen® and Serostim®, somatropin). 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 32,700 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