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**KIOVIG IVIG THERAPY FOR TREATMENT OF MULTIFOCAL MOTOR  
NEUROPATHY NOW AVAILABLE IN THE UK**

11<sup>th</sup> October 2011 – Baxter International Inc. (NYSE:BAX) has announced the availability of KIOVIG in the UK for multifocal motor neuropathy (MMN), a severe, debilitating disorder requiring lifelong treatment. On July 27, 2011 Baxter received marketing authorisation for KIOVIG MMN indication in all European Union (EU) Member States- the first centrally-licensed indication for an immunoglobulin preparation for MMN. MMN is a rare autoimmune disorder characterised by progressive muscle weakness in the limbs, leading to significant difficulty with simple manual tasks.<sup>1</sup>

“Baxter is pleased to now offer patients suffering from MMN a licensed treatment option to improve and maintain motor function and limb strength,” said Professor Hartmut Ehrlich, vice president, global research and development for Baxter’s BioScience business. “Baxter remains committed to building upon its long history and proven experience with IVIG therapy to advance treatment in targeted neurological disorders, such as MMN.”

The KIOVIG EU marketing authorization for the indication MMN was based on two prospective, open label, investigator initiated clinical efficacy studies in patients with MMN, both showing maintenance of muscle strength and reduction in patients’ disability.

“MMN is a debilitating auto-immune disorder that affects individuals’ limb strength and motor skills at the prime age of their lives, requiring life-long treatment,” said Leonard van den Berg, MD, PhD, Professor in Neurology at the University Medical Center, Utrecht, The Netherlands. “IVIG therapy has long been recognised as recommended therapy for MMN by neurologists. However, due to the rarity of this disorder the availability of efficacy data and treatment options for MMN remain low despite years of research. The availability of KIOVIG for MMN marks an important new opportunity for physicians to improve the lives of patients suffering from MMN.”

KIOVIG is also the only IVIG treatment offered in a 30 gram vial. This larger vial size offers added convenience of dosing for patients requiring larger doses of IVIG treatment.

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## **Note to Editors:**

### **About Multifocal Motor Neuropathy (MMN)**

MMN is a rare, auto immune-mediated disorder characterised by slowly progressive, asymmetric, distal weakness of one or more limbs, most commonly starting with the arms, leading to significant difficulty with simple manual tasks.<sup>1</sup> MMN is caused by disorder/malfunctions in the conduction pathway of motor nerves, limiting transmission of electrical impulses with no sensory loss. If left untreated, MMN often progresses to more severe weakness, including muscle atrophy, involuntary twitching and cramps. Almost 80% of people with MMN are between 20 and 65 years of age at onset of the disease, and men are more frequently affected than women (3:1). The prevalence is estimated to be 1-2 per 100,000 persons qualifying MMN as a rare (orphan) disease.<sup>2</sup>

Treatment options for MMN patients are limited. IVIG has been the standard of care for the treatment of MMN for almost 20 years. Available data on the efficacy of IVIG treatment in patients with MMN have been limited due to the rare nature of the condition, small patient populations studied and the inter-individual variability in response rates.

An analysis (Cochrane Review) across all randomised controlled-trials on IVIG treatment in MMN demonstrated a non-significant trend towards improvement in disability after intravenous immunoglobulin compared with placebo, but a significant improvement in muscle strength.<sup>3</sup>

The treatment of MMN with IVIG is recommended by the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) in their Guideline on Management of Multifocal Motor Neuropathy<sup>4</sup> and the Guideline for the Use of IVIG in the Treatment of Neurological Diseases<sup>5</sup>, the UK Department of Health, Clinical Guidelines for

Immunoglobulin Use<sup>6</sup>, Canadian IVIg Haematology and Neurology Expert Panels, Guidelines on the Use of Intravenous Immune Globulin for Neurologic Conditions<sup>7</sup>

### **About KIOVIG**

KIOVIG was approved in Europe in 2006 and has been available in the United States since 2005 (marketed as GAMMAGARD LIQUID™ [Immune Globulin Intravenous (Human)]). KIOVIG is a human normal immunoglobulin (IVIg), 10% solution indicated in adults, children and adolescent (0-18years) for replacement therapy in the treatment of Primary Immunodeficiency Syndromes, hypogammaglobulinemia and recurrent bacterial infections in patients with chronic lymphocytic leukemia and in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation, hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT) and congenital AIDS with recurrent bacterial infections.

KIOVIG is also indicated for immunomodulation in idiopathic thrombocytopenic purpura (ITP), Guillain Barré syndrome, Kawasaki Disease. On July 27 2011, marketing authorization was granted for the extension of the therapeutic indications of KIOVIG to include a new indication for MMN.

A 30g/300 ml vial size for KIOVIG was approved on 5 May 2010. The addition of the 30g format can be combined with the 20g, 10g, 5g, 2.5g and 1g vial sizes to meet dosing requirements with fewer vials.

### **KIOVIG Important Safety Information**

Side effects for KIOVIG include the following: very common: headache, pyrexia; common: bronchitis, nasopharyngitis, dizziness, migraine, vertigo, tachycardia, flushing, hypertension, cough, rhinorrhoea, diarrhoea, nausea, vomiting, pruritus, rash, urticaria, back pain, myalgia, pain in extremity, fatigue, influenza-like illness, infusion site pain, infusion site swelling, rigors, increased body temperature.

See Summary of Product Characteristics for more detail and information on KIOVIG is available on the website of the European Medicines Agency (EMA) <http://www.ema.europa.eu/>.

## About Baxter

Baxter Healthcare Ltd. is the primary domestic operating subsidiary of Baxter International Inc. (NYSE: BAX). Baxter is a global, diversified healthcare company that develops products and therapies to make a meaningful difference in the lives of people with life-threatening conditions such as haemophilia, kidney disease, immune disorders and other chronic and acute conditions.

## References

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- <sup>2</sup> Nobile-Orazio, E Multifocal Motor Neuropathy, Journal of Neuroimmunology, 2001 v115 p4-18
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- <sup>6</sup> UK Department of Health (2008), Clinical Guidelines for Immunoglobulin Use, Second edition. [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085235](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085235).
- <sup>7</sup> Feasby T, Banwell B, Benstead T et al. (2007) Guidelines on the use of intravenous immune globulin for neurologic conditions. Transfus.Med.Rev., 21, S57-107.