

PRESS STATEMENT: RESPONSE TO NICE GUIDANCE UPDATE FOR TYPE 2 DIABETES

28 May 2008 – Merck Sharp & Dohme welcomes the new type 2 diabetes national clinical guideline issued today from the National Institute for Health and Clinical Excellence (NICE) and looks forward to the rapid update for newer therapies, including incretin enhancers such as MSD's sitagliptin.

The guidance highlights the importance of optimal glucose control and the need for a more holistic approach to managing each patient as an individual, considering for example key issues such as risk of hypoglycaemia and weight management. It also acknowledges that given the progressive nature of type 2 diabetes, with time, the majority of type 2 diabetes patients will require more than one therapy to control their blood sugar level.¹

The EMEA recently flagged incretin enhancers (DPP-4 inhibitors) as medicines of notable public health interest.² Incretin enhancers, including sitagliptin, have already been approved for use in certain patients by the Scottish Medicines Consortium (SMC) in Scotland. These newer agents are not covered in this NICE guideline but are currently being considered by NICE as part of a rapid update.

Approximately eighty percent of type 2 diabetes patients remain uncontrolled after adding a sulphonylurea (SU) or glitazone to their metformin therapy.³

In addition, hypoglycaemia, or fear of hypoglycaemia, and weight gain can limit the ability of commonly prescribed diabetes medications to achieve and maintain the optimum glucose levels needed to prevent the onset of complications.^{4,5} It is estimated that each year in the UK over 5,000 patients will experience a severe event caused by their SU therapy which will require emergency intervention.⁵

Regular review and the availability of newer, alternative oral treatment options, such as sitagliptin, are therefore key to helping patients reach glucose targets and so potentially helping to prevent the onset of costly complications,^{1,6} whilst benefiting from being managed largely in primary care.

Sitagliptin was first licensed in the UK in April 2007 and currently offers the broadest range of indications of all licensed DPP-4 inhibitors in the UK.⁷ To date, there have been over four million prescriptions worldwide.⁸

Professor Anthony Barnett, Birmingham & Heartlands Trust, comments: "It is encouraging to see the emphasis the new Type 2 Diabetes Guideline has placed on optimising glucose control while bearing in mind the specific needs of individual patients such as those at risk of hypoglycaemia and weight gain. It is important that patients have access to newer agents, such as DPP-4 inhibitors and incretin mimetics, and although not fully reviewed in this Guideline we look forward to NICE recognising this in the rapid update."

-ENDS-

Notes to editor

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¹ Type 2 diabetes (update): national clinical guideline for the management in primary and secondary care. National Institute for health and Clinical Excellence, May 2008.

² EMEA annual report 2007, pg 21. Accessed 22 May 2008.

<http://www.emea.europa.eu/pdfs/general/direct/emeaar/AnnualReport2007.pdf>

³ RECAP study: glycaemic control goal attainment among type 2 diabetic patients who initiated oral combination therapy in Europe: EASD 2007

⁴ Amiel SA, Dixon T, Mann R *et al.* Hypoglycaemia and Type Diabetes. *Diabetic Medicine*

⁵ Barnett A, A review of the effects of antihyperglycaemic agents on body weight, *CMRO*, Vol23. No7, 2007, 1493-1507

⁶ UKPDS Group. Glycaemic control with diet, metformin, sulphonylurea, or insulin in patients with type 2 diabetes. *JAMA* 1999; Vol 281: No 21: 2005-2012

⁷ 'Januvia' (sitagliptin). Summary of Product Characteristics. MSD UK 2007

⁸ IMS Health, NPA™ Weekly, TRxs, week-ending October 20, 2006 through week-ending March 21, 2008.