European Medicines Agency

London, 23 November 2009
Doc. Ref.: EMEA/763788/2009

PUBLIC STATEMENT ON

Irbesartan BMS
(irbesartan)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 19 January 2007 the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Irbesartan BMS (irbesartan). Irbesartan BMS is approved for the treatment of essential hypertension and the treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.

The marketing authorisation holder (MAH) responsible for Irbesartan BMS was Bristol-Myers Squibb Pharma EEIG. The European Commission was notified by letter dated 20 October 2009 of the MAH's decision to voluntarily withdraw the Marketing Authorisation for Irbesartan BMS for commercial reasons.

Irbesartan BMS has not been marketed anywhere in the European Union and there is no intention to market Irbesartan BMS in the future. Irbesartan BMS was an informed consent application to Karvea.

The MAH will maintain the Marketing Authorisation for another medicinal product containing irbesartan, i.e. Karvea.

On 11 November 2009 the European Commission issued a decision to withdraw the marketing authorisation for Irbesartan BMS. Pursuant to this decision the European Public Assessment Report for Irbesartan BMS will be updated to reflect that the Marketing Authorisation is no longer valid.

Xavier Luria
Head of Sector
Safety and Efficacy of Medicines

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu