London, 19 November 2007 Doc. Ref. EMEA/522741/2007

PUBLIC STATEMENT ON THE CESSATION OF MARKETING OF

EXUBERA (Insulin human)

On 24 January 2006 the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Exubera, insulin human, 1 mg and 3 mg pre-dispensed inhalation powder, which has been approved for the treatment of type 2 diabetes mellitus in adults not adequately controlled with oral antidiabetic agents and requiring insulin therapy.

The Marketing Authorisation Holder (MAH) responsible for Exubera is Pfizer Limited. The European Medicines Agency was notified by the MAH in a letter dated 19 October 2007 of its decision to cease selling and supplying Exubera in all European Union markets from 16 January 2008 based on commercial reasons. The letter from the MAH is available here.

Therapeutic alternatives are available throughout the European Union. Patients taking Exubera or participating in an Exubera clinical trial are advised to consult their physician.

The European Public Assessment Report for Exubera is available here.

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