European Medicines Agency
Press office

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PRESS RELEASE
EMEA recommends information on lung cancer cases to be included in Exubera product information

The European Medicines Agency (EMEA) has recommended that the product information for Exubera be updated with new information on cases of lung cancer seen in patients taking the medicine.

Exubera, from Pfizer Limited, is a fast-acting insulin powder for inhalation, used for the treatment of adults with type 1 or type 2 diabetes.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) reviewed the information on cases of lung cancer as part of the continuous monitoring of medicines. A total of seven cases of lung cancer associated with the use of Exubera have been reported. Five of the cases occurred in patients who took Exubera in clinical studies comparing the medicine with other diabetes treatments (corresponding to 3,800 patient-years of exposure). In contrast, lung cancer was diagnosed in one patient who had taken a comparator medicine, out of 3,900 patient-years of exposure. One additional case was reported in a study where Exubera was not compared with other treatments. The remaining case was reported in a patient who received the medicine once it was available on the market. All of the lung cancer cases occurred in patients who had been cigarette smokers.

The relatively small number of cases and the limited information provided, as well as the fact that they only occurred in patients who had been smokers did not allow the CHMP to establish a causal relationship between the cases of lung cancer and treatment with Exubera. However, as a precautionary measure, the CHMP recommended to update the product information. In addition, the Committee requested the marketing authorisation holder to perform a study to look at the possible risk of lung cancer developing in patients who have taken Exubera.

The marketing authorisation holder stopped distribution of Exubera in January 2008 for commercial reasons. It is expected that the medicine will no longer be available in the European Union from September 2008.

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Notes:

1. More information is available in a question-and-answer document.
2. Exubera was first authorised in the European Union on 24 January 2006. More information about the medicine is available in the European Public Assessment Report (EPAR), which can be found at: http://www.emea.europa.eu/humandocs/Humans/EPAR/exubera/exubera.htm
3. One patient-year is the equivalent of one patient taking the medicine for one year.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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