European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency update on safety of insulin glargine

The European Medicines Agency (EMEA) is looking into four recently published registry studies investigating a possible relationship between insulin analogues, in particular insulin glargine, and the risk of cancer. The studies were published on the Diabetologia website on 26 June 2009.

Insulin glargine is a long-acting insulin analogue, authorised in the European Union (EU) as Lantus and Optisulin, for the treatment of adults, adolescents and children aged six years or above with diabetes, when treatment with insulin is required.

The results of the four studies were found to be inconsistent. In two studies (Scottish Diabetes Research Network Epidemiology Group and Jonasson et al) an association between breast cancer was found in a group of patients taking insulin glargine as monotherapy, but not in another group of patients using insulin glargine together with other types of insulin. For other cancers, no association was found. In these two studies dose-dependency was not evaluated. The third study (Hemkens et al) reported a dose-dependent association between use of insulin glargine and malignancies. However, no information is available on the types of cancer found in this study. In the fourth study (Currie et al), no association between cancer (either breast, colorectal, pancreatic or prostate cancer) and the use of insulin glargine, or any other insulin, was found.

On the basis of the currently available data, a relationship between insulin glargine and cancer cannot be confirmed nor excluded. However, the concerns raised by the four studies require further in-depth evaluation.

The Agency's Committee for Medicinal Products for Human Use (CHMP) will perform a detailed assessment of the studies' results and any other relevant information. This review will also address issues, such as dose-response effects, the implications of the relatively short duration of the studies and influence of other factors on the risk of breast cancer and other cancers (e.g. age, body mass index (BMI), menopausal status, parity, socioeconomic status).

The Marketing Authorisation Holder for Lantus and Optisulin, Sanofi-Aventis, has been asked to comment on this potential safety concern.

Patients being treated with insulin glargine are advised to continue their treatment as normal. At this time there is no recommendation that patients should change their current treatment. In case of any concerns, patients should consult their doctor.

Further information will be provided once the CHMP has concluded its review.

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Notes:

1. The articles are available online here: http://www.diabetologia-journal.org/cancer.html
2. Insulin analogues, such as insulin glargine, are substances that are similar to human insulin, but with some modifications that change properties such as the way the insulin is absorbed after injection or its duration of action.
3. Lantus and Optisulin have been authorised in the European Union since June 2000. They are marketed in all 27 EU Member States.
4. More information on Lantus and Optisulin is available in the European Public Assessment Report EPAR. For Lantus, please see:

http://www.emea.europa.eu/humandocs/Humans/EPAR/lantus/lantus.htm; For Optisulin, please see: http://www.emea.europa.eu/humandocs/Humans/EPAR/optisulin/ optisulin.htm

5. 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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