



Incretin Mimetic Drugs for Type 2 Diabetes: Early Communication – Reports of Possible Increased Risk of Pancreatitis and Pre-cancerous Findings of the Pancreas

[Posted 03/14/2013]

FDA正在評估一項未發表研究的新發現：第二型糖尿病患者使用incretin mimetics藥物，會增加胰臟炎和癌前期細胞變化(pancreatic duct metaplasia)的風險。此研究發現，是根據少量胰臟組織的檢驗結果，胰臟組織取自於未明原因死亡的患者。FDA已要求研究人員提供的該項研究的方法，以利機構進一步研究。

建議

FDA尚未對incretin mimetic drugs的安全性做出結論。提早發布安全訊息的目的，是為了公告大眾及醫療人員：FDA會進一步評估此訊息，並在2013年6月參加NIDDK、NCI研討會討論胰臟炎/糖尿病/胰臟癌的議題。

Incretin mimetic drugs的仿單和注意事項有標註急性胰臟炎的風險警告。FDA之前未發布相關風險，未來不排除其可能性。

病患應繼續依照指示使用藥品，有相關問題時，醫療人員應依據藥品仿單開立處方。

[Posted 01/10/2013]

AUDIENCE: Gastroenterology, Endocrinology, Oncology, Patient

ISSUE: FDA is evaluating unpublished new findings by a group of academic researchers that suggest an increased risk of pancreatitis and pre-cancerous cellular changes called pancreatic duct metaplasia in patients with type 2 diabetes treated with a class of drugs called incretin mimetics. These findings were based on examination of a small number of pancreatic tissue specimens taken from patients after they died from unspecified causes. FDA has asked the researchers to provide the methodology used to collect and study these specimens and to provide the tissue samples so the Agency can further investigate potential pancreatic toxicity associated with the incretin mimetics.

BACKGROUND: Drugs in the incretin mimetic class include exenatide (Byetta, Bydureon), liraglutide (Victoza), sitagliptin (Januvia, Janumet, Janumet XR, Juvisync), saxagliptin (Onglyza, Kombiglyze XR), alogliptin (Nesina, Kazano, Oseni), and linagliptin (Tradjenta, Jentadueto). These drugs work by mimicking the incretin hormones that the body usually produces naturally to stimulate the release of insulin in response to a meal. They are used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

RECOMMENDATIONS: FDA has not reached any new conclusions about safety risks with incretin mimetic drugs. This early communication is intended only to inform the public and health care professionals that the Agency intends to obtain and evaluate this new information. FDA will participate in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and National Cancer Institute's (NCI) Workshop on Pancreatitis-Diabetes-Pancreatic Cancer in June 2013 to gather and share additional information. FDA will communicate its final conclusions and recommendations when its review is complete or when the Agency has additional information to report.

The Warnings and Precautions section of drug labels and patient Medication Guides for incretin mimetics contain warnings about the risk of acute pancreatitis. FDA has not previously communicated about the potential risk of pre-cancerous findings of the pancreas with incretin mimetics. FDA has not concluded these drugs may cause or contribute to the development of pancreatic cancer.

At this time, patients should continue to take their medicine as directed until they talk to their health care professional, and health care professionals should continue to follow the prescribing recommendations in the drug labels.