Saxagliptin (marketed as Onglyza and Kombiglyze XR): Drug Safety Communication – FDA to Review Heart Failure Risk

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FDA要求saxagliptin製造商提出臨床試驗數據，藉以調查使用第二型糖尿病藥物與心衰竭的關聯性。FDA要求一篇發表於NEJM的研究提供研究結果，該篇研究報告：心臟無法輸出足量血液的患者，分別使用saxagliptin與安慰劑(an inactive treatment)，前者心衰竭住院的風險較高。使用saxagliptin的患者，該研究未發現死亡率或其他嚴重心血疾病風險有增加。Saxaglitpin製造商預計於2014年3月上旬將試驗數據提交給FDA，FDA將進行分析並公布調查結果。

FDA目前認為NEJM研究結果是初步的。分析saxagliptin臨床實驗數據，是評估「所有第二型糖尿病藥物和心血管疾病風險」的一部分。

建議

患者不應停止服用saxagliptin，有任何問題或疑慮，應向醫療人員討論；醫療人員應繼續依仿單建議處方該藥物。

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AUDIENCE: Cardiology, Endocrinology, Pharmacy

ISSUE: FDA has requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of the type 2 diabetes drug and heart failure. FDAs request resulted from a study published in the New England Journal of Medicine (NEJM), which reported an increased rate of hospitalization for heart failure, when the heart does not pump blood well enough, with use of saxagliptin (marketed as Onglyza and Kombiglyze XR) compared to an inactive treatment. The study did not find increased rates of death or other major cardiovascular risks, including heart attack or stroke, in patients who received saxagliptin. The manufacturer is expected to submit the trial data to FDA by early March 2014, after which FDA will conduct a thorough analysis and report findings publicly.

At this time, FDA considers information from the NEJM study to be preliminary. Analysis of the saxagliptin clinical trial data is part of a broader evaluation of all type 2 diabetes drug therapies and cardiovascular risk.

BACKGROUND: Saxagliptin is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. It works by increasing the amount of insulin produced by the body after meals, when blood sugar is high.

RECOMMENDATION: Patients should not stop taking saxagliptin and should speak with their health care professionals about any questions or concerns. Health care professionals should continue to follow the prescribing recommendations in the drug labels.