Bristol-Myers Squibb/AstraZeneca EEIG
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8th March 2012
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Direct Healthcare Professional Communication on the association of saxagliptin (Onglyza®) with serious hypersensitivity reactions and acute pancreatitis

Dear Healthcare Professional,

This letter is to inform you of important new safety information regarding saxagliptin use and the associated risk of serious hypersensitivity reactions and acute pancreatitis.

Summary

- Cases of serious hypersensitivity reactions, including angioedema and anaphylactic reactions and acute pancreatitis have been reported with the use of saxagliptin (Onglyza).
- Because of these safety concerns, the following recommendations for saxagliptin use have been made:

Regarding hypersensitivity reactions:

- Saxagliptin is now contra-indicated in patients with a history of serious hypersensitivity reactions, including anaphylactic reaction, anaphylactic shock, or angioedema, to saxagliptin, any dipeptidyl peptidase 4 (DPP-4) inhibitor.
- If a serious hypersensitivity reaction to saxagliptin is suspected, this treatment should be discontinued.

Regarding pancreatitis:

- Patients should be informed of the characteristic symptom of acute pancreatitis: persistent, severe abdominal pain.
- If pancreatitis is suspected, saxagliptin should be discontinued.

The information in this communication has been agreed with the European Medicines Agency (EMA) and the Irish Medicines Board (IMB).

Further information on the safety concern and recommendations to healthcare professionals

Saxagliptin is a dipeptidyl peptidase 4 (DPP-4) inhibitor indicated in adults with type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with metformin, a PPAR-γ agonist, a sulphonylurea and insulin (with or without metformin).

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A review of pharmacovigilance data identified several serious reports of angioedema and associated events and reports of anaphylactic reactions with saxagliptin use. There were also some reports of positive rechallenge. Based on the totality of available information, it was decided to contra-indicate the use of saxagliptin in patients with a history of a serious hypersensitivity reaction, such as anaphylaxis or angioedema, to any DPP-4 inhibitor.

A review of reports of pancreatitis from post-marketing experience revealed that signs of pancreatitis occurred after the start of saxaglitpin treatment and resolved after discontinuation, which is suggestive of a causal relationship. Moreover, pancreatitis has been recognized as an adverse event for other DPP-4 inhibitors.

In consideration of the above, the product information for Onglyza (saxagliptin) has been updated with information on hypersensitivity and pancreatitis (see Annex).

If pancreatitis or a serious hypersensitivity reaction to saxagliptin is suspected, treatment should be discontinued.

Call for reporting

Suspected adverse reactions should be reported to the Irish Medicines Board (IMB) using a Yellow Card obtained either from the IMB, or electronically via the website at www.imb.ie

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions, for Onglyza may also be reported to Bristol-Myers Squibb via telephone 1 800 749 749 or via email at medical.information@bms.com.

Communication information

Should you have any questions regarding the use of Onglyza, please contact Bristol-Myers Squibb Medical Information 1 800 749 749 or via email at medical.information@bms.com.

Yours sincerely,

Siobhán Mitchell.

Dr Siobhan Mitchell PhD
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On behalf of Bristol-Myers Squibb/AstraZeneca EEIG

Annex: Revised wording for Onglyza Summary of Product Characteristic (SPC)