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AstraZeneca, BMS gets positive regulatory feedback on Type 2 diabetes drug

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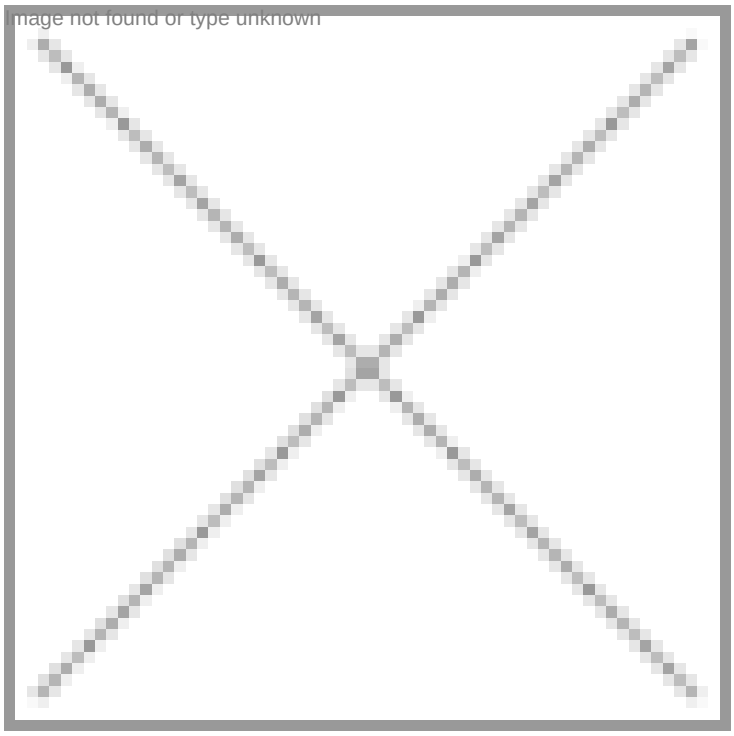

Singapore: Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has provided AstraZeneca and Bristol-Myers Squibb a positive opinion recommending approval of Xigduo (dapagliflozin and metformin hydrochloride) for adults aged 18 and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their current metformin-based treatment regimen or who are currently being treated with the combination of dapagliflozin and metformin as separate tablets.

Xigduo combines dapagliflozin (tradename Forxiga), a selective and reversible inhibitor of sodium-glucose cotransporter 2 (SGLT2), and metformin hydrochloride in a twice daily tablet. This is the first CHMP recommendation for a SGLT2 and metformin hydrochloride fixed dosage combination. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland and Norway.

Xigduo combines Forxiga and metformin hydrochloride, two anti-hyperglycaemic products with complementary mechanisms of action to improve glycaemic control. Forxiga, the first medicine in the SGLT2 class to gain regulatory approval, is currently approved for the treatment of type 2 diabetes in the European Union, Argentina, Australia, Brazil, Iceland, Mexico, Norway and New Zealand.