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AstraZeneca, Bristol-Myers Squibb - Complete Response for Dapagliflozin

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Abstracts

Today BMY and AstraZeneca jointly announced the receipt of complete response letter from FDA for its first-in-class Dapagliflozin (SGLT-2 inhibitor) which is earlier than expected PDUFA date Jan 28th (Postponed from Oct 28, 2011). FDA has requested additional data from on-going clinical studies and may require information from new clinical studies. This set back is not unexpected, as earlier in July FDA advisory committee recommended against the approval of Dapagliflozin (Vote: 9 No to 6 Yes) because of liver damage and cancer related safety concerns (possible increased risk of breast and bladder cancer). It is still unclear that the new studies would be designed to assess the risk of cancer. If it is so, it will require much larger trial to evaluate the risk of cancer with statistical significance which will further increase the cost burden for both AZN and BMY.

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COMPANIES MENTIONED

AstraZeneca, Bristol-Myers Squibb

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