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Abstracts

In line with our expectation (see our note - ADA - 2011 - Interim Review And Key Take Away dated June 29, 2011), FDA Advisory committee voted against the approval of Dapagliflozin for adults with Type 2 diabetes (voting 9 vs. 6). The vote reflects the caution that has set in post Actos and Avandia saga - to approve a chronic therapy with safety concerns, which is not particularly satisfying a major unmet need. The PDUFA date is on 28th Oct. The rejection was mainly due to the imbalance of breast and bladder cancer observed in Dapagliflozin against control arm, although in the preclinical studies conducted in rats/mice, carcinogenicity was not observed with dapagliflozin even with very high doses. However, an increased incidence and severity of atypical hyperplasia of the renal tubules was observed at all doses of dapagliflozin in rats, but there was no increase in renal tubule adenoma or carcinoma.

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