- Inhibition of the sodium-glucose co-transporter 2 (SGLT2) is a new treatment option for type 2 diabetes mellitus that increases urinary glucose excretion to reduce hyperglycemia, along with causing weight loss and blood pressure reduction.
- Dapagliflozin is a highly selective inhibitor of SGLT2 whose extensive clinical program provides reassurance on the absence of human malignancy risk, which is further supported by a substantial body of nonclinical evidence.
- Studies using complimentary approaches at high multiples of human exposures (100–3,000×) showed no indication of tumor initiation or promotion in mice, rats (≤2 years) or dogs (≤1 year) associated with dapagliflozin treatment or with SGLT2 genetic ablation, both of which caused chronic glucosuria. There were also no mechanistic indicators such as proliferative effects directly related to dapagliflozin that would suggest a tumor risk.
- Assessments of human bladder transitional cell tumors *in vitro* and *in vivo* with increasing concentrations of glucose, dapagliflozin, and/or its primary 3-O-glucuronide metabolite also did not suggest any tumor growth enhancement.
- The weight of evidence indicates that SGLT2 inhibition in general, and dapagliflozin specifically, are not associated with increased cancer risk.

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