Entacapone-Containing Products – Safety update

- On August 13, 2019, the FDA announced that there is no increased risk of prostate cancer with the use of entacapone [ie, Comtan® (entacapone) and Stalevo® (carbidopa/levodopa/entacapone)] to treat Parkinson's disease (PD) and the recommendations for using these medicines will remain the same as labeled in the prescribing information.

    — Comtan is indicated as an adjunct to levodopa/carbidopa to treat end-of-dose "wearing-off" in patients with PD.
    — Stalevo is indicated for the treatment of PD.

- In March 2010, the FDA alerted the public that a clinical trial suggested a possible increased risk of prostate cancer with the entacapone component of Stalevo. The FDA subsequently required the Stalevo manufacturer, Novartis, to conduct a study to further evaluate this potential risk.

- The FDA also studied this issue independently using data from the Department of Veterans Affairs health care system. Based on these additional studies, the FDA concludes that entacapone use is not associated with an increased risk of prostate cancer.

- Healthcare providers should follow standard prostate cancer screening recommendations for patients.

- Patients and caregivers should continue to take their medicine as prescribed and discuss any questions or concerns regarding their therapy with their healthcare provider.

- Novartis' observational cohort study of 11,396 men in Finland with PD showed that treatment with entacapone plus levodopa/carbidopa was not associated with an increased risk of prostate cancer (HR = 1.05; 95% CI: 0.76, 1.44) or prostate cancer mortality (HR = 0.93; 95% CI: 0.43, 1.98) vs. treatment with levodopa/carbidopa without add-on entacapone.

- A retrospective cohort study of 17,666 U.S. male veterans with PD treated with levodopa/carbidopa, comparing add-on entacapone therapy to the control cohort, which received add-on therapy with a dopamine agonist or monoamine oxidase B inhibitor showed no difference in risk of prostate cancer between cohorts for increased duration of cumulative entacapone treatment of more than 2 years (adjusted HR = 1.08; 95% CI: 0.46, 2.51). The mean follow up time was 3.1 years and 4.0 years, respectively in the entacapone and control cohorts.

- A prior FDA announcement of the initial entacapone safety announcement can be found here.