Opana® ER (oxymorphone) – Request for market removal

- On June 8, 2017, the FDA requested that Endo remove Opana ER (oxymorphone hyrdochloride) extended-release tablets from the market as the FDA has concluded that the benefits of the drug may no longer outweigh its risks.

- This is the first time the FDA has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.

- The FDA's decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation.

    — Injection abuse of reformulated Opana ER has been associated with a serious outbreak of human immunodeficiency virus and hepatitis C, as well as cases of thrombotic microangiopathy.

- This decision follows a March 2017 FDA Advisory Committee meeting where a group of independent experts voted 18-8 that the benefits of reformulated Opana ER no longer outweigh its risks.

- Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting.

- While Opana ER met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER.

- The FDA has requested that Endo voluntarily remove Opana ER from the market. Should the company choose not to remove the product, the FDA intends to take steps to formally require its removal by withdrawing approval. In the interim, the FDA is making health care professionals and others aware of the particularly serious risks associated with the abuse of this product.

- The FDA will continue to examine the risk-benefit profile of all approved opioid analgesic products and take further actions as appropriate as a part of their response to this public health crisis.