Kynmobi™ (apomorphine) – New drug approval

- On May 21, 2020, Sunovion Pharmaceuticals announced the FDA approval of Kynmobi (apomorphine), for the acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease.

- Parkinson’s disease is a chronic neurodegenerative disease in which dopamine producing cells are lost. Within the first four to six years after diagnosis, regardless of disease severity, up to 60% of people with Parkinson’s disease experience “off” episodes.

- Kynmobi is a non-ergoline dopamine agonist.

- Apomorphine is also available as a subcutaneous injection (Apokyn®) for a similar indication as Kynmobi.

- The efficacy of Kynmobi was established in a randomized, double-blind, placebo-controlled study in 109 patients with Parkinson’s disease. Patients received Kynmobi or placebo. The primary endpoint of the study was the mean change from pre dose to 30 minutes post dose in the Movement Disorder Society-Unified Parkinson’s Disease Rating Scale, Part III (MDS-UPDRS III) (motor examination) at the 12-week visit of the maintenance phase.
- Kynmobi is contraindicated in patients:

    — Using concomitant 5HT3 antagonists, including antiemetics (eg, ondansetron, granisetron, dolasetron, palonosetron) and alosetron. There have been reports of profound hypotension and loss of consciousness when subcutaneous apomorphine was administered with a 5HT3 antagonist.
    — With hypersensitivity/allergic reaction to apomorphine or to any of the ingredients of Kynmobi. Angioedema or anaphylaxis may occur.

- Warnings and precautions for Kynmobi include nausea and vomiting; falling asleep during activities of daily living and somnolence; hypersensitivity; syncope/hypotension/orthostatic hypotension; oral mucosal irritation; falls; hallucinations/psychotic-like behavior; impulse control/compulsive behaviors; withdrawal-emergent hyperpyrexia and confusion; QTc prolongation and potential for proarrhythmic effects; fibrotic complications; priapism; and retinal pathology in albino rats.

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- The most common adverse reactions (≥ 10% in patients treated with Kynmobi and > placebo) with Kynmobi use were nausea, oral/pharyngeal soft tissue swelling, oral/pharyngeal soft tissue pain and paraesthesia, dizziness, and somnolence.

    — Dose initiation should be supervised by a healthcare provider.
    — Doses should be separated by at least 2 hours. If a single dose of Kynmobi is ineffective for a particular “off” episode, a second dose should not be given for that “off” episode. The efficacy or safety of administering a second dose for a single “off” episode has not been studied.
    — More than 5 doses per day should not be administered. The maximum single dose of Kynmobi is 30 mg.

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- Because of the high incidence of nausea and vomiting with Kynmobi when administered at recommended doses, an antiemetic, beginning 3 days prior to the initial dose of Kynmobi, is recommended. Treatment with the antiemetic should only be continued as long as necessary to control nausea and vomiting, and generally no longer than two months after initiation of treatment with Kynmobi.

- Sunovion plans to launch Kynmobi in September 2020. Kynmobi will be available as 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg sublingual films.