TREATMENT OF OPIOID USE DISORDER (OUD)

SUBLOCADE® (BUPRENNORPHINE EXTENDED-RELEASE) INJECTION (US)

- Post Marketing Commitments: all approved by the FDA and considered closed.
- Post Marketing Requirement studies: all completed except for one clinical study scheduled to start Q4-2020.
- Lifecycle Evidence Generation & Optimization (LEGO) Studies: These studies are dedicated to (1) understand the root causes of buprenorphine abuse, diversion and misuse; (2) assess how to induce SUBLOCADE treatment in the emergency department environment, and (3) investigate how high plasma concentrations of buprenorphine, consistent with those delivered by the two approved dosing regimens of SUBLOCADE, may reduce the effects of respiratory depression produced by fentanyl. All studies are on track.
- RECOVER™ (REmission from Chronic Opioid use: Studying enVironmental and socioEconomic factors on Recovery) study: 1-year outcomes were published in the Journal of Addiction Medicine (see publication list). The two-year outcomes were presented at the CPDD meeting (see publication list); a peer-reviewed publication is also in preparation. The scope and duration of the RECOVER™ outcomes are being pursued through a partnership with the Virginia Polytechnic Institute and State University (Virginia Tech).

SUBUTEX® PROLONGED-RELEASE SOLUTION FOR INJECTION (ex-US):

- Regulatory approvals: Israel, Sweden, and Finland.
- Under review by local Regulatory Authorities: Denmark, Germany, UK, Italy, Norway and New Zealand.

SUBOXONE® (BUPRENNORPHINE / NALOXONE) FILM:

- Regulatory Approvals: Israel, Europe (27 EU member states + United Kingdom, Norway, Iceland, Liechtenstein) and Canada.
- Under review by local Regulatory Authorities: New Zealand, Kuwait, Qatar and United Arab Emirates.
- Pending regulatory dossier submissions: Kingdom of Saudi Arabia.

TREATMENT OF SCHIZOPHRENIA

PERSERIS™ ONCE MONTHLY RISPERIDONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION:

- US: Post Marketing Commitment studies on track.
- Canada: Partnership with HLS Therapeutics. The NDS was submitted to Health Canada on November 7, 2019 and was accepted into formal review on January 23, 2020. The Notice of Compliance (NOC) date is November 16, 2020.

EARLY STAGE ASSET DEVELOPMENT (ESAD)

- INDV-2000 (Selective Orexin 1 [OX1] receptor antagonist):
  - The Single Ascending Dose (SAD) study is ongoing. The first subject was dosed on July 28, 2020.
  - Nonclinical pivotal toxicokinetics and embryofetal studies have been completed.
- INDV-1000 (GABA<sub>A</sub> positive allosteric modulator):
  - New lead identification and optimization program is ongoing in partnership with Addex Therapeutics.
- INDV-3000 (Selective dopamine [DA] D3 receptor antagonist):
  - Preparation of IND-related activities.

PEER-REVIEWED PUBLICATIONS (2020)


CONFERENCE ABSTRACTS (2020)


