Q2-2020 R&D UPDATE

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TREATMENT OF OPIOID USE DISORDER (OUD)

SUBLOCADÉ® (BUPRENORPHINE 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 ongoing and delayed due to the COVID-19 pandemic.
- 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 SUBLOCADÉ 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 SUBLOCADÉ, 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, France (including Belgium; Czech Republic; Latvia; Luxembourg), Norway and New Zealand.

SUBOXONE® (BUPRENORPHINE / 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 and Kuwait.
- Pending regulatory dossier submissions: Kingdom of Saudi Arabia, United Arab Emirates, and Qatar.

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-1000 (Selective Orexin 1 [OX1] receptor antagonist):
  - On September 26, 2019 the National Institutes of Health (NIH) granted Indivior’s application entitled “Clinical Evaluation of C4X3256, a Non-Opioid, Highly-Selective Orexin-1 Receptor Antagonist for the Treatment of Opioid Use Disorder” pursuant to Funding Opportunity Announcement RFA-DA-19-002 dedicated to the development of medications to prevent and treat opioid use disorder and overdose.
- Our development plans were presented at the first HEAL Investigator Meeting in Bethesda on January 16-17, 2020 (see publication list).
- The Single Ascending Dose (SAD) study was planned to start in April 2020 but was delayed by approximately 3 months due to the COVID-19 pandemic. The first dosing in Man is currently scheduled for August 2020.
- Nonclinical pivotal toxicokinetics and embryofetal studies have been completed.

- **INDV-2000 (GABA\textsubscript{B} 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)**


