R&D / Pipeline Update

Treatment of Opioid Use Disorder (OUD)

SUBLOCADE™ (BUPRENORPHINE EXTENDED-RELEASE) INJECTION:
- In the US:
  - All Post Marketing Requirement (PMR) and Commitment (PMC) studies are on track.
  - Lifecycle Evidence Generation & Optimization (LEGO) Studies: These studies are dedicated to (1) understand the use of diverted buprenorphine (see our publication list); (2) study the effects of SUBLOCADE™ in the emergency room environment to potentially prevent repeated opioid overdoses and potentially change standards of care, and (3) investigate how high plasma concentrations of buprenorphine, consistent with those delivered by the two approved dosing regimens of SUBLOCADE™, could potentially block the effects of respiratory depression produced by fentanyl that has been increasingly and directly related to drug overdose deaths in the United States. All studies are on track.
  - RECOVER™ Study (REmission from Chronic Opioid use: studying enVironmental and socioEconomic factors on Recovery): This is a study collecting up to 24-month longitudinal data encompassing demographics, drug use, drug treatment, family relationships, quality of life, mental and physical health, health-care utilization, crime, housing, employment, and urine drug screening (see our publication list). The 12-month longitudinal analysis findings were presented at various conferences; the 24-month final report is on track for December 2019.
- Ex-US Regulatory Activities:
  - Canada: SUBLOCADE™ approval on November 21, 2018
  - Australia: SUBLOCADE™ approval on July 17, 2019
  - SUBLOCADE™ / SUBUTEX XR ex-US regulatory filings: Filings were made in Israel (July 2018), New Zealand (September 2018) and Europe (November 2018). Reviews by local Regulatory Authorities are ongoing.

SUBOXONE® (buprenorphine / naloxone) Film:
- Canada: Supplemental New Drug Submission (SNDS) filed June 27, 2019; Screening acceptance letter received September 23, 2019. Regulatory Authority review is ongoing.
- Israel: Submission on September 3, 2018. Regulatory Authority review is ongoing.
- New Zealand: Regulatory dossier submission on track for Q4-2019.
- Turkey, Kingdom of Saudi Arabia, United Arab Emirates, Qatar and Kuwait: Regulatory dossier submissions planned for Q1-2020.

SUBOXONE® (buprenorphine / naloxone) Tablet:
- On September 11, 2018, the Chinese National Medical Products Administration (NMPA) approved SUBOXONE® Sublingual Tablets for the treatment of opioid use disorder.
- On February 4, 2019, Indivior announced a definitive agreement to divest the rights related to SUBOXONE® Sublingual Tablets (Sai Bo Song™) in China to Zhejiang Pukang Biotechnology Co., Ltd. The agreement is subject to various closing conditions (ongoing).

Treatment of Schizophrenia

PERSERIS™ (formerly RBP-7000), Monthly Long-Acting Risperidone Injection:
- PMC studies on track.
- Canada: HLS Therapeutics and Indivior held an Integration kick-off meeting on June 14, 2019. Preparation of regulatory dossier (NDS) ongoing.
Early Stage Asset Development (ESAD)

- **GABA<sub>B</sub> positive allosteric modulator:**
  - New lead identification and optimization program in partnership with ADDEX Therapeutics.
- **C4X3256 (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. A link to Indivior’s Press Release can be found here.

- **APV202701A (Selective dopamine [DA] D3 receptor antagonist):**
  - Initiation of IND dossier preparation.

Peer-Reviewed Publications (2019)


Q3-2019

INDIVIOR RESEARCH & DEVELOPMENT QUARTERLY UPDATE


Conference Abstracts (2019)


