

## **18-MONTH SAFETY AND EFFICACY OF RBP-6000 EXTENDED-RELEASE BUPRENORPHINE FOR OPIOID USE DISORDER**

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**Introduction and Aims:** Describe the safety and efficacy of RBP-6000 extended-release buprenorphine for up to 18-months across 3 studies.

**Method/Approach:** Data comes from three studies of adults with moderate-to-severe opioid use disorder. Study 1 was a 6-month, randomized, double-blind study comparing RBP-6000 (300mg monthly, or 300mg monthly for the first two injections followed by 100mg monthly) (n=404) to placebo (n=100). Study 2 was open-label, including 257 "rollover" subjects completing Study 1 (6 months) plus 412 "de novo" subjects (12 months). Study 3 was a further 6-month open-label study with 208 subjects completing Study 2.

**Results:** Retention at 6 and 12 months was similar for Study 1 subjects rolled over to Study 2 (66% and 51.4%, respectively) and de novo subjects initiating treatment in Study 2 (65.5% and 51% respectively). 166/208 (79.8%) subjects completed Study 3.

Abstinence rate (urine drug screen (UDS) and self-report) among subjects treated for 12 months was 107/174 (61.5%) for rollover subjects and 157/207 (75.8%) for de novo subjects. In Study 3, 142/157 (90.4%) were abstinent (UDS, patients with missing data excluded) at 18 months.

The most common injection-site reaction was mild pain in Study 1 (62.4%) and mild tenderness in Study 2 (64.6%) and Study 3 (35.1%). Pain scores were highest at 1-minute post-injection.

No treatment emergent adverse event was reported in  $\geq 5\%$  of subjects who rolled over from Study 1 to Study 2.

**Conclusions:** Subjects who received RBP-6000 up to 18 months had high levels of treatment retention and abstinence. No new safety signals emerged.

**Disclosure of Interest Statement:** BB is Founder and Chief Medical Officer of Pathway Healthcare; Principal Investigator for Clinical Research with Orexo, BMSI, Indivior, Braeburn, Novo Nordisk, Pfizer, Shionogi, and Boehringer Ingelheim; Advisory Consulting for BMSI, Indivior, U.S. Worldmeds, Pear Therapeutics; and Paid Speakers Bureau for BMSI, Orexo, Alkermes, and U.S. WorldMeds.

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