

## **Long-Term Treatment with BUP-XR in Patients Struggling to Abstain from Opioids**

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**Introduction:** *This integrated analysis of three clinical phase 3 studies evaluated the efficacy and safety of up to 18 months of treatment with BUP-XR, an extended-release monthly depot formulation of buprenorphine, in moderate or severe subjects with opioid use disorder (OUD) (DSM-5 criteria) struggling to abstain.*

**Methods:** *Study 1(NCT02357901), a 24-week randomized controlled trial, administered 6 monthly injections of BUP-XR 300/100 mg, BUP-XR 300/300 mg, or placebo. Study 2(NCT02510014), a 49-week, open-label trial, enrolled 257 Study 1 completers for 6 additional monthly injections and 412 new participants for 12 monthly injections. All Study 2 participants received 300 mg initially with flexible subsequent doses (100 or 300 mg). Study 3(NCT02896296), a 24-week, open-label extension, enrolled 208 Study 2 completers for 6 additional flexible-dose monthly injections. Analysis included 787 participants with up to 18 months BUP-XR treatment (placebo excluded). Subgroups were defined by percentage of abstinence in Months 1-6: ≤20% (early non-responders, n=178), >20%-to-≤50% (n=103), and >50% (early responders, n=506).*

**Results:** *Early non-responders showed delayed response after 6th injection; 16% had negative UDS at 6 months and 73% by 18 months. In the >20%-to-≤50% subgroup, 48% had negative UDS 2 weeks after 4th injection and 85% at 18 months. For early responders, 83% had negative UDS 1 week after 1st injection and ≥90% after 3rd injection. TEAEs were lower in the second and third 6-month treatment periods for all subgroups.*

**Conclusions:** *Treatment with BUP-XR beyond 6 months improved opioid abstinence for early non-responders, while TEAEs decreased over time, supporting long-term treatment benefit.*

**Disclosure of Interest Statement:** *This work was supported by Indivior, Inc., North Chesterfield, VA, USA.*