

1. Abstract title: Examining efficacy and safety of extended-release buprenorphine in subgroups of subjects with moderate to severe opioid use disorder

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4. Objectives:

SUBLOCADE® is a once-monthly, extended-release depot formulation of buprenorphine for treating moderate to severe opioid use disorder (OUD). We conducted post-hoc subgroup analyses from the pivotal Phase III study (NCT02357901)¹ to compare efficacy and safety of SUBLOCADE® 300mg and 100mg with placebo.

5. Materials and methods

Adults (n = 489) with moderate or severe OUD were randomized to SUBLOCADE® 300/100mg, 300/300mg (2 initial monthly injections of 300mg followed by 4 monthly maintenance doses of 100mg or 300mg), or placebo for 24 weeks. Opioid abstinence assessment was based on weekly opioid-negative urine samples and negative self-reports.

Sensitivity analyses were performed to assess whether changes in age, gender, BMI, intravenous drug use, polydrug use, underlying liver conditions or psychiatric illness were associated with changes in primary and secondary efficacy endpoints and also for changes in TEAEs, SAEs, AEs leading to death and AEs leading to discontinuation.

6. Results and conclusions

In all cases, and for both dosing schedules, SUBLOCADE® treatment showed superior efficacy vs. placebo treatment. For safety analysis, the only observed difference was that the subgroup of participants with a history of psychiatric conditions had a modest increase in subjects with any AEs, treatment related AEs and serious AEs relative to subjects without a psychiatric disorder, but this was noted in both the active treatment and placebo patients and was independent of treatment with SUBLOCADE®.

In conclusion, the safety and efficacy of SUBLOCADE® was consistent across subgroups. This observed consistency supports the relevance of the results to settings outside the United States despite potential differences in populations with OUD.

7. Conflicts of interest: This study was funded by Indivior. MF and SZ are employees of Indivior. KW served as site PI for several SUBLOCADE® and RECOVER trials and has received consultant and honorarium fees from Indivior. BB has received consultant and honorarium fees from Indivior