

**RNS STATEMENT RE: DELAYED FDA APPROVAL of SUBLOCADE LABEL CHANGES**

RELEASE DATE: FEBRUARY 12, 2025

**RELEASE TIME:** 7:00 AM GMT

Indivior provides the following update regarding its PDUFA action date for label changes (rapid initiation protocol and alternative injection sites) for SUBLOCADE® (buprenorphine extended-release) Injection, which was scheduled for February 7, 2025:

*Yesterday, February 11th, the FDA informed Indivior that, following acceptance of the proposed label for SUBLOCADE, there were no outstanding items to address, but that final review of the SUBLOCADE label changes has been delayed.*

*Indivior will provide further updates on the status of the approval of the proposed SUBLOCADE label changes as appropriate.*

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