Indivior Provides Update on Aelis Farma's Clinical Phase 2B Study Results with AEF0117 in Participants with Cannabis Use Disorder

September 4, 2024
THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF THE MARKET ABUSE REGULATION (EU) 596/2014 (AS IT FORMS PART OF DOMESTIC LAW IN THE UK BY VIRTUE OF THE EUROPEAN UNION (WITHDRAWAL) ACT 2018).

- Primary and Secondary End Points of the Study were Not Met
- If approved by the FDA, label would expand to include alternative injection sites in the thigh, buttock and back of the arm for induction and maintenance as well as rapid induction one hour after a single transmucosal buprenorphine dose; both of which address significant patient and healthcare provider unmet needs.

SLOUGH, United Kingdom and RICHMOND, VA, September 4, 2024 - Indivior PLC (Nasdaq/LSE: INDV) is today providing an update following Aelis Farma's announcement of the results from its clinical Phase 28 trial with AEF01171, evaluating the efficacy and safety in treatment-seeking participants with moderate to severe Cannabis Use Disorder (CUD). The purpose of this trial was twofold: (1) to show that AEF0117 (0.1, 0.3, 1 mg once a day for 12 weeks) lowers cannabis use and (2) to determine the endpoints and optimal dosage of AEF0117 for use in future studies. In this phase 28 study, patients were treatment-seeking participants, 84% of whom had severe CUD.

The results of the study demonstrated that the primary endpoint, the proportion of participants who reduced their cannabis use to Sl day per week, as well as secondary endpoints measuring the proportion of participants reaching either complete abstinence or who used S2 day per week, were not met. Although these results are disappointing, they indicate that significant work remains to be done to understand subpopulations of patients with CUD, specifically those with severe CUD.

This clinical Phase 28 study is part of the strategic collaboration between Aelis Farma and Indivior, which includes an exclusive option for Indivior to license the global rights to AEF0117. Given the lack of separation from placebo on primary and secondary endpoints and before seeing further additional favorable clinical data, Indivior does not currently expect to exercise its option.