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

- **Primary and Secondary End Points of the Study were Not Met**
- **Indivior Does Not Currently Expect to Exercise AEF0117 Option**

Slough, UK, 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 2B trial with AEF0117[1], 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 2B 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 ≤1 day per week, as well as secondary endpoints measuring the proportion of participants reaching either complete abstinence or who used ≤2 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 2B 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.

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Important Cautionary Note Regarding Forward-Looking Statements

This news release contains certain statements that are forward-looking. Forward-looking statements include, among other things, express and implied statements regarding whether: we will be able to ultimately demonstrate the safety and efficacy of AEF0117, which is a prerequisite to filing any New Drug Application; we might ever exercise our option for AEF0117 and, if so, when; and other statements containing the words "believe," "anticipate," "plan," "expect," "intend," "estimate," "forecast," "strategy," "target," "guidance," "outlook," "potential," "project," "priority," "may," "will," "should," "would," "could," "can," "outlook," "guidance," the negatives thereof, and variations thereon and similar expressions. By their nature, forward-looking statements involve risks and uncertainties as they relate to events or circumstances that may or may not occur in the future.

Actual results may differ materially from those because they relate to future events. Various factors may cause differences between Indivior's expectations and actual results, including, among others, the risks described in our most recent annual report on Form 20-F beginning on page 9 as filed with the U.S. SEC and in subsequent releases; legal and market restrictions that may limit how quickly we can repurchaser our shares; the substantial litigation and ongoing investigations to which we are or may become a party; our reliance on third parties to manufacture commercial supplies of most of our products, conduct our clinical trials and at times to collaborate on products in our pipeline; our ability to comply with legal and regulatory settlements, healthcare laws and regulations, requirements imposed by regulatory agencies and payment and reporting obligations under government pricing programs; risks related to the manufacture and distribution of our products, most of which contain controlled substances; market acceptance of our products as well as our ability to commercialize our products and compete with other market participants; competition; the uncertainties related to the development of new products, including through acquisitions, and the related regulatory approval process; our dependence on third-party payors for the reimbursement of our products and the increasing focus on pricing and competition in our industry; unintended side effects caused by the clinical study or commercial use of our products; our ability to successfully execute acquisitions, partnerships, joint ventures, dispositions or other strategic acquisitions; our ability to protect our intellectual property rights and the substantial cost of litigation or other proceedings related to intellectual property rights; the risks related to product liability claims or product recalls; the significant amount of laws and regulations that we are subject to, including due to the international nature of our business; macroeconomic trends and other global developments such as armed conflicts and pandemics; the terms of our debt instruments, changes in our credit ratings and our ability to service our indebtedness and other obligations as they come due; changes in applicable tax rate or tax rules, regulations or interpretations and our ability to realize our deferred tax assets; and volatility in our share price due to factors unrelated to our operating performance or that may result from the potential move of our primary listing to the U.S.

Forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

This release is being made by Kathryn Hudson, Company Secretary Indivior PLC.

About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat substance use disorders (SUD), overdose and serious mental illnesses. Our vision is that all patients around the world will have access to evidence-based treatment for the chronic conditions and co-occurring disorders of SUD. Indivior is dedicated to transforming SUD from a global human crisis to a recognized and treated chronic disease.

Building on its global portfolio of OUD treatments, Indivior has a pipeline of product candidates designed to both expand on its heritage in this category and potentially address other chronic conditions and co-occurring disorders of SUD. Headquartered in the United States in Richmond, VA, Indivior employs over 1,000 individuals globally and its portfolio of products is available in over 30 countries worldwide. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/indivior.

References:

1. National Library of Medicine (U.S.) (2022, April). *Effect of AEF0117 on treatment-seeking patients with cannabis use disorder (CUD) (SICA2).* Identifier NCT05322941 https://www.clinicaltrials.gov/study/NCT05322941

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