

**INDIVIOR EXTENDS LEADERSHIP POSITION IN SUBSTANCE USE DISORDER TREATMENT WITH EXCLUSIVE AGREEMENT FOR LEADING ASSET TARGETING CANNABIS-RELATED DISORDERS**

**AEF0117 is a leading compound targeting the CB1 receptor; potentially represents the first treatment for cannabis-related disorders; executing on a key Strategic Priority to build Indivior's pipeline**

Richmond, VA, June 8, 2021 - Indivior PLC, (LON: INDV) today announced that it is extending its leadership position in substance use disorder ("SUD") treatment by expanding into the under treated cannabis-related disorders, including cannabis use disorder ("CUD") and cannabis-induced psychosis ("CIP"). Indivior has entered into a strategic collaboration with Aelis Farma ("Aelis"), a private biotechnology company based in Bordeaux, France, that includes an exclusive option and license agreement (the "Agreement") for the global rights to AEF0117, Aelis' first-in-class synthetic Signaling Specific inhibitor ("SSI") engineered to inhibit the cannabinoid type 1 ("CB1") receptor ("CB1-SSI").

Under the Agreement, Indivior will pay an initial \$30 million to secure an exclusive global option for AEF0117. In clinical Phase 1 studies, AEF0117 has shown promising safety and tolerability signals. Furthermore, in a recently completed Phase 2a study, AEF0117 has shown positive signals of efficacy in subjects with CUD<sup>1</sup>. The option gives Indivior the right to assume all development and commercialization activities for AEF0117 upon successful completion of a planned Phase 2b study by Aelis in return for an exercise fee of an additional \$100 million and a series of potential milestone payments and sales-based royalties. The Agreement also includes exclusive global rights on a patent covering AEF0117 and related compounds and on a methods of use patent for treating cannabis-related disorders, including CUD and CIP.

"Our heritage and focus at Indivior is helping address unmet needs for people struggling with substance use disorders," said Mark Crossley, Chief Executive Officer. "Increasing prevalence of cannabis from the growing movement to legalize medical and recreational marijuana use is leading to greater concern for the potential of adverse outcomes, including elevated addiction risk<sup>2</sup>. Cannabis is the most commonly used substance of abuse in the US after alcohol and tobacco<sup>3</sup>; however, we have no FDA-approved medications for cannabis-related disorders, which are complex and concerning. AEF0117 is the most advanced new chemical entity under investigation in the clinic and potentially represents a unique opportunity to address a growing unmet public health need."

Over 48 million<sup>4</sup> people used marijuana in the U.S. in 2019 and 4.8 million<sup>4</sup> people had a CUD during the same period. The United Nations also recently estimated that 192 million people globally used cannabis in 2018<sup>5</sup>, making it the most used drug in the world. The most recent global burden of disease study including 195 countries over the 1990-2016 period estimated that 22.1 million people met the diagnostic criteria for CUD (289.7 cases per 100,000 people)<sup>6</sup>.

“We are excited about the potential for our partnership with Aelis,” said Christian Heidbreder, Chief Scientific Officer. “Our collaboration to advance the clinical development of AEF0117 reflects the success of our Connect and Develop R&D strategy that seeks to marry our drug discovery and development capabilities with innovators targeting the most promising pharmacological mechanisms in substance use disorders and related CNS diseases. Favorable data in support of Aelis’ new CB1-SSis have the potential to yield the necessary clinical proof of concept to advance AEF0117 closer to regulatory approval as the first medication to treat CUD.”

### **Background on lead compound AEF0117 & milestones**

Aelis’ lead CB1-SSi compound AEF0117 is a new chemical entity (NCE) with U.S. composition of matter patent expiry in 2033 and a method of use patent extending to 2039.

Completed Phase 1 clinical (single and multiple ascending dose) studies for AEF0117 have suggested good safety and tolerability and a recently-completed 29-patient Phase 2a study in subjects with CUD demonstrated positive signals of efficacy (“*Effect of AEF0117 on Subjective Effects of Cannabis in CUD Subjects*”; ClinicalTrials.gov Identifier: NCT03717272).

Under the Agreement, Aelis will fund and manage a Phase 2b proof of concept study of AEF0117. This will be a multi-center study evaluating efficacy of the compound as a treatment of CUD and will be coordinated by Prof. Frances Levin at Columbia University, USA. Assuming successful completion of the Phase 2b study, the exclusive option gives Indivior the right to assume full control of clinical development and commercialization of AEF0117 in return for a payment to Aelis of \$100 million. Phase 3 studies and commercialization would then be at Indivior’s direction and expense. Aelis would also be entitled to certain other development and sales milestones, including payments linked to U.S. NDA filing acceptance and NDA approval, as well as royalties in the mid-teen percentage range on global net sales.

### **About Indivior**

Indivior is a global pharmaceutical company working to help change patients’ lives by developing medicines to treat addiction 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 addiction. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence 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 cooccurring disorders of addiction, including alcohol use disorder. Headquartered in the United States in Richmond, VA, Indivior employs more than 700 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit [www.indivior.com](http://www.indivior.com) to learn more. Connect with Indivior on LinkedIn by visiting [www.linkedin.com/company/indivior](https://www.linkedin.com/company/indivior).

### **Forward-Looking Statements**

This announcement contains certain statements that are forward-looking. 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 expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding the Indivior Group’s financial guidance for 2021 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan",

"expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in the commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including compliance with the U.S. Department of Justice Resolution and Settlement Agreements, noncompliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

Consequently, 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. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. 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.

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