Indivior Enters an Exclusive Licensing Agreement with Alar Pharmaceuticals

October 11, 2023

- Alar's Lead Asset ALA-1000 Potentially is the First Three-Month LAI Treatment for OUD -

Richmond, VA, October 11, 2023 – Indivior PLC (LSE/Nasdaq: INDV), a leading addiction treatment company, today announced that it has gained exclusive global rights to develop, manufacture, and commercialize Alar Pharmaceuticals Inc.'s ("Alar") portfolio of long-acting injectable formulations that release a prodrug[1] of buprenorphine at varying durations, including its lead long-acting injectable ("LAI") candidate, ALA-1000.

ALA-1000 is a sustained-release LAI prodrug of buprenorphine. With dosage intervals of potentially up to four times per year, ALA-1000 could address unmet opioid use disorder ("OUD") patient needs with a longer duration of treatment, which could provide an option for patients seeking a less frequent maintenance therapy regimen, for patients living in remote areas without easy access to care, and for high-risk patients, such as those transitioning from the Justice system.

Under the agreement with Alar, Indivior will pay $10 million to secure exclusive global rights (except in China, Hong Kong, Taiwan and Macau) to develop, manufacture and commercialize ALA-1000 and Alar's future buprenorphine-based LAI product candidates. The $10 million payment is in addition to an initial $5 million option payment made by Indivior to Alar in Q1. Alar is entitled to potential milestone payments if various developmental, regulatory, and commercial goals are achieved.

"Alar provides Indivior with a unique opportunity to further address unmet patient needs in the treatment of OUD with potentially the first three-month buprenorphine LAI," said Christian Heidbreder, Chief Scientific Officer. "By providing a therapeutic option for patients who might benefit from less frequent dosing, ALA-1000 has the potential to broaden the spectrum of care for OUD treatment as well as enhance the addressable patient population."

ALA-1000 is an investigational drug and is positioned to be the first three-month buprenorphine administered subcutaneously entering the clinical stage. Results from a single-ascending dose ("SAD") study, announced by Alar in January 2022, demonstrated the safety, tolerability and sustained release profile of ALA-1000 over 12 weeks in patients with OUD[2]. Alar has been granted composition of matter and formulation patents for ALA-1000 covering sustained-release buprenorphine formulations with expiry in 2037 and 2039.

Based in Taichung, Taiwan, Alar is a drug development company which focuses on developing long-acting drug products for central nervous system ("CNS") disorders and chronic diseases, utilizing its proprietary depot technology. Compared with other long-acting subcutaneous injection technologies, its proprietary platform has been associated with distinctive characteristics such as low viscosity solution, small injection volume and sustained drug release profile.

The transaction is not expected to have a material impact on the Group's FY 2023 adjusted results.

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 substance use disorder (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, including alcohol use disorder and cannabis use disorder. Headquartered in the United States in Richmond, VA, Indivior employs more than 1,000 individuals globally and its portfolio of products is available in 39 countries worldwide. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/indivior.

Important Cautionary Note Regarding Forward-Looking Statements

This news release contains certain statements that are forward-looking. Forward-looking statements include, among other things, implied statements regarding the safety and efficacy of ALA-1000, including its ability to potentially have a three month duration, statements regarding future clinical trials of ALA-1000 and their timing, the potential clinical benefits of ALA-1000, 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 expressed or implied in such statements because they relate to future events. Various factors may cause differences between Indivior's expectations and actual results, including, among others, the material risks described in the most recent Indivior PLC Annual Report and in subsequent releases; 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, some of which are controlled substances; market acceptance of our products as well as our ability to commercialize our products and compete with other market participants; the uncertainties related to the development of new products, including through acquisitions, and the related regulatory approval process; our dependence on a small number of significant customers; our ability to retain key personnel or attract new personnel; 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 use of hazardous materials in our manufacturing facilities; our import, manufacturing and distribution of controlled substances; 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 the COVID-19 pandemic; 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.

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.

Media Contacts:

US Media:

Cassie France-Kelly

Vice President, Communications

Indivior PLC

Tel: 804-724-0327

UK Media:

Teneo

Tel: +44 207-353-4200

Investors and Analysts:

Jason Thompson

Vice President, Investor Relations

Indivior PLC

Tel: 804-402-7123

Tim Owens

Director, Investor Relations

Indivior PLC

Tel: 804-263-3978

1. A prodrug is a pharmacologically inactive medication or compound that, after intake, is metabolized into a pharmacologically active drug.
2. 2022/01/13 Alar Announces Significant Progress on Developing Long-acting Buprenorphine Injectable ALA-1000 – 昱展新

藥生技股份有限公司 (alarpharm.com)