



**C4X Discovery Holdings plc**

("C4XD", "C4X Discovery" or the "Company")

**Indivior awarded NIH HEAL grant to undertake clinical development of C4XD's Orexin-1 for treatment of Opioid Use Disorder**

**27 September 2019** – C4X Discovery Holdings plc (AIM: C4XD), a pioneering Drug Discovery company, is pleased to note Indivior PLC's announcement that the National Institutes of Health (NIH) has granted Indivior's application entitled "*Clinical Evaluation of C4X3256, a Non-Opioid, Highly-Selective Orexin-1 Receptor Antagonist for the Treatment of Opioid Use Disorder*" pursuant to Funding Opportunity Announcement RFA-DA-19-002 dedicated to the development of medications to prevent and treat opioid use disorder and overdose.

**Dr Clive Dix, Chief Executive Officer of C4XD, said:** "*We are thrilled for Indivior to be awarded a NIH HEAL grant for clinical development of our molecule C4X3256, a non-opioid, highly-selective Orexin-1 Receptor Antagonist for the treatment of Opioid Use Disorder. This award will enable Indivior to advance our molecule through Phase I clinical evaluation as well as perform the toxicology and drug metabolism studies to enable Phase 2 studies. The support of NIH HEAL through this award not only validates our scientific expertise in Drug Discovery, but also our commercial strategy of out-licensing.*

*"We are now focused on partnering our next molecule, NRF-2, for the treatment of Sickle Cell Disease and rapidly advancing our drug discovery programmes. We believe that C4XD is building a credible and highly valuable portfolio of candidates for out-licensing to the pharma industry."*

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Below is the full announcement made today by Indivior:

**Announcement of National Institutes of Health (NIH) Grant Award through the NIH Helping to End Addiction Long-term (HEAL) Initiative**

Slough, U.K. and Richmond, VA, 27 September, 2019 - -- Indivior PLC (LON: INDV) announces that the National Institutes of Health (NIH) has granted Indivior's application entitled "*Clinical Evaluation of C4X3256, a Non-Opioid, Highly-Selective Orexin-1 Receptor Antagonist for the Treatment of Opioid Use Disorder*" pursuant to Funding Opportunity Announcement RFA-DA-19-002 dedicated to the development of medications to prevent and treat opioid use disorder and overdose.

Indivior's award is one of 375 grant awards across 41 states made by the NIH in fiscal year 2019 to apply scientific solutions to reverse the national opioid crisis. The National Institutes of Health launched the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, in April 2018 to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management.

"It's clear that a multi-pronged scientific approach is needed to reduce the risks of opioids, accelerate development of effective non-opioid therapies for pain and provide more flexible and effective options for treating addiction to opioids," said NIH Director Francis S. Collins, M.D., Ph.D., who launched the initiative in early 2018. "This unprecedented investment in the NIH HEAL Initiative demonstrates the commitment to reversing this devastating crisis."



"Despite the availability of medications to treat opioid use disorder, there is a need for improved treatment modalities that involve new mechanisms of action," said Christian Heidbreder, Ph.D., Indivior's Chief Scientific Officer. "C4X3256 is a novel non-opioid, highly-selective orexin-1 receptor (OX1R) antagonist, suitable for development for the treatment of opioid use disorder. With this award, we will advance C4X3256 from preclinical status through Phase 1 clinical evaluation and perform the necessary toxicology and drug metabolism studies to enable Phase 2 studies."

In March 2018, Indivior entered into a license agreement with C4X Discovery Holdings PLC (C4X) whereby Indivior obtained exclusive global rights to develop and commercialize C4X3256.

#### About Opioid Use Disorder (OUD)

Opioid use disorder (OUD), sometimes referred to as opioid addiction, is a chronic disease.<sup>1</sup> According to DSM-5, "OUD is characterized by signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, they are used in doses greatly in excess of the amount needed for that medical condition."<sup>2</sup>

In 2018, an estimated 10.3 million people aged 12 or older misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. Approximately 506,000 people misused prescription pain relievers and used heroin in the past year.<sup>3</sup>

#### About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. Our vision is for all patients around the world to have access to evidence-based treatment for the chronic conditions and co-occurring disorders of addiction. The name is the fusion of the words individual and endeavor, and the tagline "Focus on you" makes the Company's commitment clear. 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 strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA, Indivior employs more than 800 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](http://www.linkedin.com/company/indivior).

#### Forward-Looking Statements

This press release contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty 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 2019 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior's expectations and actual results, including: factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; 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; 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 the ongoing investigative and antitrust litigation matters; 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; 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.

This press release does not constitute an offer to sell or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

#### References

1. SUBLOCADE™ [Prescribing Information]. Indivior Inc., North Chesterfield, VA. March 2018.
2. American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.
3. Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>

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#### Notes to Editors:

##### **About C4X Discovery**

C4X Discovery (C4XD) aims to create the world's most productive Drug Discovery engine by using cutting-edge technologies and expertise to efficiently deliver best-in-class small-molecule medicines to clinical partners for the benefit of patients. The Company's business model focuses on replenishing big pharma discovery pipelines and driving returns through revenue generating pre-clinical licensing deals. In 2018, C4XD successfully out-licensed a pre-clinical programme in addictive disorders to Indivior in a deal worth up to \$294m.



C4XD has a state-of-the-art suite of proprietary technologies across the Drug Discovery process and accesses further innovative capabilities and expertise through its growing network of partners. The Company is actively advancing its diverse pre-clinical discovery portfolio which is focused on inflammation, neurodegeneration and oncology (including immuno-oncology). Opportunities to maximise value from the portfolio are proactively driven by C4XD's commercial division. The Company is led by a highly experienced management team and Board who have delivered significant value creation within the healthcare sector.

For additional information please go to: [www.c4xdiscovery.com](http://www.c4xdiscovery.com)