Isofol announces licensing agreement for Paladin Labs Inc. to commercialize arfolitixorin in Canada

GOTHENBURG, Sweden, November 2, 2020 - Isofol Medical AB (publ) ("Isofol"), (Nasdaq First North Premier Growth Market: ISOFOL) is pleased to announce today a definitive license agreement with Endo Ventures Limited, a subsidiary of Endo International plc (NASDAQ: ENDP) plc, for the registration and commercialization of arfolitixorin on an exclusive basis in Canada. With the consent of Isofol, Endo Ventures Limited has designated Paladin Labs Inc., an operating company of Endo, to be responsible for seeking regulatory approval for arfolitixorin in Canada and after receipt of such approval, to be responsible for the commercialization of arfolitixorin in Canada, including distribution, marketing, medical affairs, pricing and reimbursement activities. Isofol may receive up to $US 23.05 million (SEK 205 million**) as upfront, development, regulatory and sales-based milestone payments. In addition, Isofol will receive tiered royalties on net sales in solid double-digit figures.**

The license agreement is focused on the registration and commercialization of arfolitixorin as first-line treatment for metastatic colorectal cancer (mCRC) patients in Canada. Isofol will be responsible for supplying the drug to Endo and will retain all international development rights.

"This licensing agreement between Isofol and Endo is a strong validation of the potential for arfolitixorin to address the large unmet medical need for patients treated for CRC. The collaboration will allow Canadian patients access to arfolitixorin upon receipt of the requisite regulatory approval, advancing the treatment regimens of difficult to treat cancers and also demonstrates our commitment to advance the quality of cancer care worldwide. Endo, through Paladin, has a very successful track record of commercializing innovative pharmaceutical products in Canada and our collaboration with them will be an invaluable component of our strategy to ensure global access to arfolitixorin," said Ulf Jungnelius, M.D, CEO of Isofol.

Isofol will remain as global sponsor of the AGENT study and Endo will be responsible for registrational filing and pursuing potential regulatory approval. Paladin will, as the Market Authorization holder, be responsible for the commercialization of arfolitixorin in Canada. Furthermore, Isofol will receive solid double-digit tiered royalty rates on future net sales applicable for the deal.

*"Arfolitixorin is an important addition to our portfolio of innovative oncology therapies," said Livio Di Francesco, Vice President and General Manager of Paladin. "Colorectal cancer is the third most common cancer affecting nearly 27 thousand Canadians annually***. Paladin is dedicated to bringing new treatment options to Canadians, such as arfolitixorin, which could*

potentially provide an additional therapeutic option to patients undergoing chemotherapy treatment for metastatic colorectal cancer."

Isofol's drug candidate arfolitixorin is being evaluated in the ongoing global Phase III AGENT study, as a first-line treatment for mCRC. The study is currently being conducted in the U.S., Canada, Europe, Australia and Japan in over 90 clinics that are open worldwide.

*** The amount given in SEK is subject to exchange rate*

**** Canadian Cancer Society (www.cancer.ca/en/cancer-information/cancer-type/colorectal/statistics)*

Isofol was advised on the transaction by Shadow Lake Group Inc., and Setterwalls Law Firm.

Invitation to a conference call and webcast on November 2, 2020 at 15:00 (CET)

Isofol invites investors, analysts and media to a conference call in connection with the licensing agreement with Endo/Paladin. The presentation will be held by CEO Ulf Jungnelius in English and will conclude with a Q&A session. Questions can be asked on the telephone conference or in written form through the webcast. No preregistration is needed.

Date and time
November 2, 2020 at 15:00 (CET)

Webcast link
https://tv.streamfabriken.com/investor-meeting-november

To participate via telephone, please dial-in on the numbers below
SE: +46 856642651
UK: +44 3333000804
US: +1 8558570686

Participant Pin-code
57982566#

After the presentation, a recording of the webcast will be available on the webcast link.

For further information, please contact

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This information is information that Isofol Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 13:00 CET on November 2, 2020.

About Endo International and Paladin Labs Inc.

Endo International plc (NASDAQ: ENDP) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from a global team of passionate employees collaborating to bring the best treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Endo has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. Learn more at www.endo.com or connect with us on LinkedIn.

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. Paladin has a focused marketing and sales organization that has helped it evolve into one of Canada's leading specialty pharmaceutical companies. Endo Ventures Limited and Paladin are operating companies of Endo International plc (NASDAQ: ENDP). Learn more at www.endo.com or www.paladin-labs.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including the statements by Dr. Jungnelius and Mr. Di Francesco and other statements relating to the regulatory approval and commercialization of arfolitixorin, within the meaning of the Private Securities Litigation Reform Act of 1995 and the relevant Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties and readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents led by Endo International plc with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on System for Electronic Document Analysis and Retrieval ("SEDAR") and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in any forward-looking statements. The forward-looking statements in this press release are qualified by these risk factors which, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

About the AGENT study

The Phase III AGENT study is a randomized, controlled, multi-centre study assessing the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin, both used in combination with 5- FU, oxaliplatin, and bevacizumab, in first line metastatic colorectal cancer patients. Patients are randomized in a 1:1 ratio and the primary endpoint is overall response rate (ORR). The key secondary endpoints are progression free survival (PFS) and duration of response (DOR). Other secondary endpoints include overall survival (OS), number of curative metastasis resections, safety, and patient reported outcomes such as quality of life (QoL). Exploratory endpoints include pharmacokinetic (PK) measurements and level of gene expression of folate relevant genes in tumour cells. The study is designed to show superiority for arfolitixorin over leucovorin. The study is ongoing at

approximately 90 sites in the U.S., Canada, Europe, Australia and Japan. Further information about the study, including patient eligibility requirements, is available at www.clinicaltrials.gov id: NCT03750786.

About arfolitixorin

Arfolitixorin is Isofol's proprietary drug candidate being developed to increase the efficacy of standard of care chemotherapy for advanced colorectal cancer. The drug candidate is currently being studied in a global Phase III study, AGENT. As the key active metabolite of the widely used folate-based drugs, arfolitixorin can potentially benefit all patients with advanced colorectal cancer, as it does not require complicated metabolic activation to become effective.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical stage biotech company developing arfolitixorin to improve the efficacy of standard of care chemotherapy for advanced colorectal cancer by increasing tumor response and progression free survival. Isofol holds a worldwide exclusive license agreement with Merck KGaA, Darmstadt, Germany to develop and commercialize arfolitixorin for oncology indications. Isofol Medical AB (publ) is traded on the Nasdaq First North Premier Growth Market. Certified Adviser is FNCA Sweden AB.

www.isofolmedical.com