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Isofol announces its intention to carry out a fully guaranteed preferential rights issue of approximately SEK 400 million and a potential over-allotment option of up to approximately SEK 100 million

GOTHENBURG, Sweden, April 28, 2021 - Isofol Medical AB (publ), (Nasdaq First North Premier Growth Market: ISOFOL), hereby announces that the Board of Directors has the intention to carry out an issue of shares of approximately SEK 400 million with preferential rights for the Company's existing shareholders (the "Rights Issue"). An extraordinary general meeting will be held around May 14, 2021 (the "EGM") to propose to resolve to authorize the Board of Directors to resolve on the Rights Issue and the terms thereof. The EGM is also proposed to resolve to authorize the Board of Directors to resolve on a directed share issue, corresponding to approximately SEK 100 million, with deviation from the shareholders' preferential rights (the "Over-Allotment Option"), in order to meet potential additional demand from strategic investors and thereby broaden the shareholder base. The notice to the EGM will be announced through a separate press release.

Summary

- The Board of Directors announces its intention to propose an EGM to authorize the Board of Directors to carry out the Rights Issue and the potential Over-Allotment Option (provided that the Rights Issue is oversubscribed). The EGM scheduled to be held around May 14, 2021, will be announced through a separate press release.
- The net proceeds from the Rights Issue and the potential Over-Allotment Option will be used to fund i) clinical development activities relating to the AGENT study beyond top-line results and activities for finalization of the NDA application, (ii) finalization of the development and validation of CMC, iii) global preparedness activities including the development of medical affairs and commercial launch packages, as well as continued partnering activities, iv) clinical development activities, including gene expression analysis and initiation of studies in additional indications and (v) general corporate purposes.
- Subject to the EGM's resolutions, the Rights Issue is fully guaranteed through subscription undertakings from current shareholders and guarantee commitments from current shareholders and external investors.
- The potential Over-Allotment Option will be conditional upon the Rights Issue being oversubscribed.

Isofol's CEO Ulf Jungnelius comments: "During the last year, Isofol has achieved several important milestones such as two partnership deals, a fully recruited AGENT study and in Q1 2021 a positive outcome of the interim analysis. Strengthening our financial position enables us to secure the financing needed to submit a New Drug Application to FDA and EMA, expected in H2 2022. Furthermore, it allows us to maintain a high pace in the pre-commercialization activities to ensure the prerequisites for a successful launch of arfolitixorin upon potential approval. We also see good potential to continue the development of gene expression analysis for arfolitixorin in order to bring new treatment options for cancer patients and to create value for our shareholders."

Background and intention

Isofol 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.

Arfolitixorin – the key active metabolite of widely used folate-based drugs – can potentially benefit more patients with advanced colorectal cancer as it does not require complicated metabolic activation to become effective. Arfolitixorin is currently being studied in the global Phase III AGENT study.

The 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 tumor cells. The study is designed to show superiority for arfolitixorin over leucovorin.

The AGENT study is fully recruited and is ongoing at approximately 90 sites in the U.S., Canada, Europe, Australia and Japan, where Isofol currently has 15 active sites.

Isofol raised approximately SEK 180 million in June 2020 through a rights issue and an over-allotment option. Since the June 2020 capital raise, Isofol has reached the mentioned and critical milestones for that capital raise, such as; the study is fully recruited, the interim result has been presented and the Company has signed licensing agreements with Solasia in Japan and Endo/Paladin in Canada. These licensing agreements are expected to positively affect Isofol's financial position over time.

In March 2021 the independent Data Safety and Monitoring Board ("iDSMB") recommended continuation of the AGENT study with 440 patients, in accordance with the study design for arfolitixorin. The interim analysis was the fifth time the iDSMB has assessed safety data. Isofol views the iDSMB's recommendation to continue the study without any amendments to the study protocols as an important signal that the treatment is safe. The treatment of enrolled patients will continue with follow-ups and repeated tumor measurements according to the study's protocol. After 300 PFS events have taken place, either with tumor growth or that the patient has passed away, a data read out is initiated, with compilation and statistical analysis to present top line results. The Company expects these events to occur during the first and second halves of 2022.

The Board of Directors intends to carry out the Rights Issue and the potential Over-Allotment Option to ensure the continued and successful development of the Company, in accordance

with its business plan and strategy. The intention of the Rights Issue and the potential Over-Allotment Option is primarily to fund i) clinical development activities relating to the AGENT study beyond top-line results and activities for finalization of the NDA application, (ii) finalization of the development and validation of CMC, iii) global preparedness activities including the development of medical affairs and commercial launch packages, as well as continued partnering activities, iv) clinical development activities, including gene expression analysis and initiation of studies in additional indications and (v) general corporate purposes.

Through the potential Over-Allotment Option, if exercised in full, the Company will receive an additional financing of approximately SEK 100 million before transaction costs. The potential Over-Allotment Option is conditional upon the Rights Issue being oversubscribed. The reason to deviate from the shareholders' preferential rights is that the Board of Directors, in the event of strong interest from investors, wishes to further strengthen the Company's capital as well as broaden the Company's shareholder base with new strategic investors.

Subscription undertakings and guarantee commitments

The Rights Issue is fully guaranteed through subscription and guarantee commitments.

A number of investors have provided guarantee commitments, which together with subscription undertakings from several existing shareholders, including The Fourth Swedish National Pension Fund ("AP4"), in total represent SEK 400 million. In addition, certain shareholders including Handelsbanken Fonder and Swedbank Robur have expressed that they are supportive to the Rights Issue and that they intend to subscribe for their respective pro rata shares.

Members of the Board of Directors and Management, comprising Ulf Jungnelius, Pär-Ola Mannefred, Gustaf Albèrt and Anna Belfrage, who jointly hold approximately 0.4 percent of the Company's outstanding shares have committed to subscribe their respective pro rata shares in the Rights Issue amounting to approximately SEK 1.8 million.

Shareholders representing in total approximately 12.3 percent of the shares and votes in the Company have undertaken to at the EGM vote to authorize the Board of Directors to carry out the Rights Issue and the potential Over-Allotment Option.

EGM and expected timetable for the Rights Issue

The Board of Directors convene the shareholders to the EGM through a separate press release. The EGM will take place around May 14, 2021. A detailed timetable and terms of the Rights Issue will be announced if the Board of Directors resolves on the Rights Issue.

Advisors

Carnegie Investment Bank AB (publ) and Pareto Securities AB act as Joint Bookrunners in connection with the Rights Issue and the potential Over-Allotment Option. Vinge law firm acts as legal adviser to Isofol, and Schjødt law firm acts as legal adviser to the Joint Bookrunners.

For further information, please contact

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This 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 18:00 CEST on April 28, 2021.

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 more 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.

Important information

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Forward-looking statements

This press release contains forward-looking statements that reflect the Company’s intentions, beliefs, or current expectations about and targets for the Company’s future results of operations, financial condition, liquidity, performance, prospects, anticipated growth, strategies and opportunities and the markets in which the Company operates. Forward-looking statements are statements that are not historical facts and may be identified by words such as “believe”, “expect”, “anticipate”, “intend”, “may”, “plan”, “estimate”, “will”, “should”, “could”, “aim” or “might”, or, in each case, their negative, or similar expressions. The forward-looking statements in this press release are based upon various assumptions, many of which are based, in turn, upon further assumptions. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurances that they will materialize or prove to be correct. Because these statements are based on assumptions or estimates and are subject to risks and uncertainties, the actual results or outcome could differ materially from those set out in the forward-looking statements as a result of many factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this release by such forward-looking statements. The Company does not guarantee that the assumptions underlying the forward-looking statements in this press release are free from errors nor does it accept any responsibility for the future accuracy of the opinions expressed in this press release or any obligation to update or revise the statements in this press release to reflect subsequent events. Undue reliance should not be placed on the forward-looking statements in this press release. The information, opinions and forward-looking statements contained in this press release speak only as at its date and are subject to change without notice. The Company does not undertake any obligation to review, update, confirm or to release publicly any revisions to any forward-looking statements to reflect events that occur or circumstances that arise in relation to the content of this press release.

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