Isofol announces its intention to carry out a fully guaranteed preferential rights issue of approximately SEK 150 million and a potential over-allotment option of up to approximately SEK 30 million

GOTHENBURG, Sweden, March 30, 2020 - Isofol Medical AB (publ), (Nasdaq First North Premier Growth Market: ISOFOL), today announced that the Board has the intention to carry out a rights issue of approximately SEK 150 million with preferential rights for the Company's existing shareholders (the "Rights Issue"). An extraordinary general meeting will be held around May 5, 2020 (the "EGM") where the EGM is proposed 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 30 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. The Rights Issue and the potential Over-Allotment Option will require the Company's articles of association to be amended by the EGM in respect of the level of share capital and number of shares that can be issued.

Summary

- The Board of Directors announces its intention to carry out the Rights Issue and the potential Over-Allotment Option (provided that the Rights Issue is oversubscribed). An EGM scheduled to be held around May 5, 2020, that will be announced through a separate press release, is proposed to resolve to authorize the Board of Directors to resolve on the Rights Issue and the terms thereof and the potential Over-Allotment Option (as a directed share issue).
- The Rights Issue and the potential Over-Allotment Option will require that the EGM resolves on amendments of the articles of association of the Company in respect of the level of share capital and number of shares that can be issued (which will be announced in the notice to the EGM).
- The net proceeds from the Rights Issue and the potential Over-Allotment Option will be used to i) fund the ongoing Phase III AGENT study to enable interim analysis based on 330 patients and enroll the 440 patients as per protocol (both expected to take place in H2 2020), (ii) additional clinical development activities including final analysis of the ISO-CC-005 study, iii) further gene expression analysis of additional populations including other cancer indications, iv) selected pre-commercialization activities and (v) general corporate purposes.

- Subject to the EGM's resolutions, the Rights Issue is fully guaranteed, including commitments from members of the Board of Directors and Management team to subscribe for their pro rata shares amounting to SEK 0.8 million, as well as guarantee commitments from existing shareholders and non-shareholders, including the Chairman of the Board, Pär-Ola Mannefred (through Aktiebolaget Äpplet).
- The potential Over-Allotment Option will be conditional upon the Rights Issue being oversubscribed.
- The subscription price in the Rights Issue and the potential Over-Allotment Option will not exceed SEK 9.

Isofol's CEO Ulf Jungnelius comments: "Strengthening our cash position will secure the recruitment of patients for the Phase III AGENT trial and to maintain critical activities to maintain our recruitment pace. We currently have over 260 patients included and with maintained recruitment rate we expect to have 440 patients recruited by the fourth quarter. The COVID-19 pandemic may have an impact on our program and the company needs to use the proceeds of the capital raise to secure our clinical program and as the FDA has indicted, amend study protocols in light of the new circumstances pertaining to clinical development. Furthermore, we are also working to secure a commercial partner in Japan during 2020. I look forward to continuing the development of arfolitixorin with the clear goal to launch the drug globally during 2023."

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 all 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 trial, AGENT.

The Phase III AGENT trial is a randomized, controlled, multi-center study assessing the efficacy and safety of arfolitixorin, [6R]-5, 10-methylene-tetrahydrofolic 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), a 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 of arfolitixorin over leucovorin.

The AGENT study is ongoing at approximately 80 sites in the U.S., Canada, Europe, Australia and recently also Japan, where the trial is planned to start in up to 15 clinics.

Isofol raised SEK 430 million in April 2017 through an initial public offering (the "IPO") focused on the funding of the Phase III AGENT study for its lead drug candidate arfolitixorin. The study targets 440 patients to receive first line treatment for metastatic colorectal cancer and has an adaptive design, meaning that there is an option to, based on an interim analysis of 330 patients, increase the sample with an additional 220 patients. The potential upsizing in number of patients was not funded at the time of the IPO. Some limited additional activities were included in the stated use of proceeds, including a few limited studies intended to support

arfolitixorin's path toward market authorization, some lean business development activities as well as general corporate purposes.

However, at the time of the IPO, the Phase III AGENT study was only an outline and after a 5-month regulatory process, the U.S Food and Drug Administration (the "FDA") concluded, after an SPA-process, that Avastin was required as a part of the study arms to reflect USA-approved standard of care. The consequences of this decision were not taken into account in the use of proceeds of the IPO.

Furthermore, the Phase III AGENT study has taken longer to recruit (3 months delay) with significantly higher costs pertaining to Avastin and the approval of Avastin biosimilars in the US and Canada. Thus, Isofol has asked the FDA to approve the use of Avastin biosimilars in the protocol which was accepted by FDA as long as the study protocol was amended. The amendment process is ongoing which has led to higher CRO costs, increases in costs per patient as well as regulatory & IPR-related costs.

Additionally, Isofol has expanded the scope of some of the additional studies to enhance the safety database and gene expression analyses of folate relevant genes that were not included in the original budget at the time of the IPO.

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 i) fund the ongoing Phase III AGENT study to enable interim analysis based on 330 patients and enroll the 440 patients as per protocol (both expected to take place in H2 2020), (ii) additional clinical development activities including final analysis of the ISO-CC-005 study, iii) further gene expression analysis of additional populations including other cancer indications, iv) selected pre-commercialization activities 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 30 million before transaction costs. The potential Over-Allotment Option is conditional upon the Rights Issue being oversubscribed.

Isofol believes the planned interim analysis will be a major inflexion point. One outcome from this analysis is that the independent Data and Safety Monitoring Board will recommend that an additional 220 patients are recruited in order to achieve statistical significance. In such a scenario, additional financing will have to be secured to fund an additional 220 patients at an estimated cost of SEK 150 million. In addition to this, Isofol estimates an additional funding requirement of SEK 150 million to take the Company to market authorization.

Subscription undertakings and guarantee commitments

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

A number of investors, including the Chairman of the Board, Pär-Ola Mannefred (who through Aktiebolaget Äpplet has provided a guarantee commitment corresponding to SEK 1 million), have provided guarantee commitments, which together with subscription undertakings from certain members of the Board of Directors and Management, represent SEK 150 million.

In addition, certain shareholders including Handelsbanken Fonder and Swedbank Robur have expressed that they are positive to the Rights Issue and that they intend to subscribe for their pro rata shares.

The Fourth Swedish National Pension Fund ("AP4") has expressed its intention to apply for subscription of shares in the Rights Issue corresponding to up to approximately 3 percent of

the total number of shares in the Company following the Rights Issue. AP4 does not hold any shares in the Company today.

Members of the Board of Directors and Management, comprising Ulf Jungnelius, Pär-Ola Mannefred, Gustaf Albèrt, Sven Erickson and Robert Marchesani, who hold approximately 0.5 percent of the Company's outstanding shares have committed to subscribe their pro rata shares in the Rights Issue amounting to approximately SEK 0.8 million.

EGM and expected timetable for the Rights Issue

The Board of Directors convene the shareholders to the EGM through a separate press release and the EGM will take place around May 5, 2020. A detailed timetable and terms of the Rights Issue will be announced if the Board of Directors resolves on the Rights Issue. The subscription price in the Rights Issue and the potential Over-Allotment Option will not exceed SEK 9.

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 Baker McKenzie acts as legal adviser to the Joint Bookrunners.

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 (EU) No 596/2014. The information was submitted for publication through the agency of the Company's CEO at 08:00 CET on March 30, 2020.

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 3 trial, 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.

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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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