Isofol's Board of Directors resolve on a fully guaranteed preferential rights issue of approximately SEK 150 million

GOTHENBURG, Sweden, May 7, 2020 - Isofol Medical AB's (publ) (Nasdaq First North Premier Growth Market: ISOFOL) ("Isofol" or the "Company") Board of Directors have today, pursuant to the authorization granted by the extra general meeting on May 5, 2020, resolved on a fully guaranteed new share issue of a maximum of 42,739,736 shares with preferential rights for the Company's existing shareholders (the "Rights Issue"). The subscription price in the Rights Issue is SEK 3.5 per share. Through the Rights Issue, the Company will receive approximately SEK 150 million before transaction costs related to the Rights Issue. In addition to the Rights Issue, the Board of Directors is authorized to carry out a directed issue with deviation from the shareholders' preferential rights of up to approximately SEK 30 million (the "Over-Allotment Option").

Summary

- The net proceeds from the Rights Issue and the potential Over-Allotment Option will be used to fund i) the ongoing global Phase 3 study AGENT to enable interim analysis based on 330 patients and enroll all 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) select pre-commercialization activities and (v) other operating activities.
- Existing shareholders in the Company will receive 1 (one) subscription right for each share held as of the record date. 3 (three) subscription rights entitle the holder to subscribe for 4 (four) new shares in the Rights Issue.
- Record date for participation in the Rights Issue is set to May 14, 2020.
- Subscription period of the Rights Issue is set to May 18 – June 1, 2020.
- Through the Rights Issue, the Company will receive approximately SEK 150 million before deduction of transaction costs related to the Rights Issue.
- The subscription price in the Rights Issue is SEK 3.5 per share, which corresponds to a discount of approximately 36 percent compared with the theoretical price after separation of subscription rights, based on the closing price of the Isofol share on Nasdaq First North Premier Growth Market on May 6, 2020.
- For existing shareholders not participating in the Rights Issue, a dilution effect corresponding to 57.1 percent of the total number of shares and votes in the Company following the Rights Issue will arise.
- The Rights Issue is fully guaranteed, including commitments from members of the Board of Directors and Management 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).

- In addition to the Rights Issue, the Board of Directors is authorized to exercise the potential Over-Allotment Option, which would provide Isofol with a maximum of approximately SEK 30 million before transaction costs.
- The Over-Allotment Option can be exercised to meet potential additional demand from strategic investors, thereby broadening Isofol's shareholder base and is conditional upon the Rights Issue being oversubscribed.

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 3 study AGENT.

The AGENT study 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 Japan.

Isofol raised SEK 430 million in April 2017 through an initial public offering (the "IPO") focused on the funding of the 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 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 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.

Use of Proceeds

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) the ongoing 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) select pre-commercialization activities and (v) other operating activities. 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.

The Rights Issue

The Board of Directors of the Company has today, pursuant to the authorization granted by the extraordinary general meeting held on May 5, 2020, resolved on a new share issue of up to a maximum of SEK 149,589,076 with preferential rights for the Company's existing shareholders in proportion to their shareholdings as of the record date May 14, 2020.

Shareholders receive 1 (one) subscription right for each share held on the record date. 3 (three) subscription rights entitle to subscription of 4 (four) shares in the Rights Issue, at a subscription price of SEK 3.5 per share. The subscription price corresponds to a discount of approximately 36 percent compared to the theoretical price after the separation of subscription rights, based on the closing price of the Isofol share on May 6, 2020 on Nasdaq First North Premier Growth Market. The Rights Issue will provide Isofol with a maximum of SEK 149,589,076, before deduction of transaction costs, by issuing a maximum of 42,739,736 shares.

The Rights Issue will result in an increase of the share capital of SEK 1,308,562.5. After the Rights Issue, the number of shares in Isofol will amount to 74,794,538 shares and the share capital will amount to SEK 2,290,010.9. For existing shareholders not participating in the Rights Issue, a dilution effect corresponding to approximately 57.1 percent of the total number of shares and votes in the Company following the Rights Issue will arise. Shareholders who choose not to participate in the Rights Issue have the opportunity to compensate for the economic dilution effect by selling their subscription rights.

The last day of trading in Isofol's shares, including the right to receive subscription rights in the Rights Issue, is May 12, 2020. Subscription of shares with subscription rights shall be made by cash payment during the period from May 18 – June 1, 2020. Subscription of shares without subscription rights shall be made on a special subscription list during the period from May 18 – June 1, 2020. Payment for shares subscribed without subscription rights shall be made in cash no later than two banking days following the issue of the settlement note, which

indicates notification of allocation. The Board of Directors is entitled to extend the subscription period and the last day for payment.

If all of the new shares are not subscribed for with subscription rights, allotment of new shares shall be made as follows:

- Firstly, those who subscribed for new shares with subscription rights and who applied to subscribe for additional new shares shall receive allocation, regardless if the subscriber was a shareholder on the record date May 14, 2020 or not, and in the case of oversubscription, pro rata to the number of shares subscribed for with subscription rights.
- Secondly, those who subscribed for new shares without subscription rights (except through investment commitments) shall receive allocation, and in the case of oversubscription, pro rata to the new number of shares stated in each subscription application, and insofar allocation cannot be done pro rata, by lottery.
- Finally, allotment of shares subscribed for without subscription rights shall be made up to a subscription level of SEK 149,589,076 to the investors who have provided guarantees in their capacity as guarantors, and insofar the guarantors cannot receive full allotment, in accordance with what has previously been agreed with the guarantors.

The full terms and conditions of the Rights Issue and information about the Company will be included in a prospectus expected to be published on the Company's website on or around May 14, 2020.

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.

Timetable for the Rights Issue

Timetable	
Last day of trading in shares including right to receive subscription rights	May 12, 2020
First day of trading in shares excluding right to receive subscription rights	May 13, 2020
Prospectus published on the Company's webpage	May 14, 2020
Record date for participation in the Rights Issue	May 14, 2020
Subscription period	May 18 – June 1, 2020
Trading in subscription rights	May 18 – May 28, 2020
Trading in BTAs	May 18 – June 3, 2020
Announcement of final outcome in the Rights Issue	Around June 3, 2020
Delivery of and trading in new shares subscribed with subscription rights	Around June 9, 2020
Delivery of and trading in new shares subscribed without subscription rights	Around June 18, 2020

The Over-Allotment Option

The Board of Directors is also authorized to decide upon a directed issue with deviation from the shareholders' preferential rights whereby the Company will receive a maximum of SEK 29,999,998 before transaction costs. The Over-Allotment Option can only be exercised if the Rights Issue is oversubscribed.

Upon the potential exercising of the Over-Allotment Option, the subscription price will equal that of the subscription price in the Rights Issue. Exercising the Over-Allotment Option would provide Isofol a maximum of SEK 29,999,998, before deduction of transaction costs, by issuing a maximum of 8,571,428 shares.

The Rights Issue and the Over-Allotment Option would result in an increase of the share capital of a maximum of approximately SEK 1,570,993.9. Upon exercising the Over-Allotment Option, the number of shares in Isofol, after the Rights Issue and the Over-Allotment Option, will amount to a maximum of 83,365,966 shares and the share capital will amount to a maximum of approximately SEK 2,552,442.3. For existing shareholders not participating in the Rights Issue and Over-Allotment Option, a dilution effect corresponding to approximately 61.5 percent of the total number of shares and votes in the Company following the Rights Issue and Over-Allotment Option will arise.

The reasons for the Over-Allotment Option's deviation from the shareholders' preferential rights is to meet potential additional demand from strategic investors, thereby broadening Isofol's shareholder base.

Advisers

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 such 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 08:30 CET on May 7, 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 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 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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