

The information in the press release is intended for investors.

Isofol Medical's Board of Directors intends to call an extraordinary general meeting with proposals for dividends and liquidation of the company

GOTHENBURG, Sweden, January 19, 2023 – Isofol Medical AB (publ) (Nasdaq Stockholm: ISOFOL), decided today to call an extraordinary general meeting to take a decision on a cash dividend of the maximum amount of capital available and to decide that the company is to be liquidated. The assessment is based on a thorough analysis of Isofol's future opportunities after the negative outcome of the company's phase III study (AGENT) and aims to ensure that as large a part of the company's remaining assets as possible benefit the shareholders.

Isofol was capitalized to conduct a phase III study (the AGENT study) and based on this study prepare to take arfolitixorin to market. Unfortunately, as previously reported, the AGENT study did not provide evidence that arfolitixorin was superior to leucovorin in the combination treatment of colorectal cancer. Neither the primary nor the most important secondary endpoints showed any difference and there was a clear tendency towards lower survival in the arfolitixorin group that fulfilled the FDA's definition of detrimental overall survival. Analysis of patient subgroups did not display any difference, nor could gene expression analyses demonstrate that any group responded better to arfolitixorin. These complementary studies were carried out, completed and presented during the autumn of 2022.

As the AGENT study was so decisive for the company's future, the board appointed two external expert groups to look at the data and the company's conclusions. Both groups concluded that the company's interpretation of the outcome of the study was correct and that no difference between arfolitixorin and leucovorin in a 5-FU based treatment regimen could be discerned. The external groups differed in their assessment of whether there was a way forward for arfolitixorin. One group concluded that there was no path forward for arfolitixorin within 5-FU based combination treatment of cancer, while the other group saw a need to further investigate arfolitixorin's potential path forward.

The board has considered a number of different factors in their assessment of a possible way forward for arfolitixorin:

- For a market approval, the board assesses that a new pivotal phase III study would need to be conducted, which would need to be preceded by a phase II study to determine the dose and dosing regimen and possibly a phase Ib study to ascertain the safety of higher doses of arfolitixorin. The assessment is that these studies together would take at least 6-8 years to carry out at a cost of at least SEK 500M.
- The remaining patent term of the current main patent after 6-8 years of further clinical development as well as additional time for registration of a drug is deemed to be too short to be commercially attractive.
- Although the development of new treatment methods for cancer is slow-going, we can state that the treatment strategy for colorectal cancer has continued to develop during

the years that Isofol has been active and will very likely continue to do so over the next 10-year period. This may mean that 5-FU based combination treatments with folates such as leucovorin/arfolitixorin may represent a smaller portion of the market at the time of a possible launch.

- The ability to raise the additional capital needed in accordance with the assessment above may be very difficult given the results of the AGENT study, future treatment regimens and patent situation.

All in all, the board assesses the probability is low that arfolitixorin in combination with 5-FU based regimens will be commercially successful, even if the clinical development could be financed, which the board considers to be very challenging in and of itself.

Furthermore, external statistical consultants have assessed whether the AGENT study could show that arfolitixorin is at least as good as leucovorin, which could possibly mean that arfolitixorin could compete with generic leucovorin. External statisticians assess that the AGENT study cannot demonstrate that arfolitixorin is equivalent to leucovorin. The AGENT study was not designed to show this and normally many more patients would be required. Additional arguments that make it difficult for arfolitixorin to be used generically are that the synthesis of arfolitixorin is more complicated than the synthesis of leucovorin and therefore would likely be more expensive to manufacture. In addition, arfolitixorin has a clear tendency for lower survival in the longer term than leucovorin in the AGENT study, which risked negatively influencing a doctor's choice of arfolitixorin over leucovorin.

In parallel with the completion of the study and external experts' assessment of the results, significant cost-saving measures have been carried out and the conditions investigated as to whether a structural deal could be carried out in order to possibly obtain a premium on Isofol's capital and determine if any value can be extracted from the company's stock market position, organization and possible loss deduction. The company and the board have been in contact with approximately 30 companies and had deeper discussions with six of them. The companies have been assessed with regard to, among other factors, value, risk associated with development, proximity to positive cash flow, maturity/ marketability, proposed premium on Isofol's assets, development plans and ownership profile, etc. The depth of the analyses differs between different companies. After thorough assessments and analyses the board has deemed that for now, no alternatives exist that would provide shareholders with more value compared with a capital dividend and a liquidation.

Against this background and to ensure that as much as possible of the company's remaining assets benefit the shareholders, the board has decided to propose that the extraordinary general meeting decide to distribute as large a portion of capital as possible and take a decision that the company is to be liquidated.

Assuming that the extraordinary general meeting decides in accordance with the board's proposal, the board will apply for the company's delisting from Nasdaq Stockholm.

"Based on the exploration of various possible courses of action during the past autumn, the board has assessed that a dividend and liquidation is the best solution available today for both the shareholders and for the company. This will give all Isofol's shareholders the opportunity to use the received capital in other desired investments or for other preferred needs", said Jan Törnell, Chairman of the Board of Isofol.

The official notice of the extraordinary general meeting will be published shortly.

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This is information that Isofol Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 13:45 CET on January 19, 2022.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical-stage biotechnology company that has focused its operations on developing and improving the current standard treatment for patients suffering from cancer by increasing treatment efficacy through the use of cytostatics. Isofol's ambition was to develop a drug for first-line treatment of advanced colorectal cancer (mCRC), thereby seeking to improve the current clinical practice by realizing the full strength of 5-FU with the addition of arfolitixorin. Isofol has an exclusive global licensing agreement with Merck & Cie in Schaffhausen, Switzerland, to develop and commercialize arfolitixorin in oncology. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

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