Ulf Jungnelius, MD
CEO
Board Certified Oncologist

ISOFOL

Pareto Healthcare conference
September 2020

ARFOLITIXORIN

A DRUG CANDIDATE
FOR THE TREATMENT
OF COLORECTAL CANCER

Disclaimer

This company presentation of Isofol Medical AB (publ) (“Isofol”) has been prepared for advertisement purposes. It is not a prospectus and has not been prepared in accordance with the prospectus requirements in the Swedish Financial Instruments Trading Act (lagen (1991:980) om handel med finansiella instrument) or the European prospectus regulation (809/2004/EC) (the “Prospectus Regulations”). This company presentation is not subject to any registration or approval requirements under the Prospectus Regulations and has not been, and will not be, examined, approved or registered by the Swedish Financial Supervisory Authority or any financial supervisory authority or other supervisory body within the EU.

The company presentation may not be forwarded, reproduced or made available in or into any jurisdiction in which such publication or distribution would require any additional documentation to be prepared or registration effected or that any measures are taken in addition to those required under Swedish law or where it would be in conflict with any law or regulation in such jurisdiction. Persons who come into possession of this document are required to inform themselves about, and to observe, such restrictions.

The courts of Sweden shall have exclusive jurisdiction over any dispute arising out of or in connection with this document company presentation and the City Court of Gothenburg, Sweden, shall be the court of first instance.

Isofol at a glance

- Developing arfolitixorin for the treatment of colorectal cancer
- Board and management with broad and long experience
- Headquarters in Gothenburg
- Strategic partnerships with Merck & Cie and Recipharm
- Strategic commercial partnership with Solasia for the Japanese market
- Listed on NASDAQ First North Premier in Stockholm (ticker: ISOFOL)

Shareholders	Number of shares	Capital/Votes (%)
Avanza Pension	4 117 908	4,94%
Bengt Gustafsson	3 515 434	4,22%
Handelsbanken Fonder	3 393 412	4,07%
Futur Pension	3 295 229	3,95%
Swedbank Robur Fonder	2 413 791	2,90%
Fjärde AP-fonden	2 400 000	2,88%
Swedbank Försäkring	1 926 660	2,31%
Urus AB	1 866 664	2,24%
Peak Partners	1 659 704	1,99%
Hans Enocson	1 586 828	1,90%
10 largest shareholders	26 175 630	31,40%
Other owners	57 190 336	68,60%
TOTAL	83 365 966	100%
Number of shareholders approx. 4500		

Source: Holdings.se, June 30 2020

The arfolitixorin Opportunity

Arfolitixorin

- mCRC has a significant unmet medical need
- [6R]-MTHF added to 5-FU regimens increases efficacy - arfolitixorin is [6R]-MTHF
- Leading KOL's active support in the development program
- A $1B opportunity in 1st line mCRC only
- Limited competition and few new drug in development for mCRC in first line
- Unprecidented low regulatory hurdle for approval in 1st line mCRC

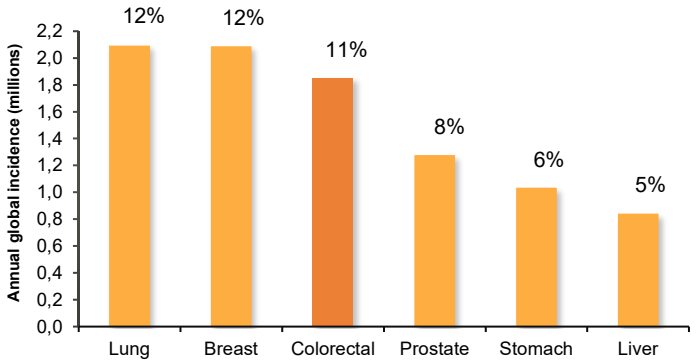
Colorectal cancer (CRC)

- 3rd most common and 2nd deadliest cancer with a high unmet need

COLORECTAL CANCER FACTSHEET

Colorectal cancer is the third most common cancer [1]

11% of cancers discovered annually are colorectal cancer



1.8m 1.8m people are diagnosed with CRC each year globally[1]

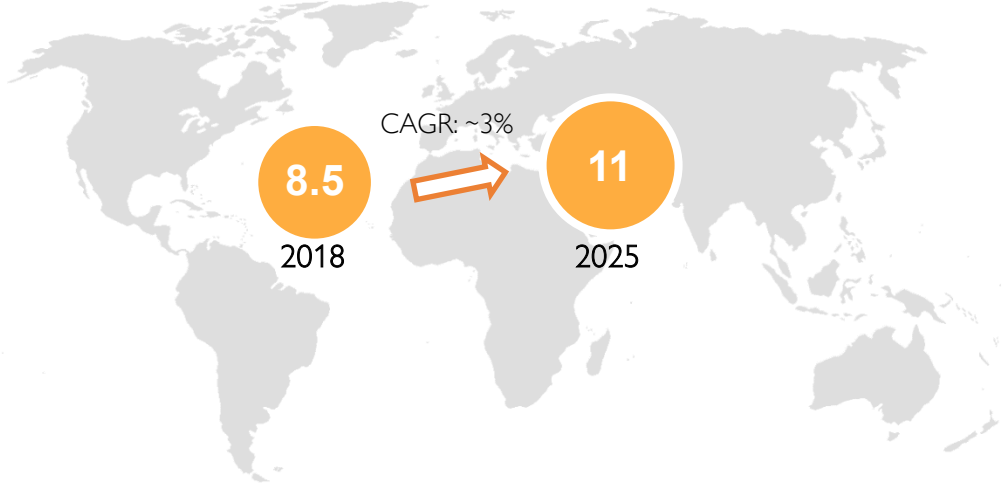
10% The 5-year survival rate for patients with stage 4 colorectal cancer falls to around 10%[2]

GROWING INCIDENCE

>70% The global burden of CRC is expected to increase by over 70% from 1,8 million 2018 cases to 3,1 million in 2040[1]

GLOBAL CRC MARKET

Total market size $bn 2018 to 2025[2]



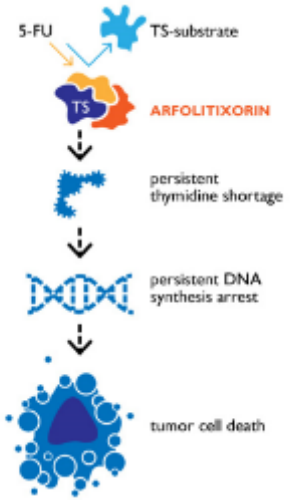
Source: (1) GLOBOCAN 2018, Cancer Incidence and Mortality Worldwide. (2) GlobalData 2017

Arfolitixorin – a novel drug for improving response and survival in mCRC patients

- Arfolitixorin could improve ORR and PFS by potentiating 5-FU cytotoxicity

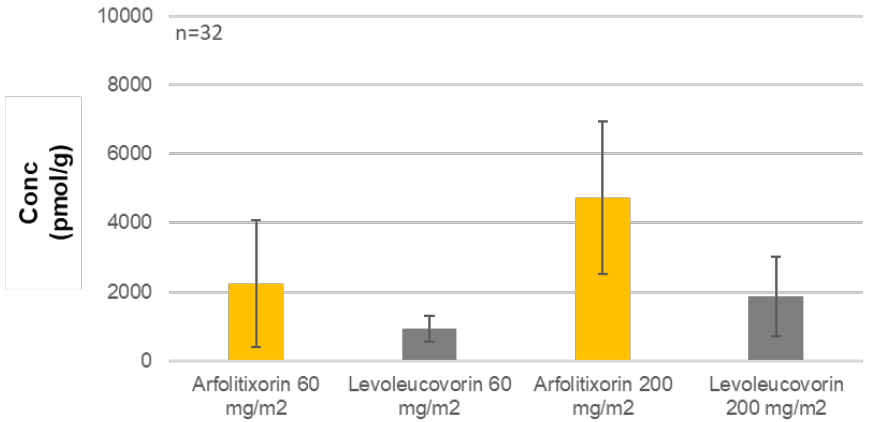
1. MTHF critical for 5-FU function

MTHF in cancer treatment



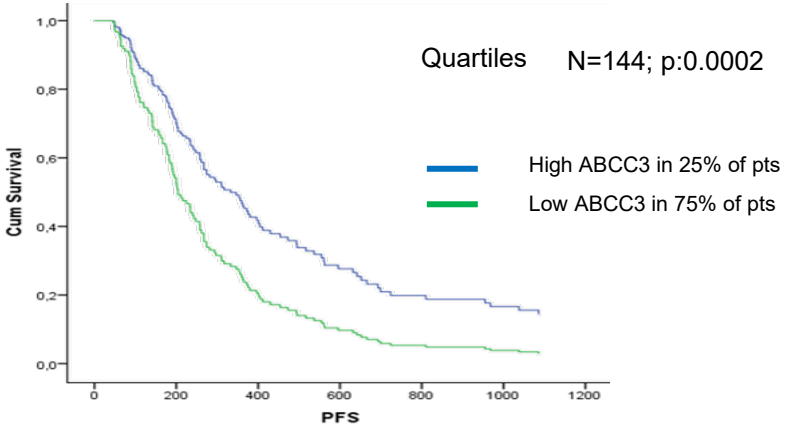
2. Arfolitixorin generates significantly higher MTHF levels in patients tumors

Methylene THF ([6R]-MTHF) levels in colorectal Tumor



3. Arfolitixorin could rescue up to ~ 75% of all mCRC patients treated with 5-FU unable to convert LV (improved Progression Free Survival PFS (11.4 vs 6.7 months)

ABCC3 expression and PFS

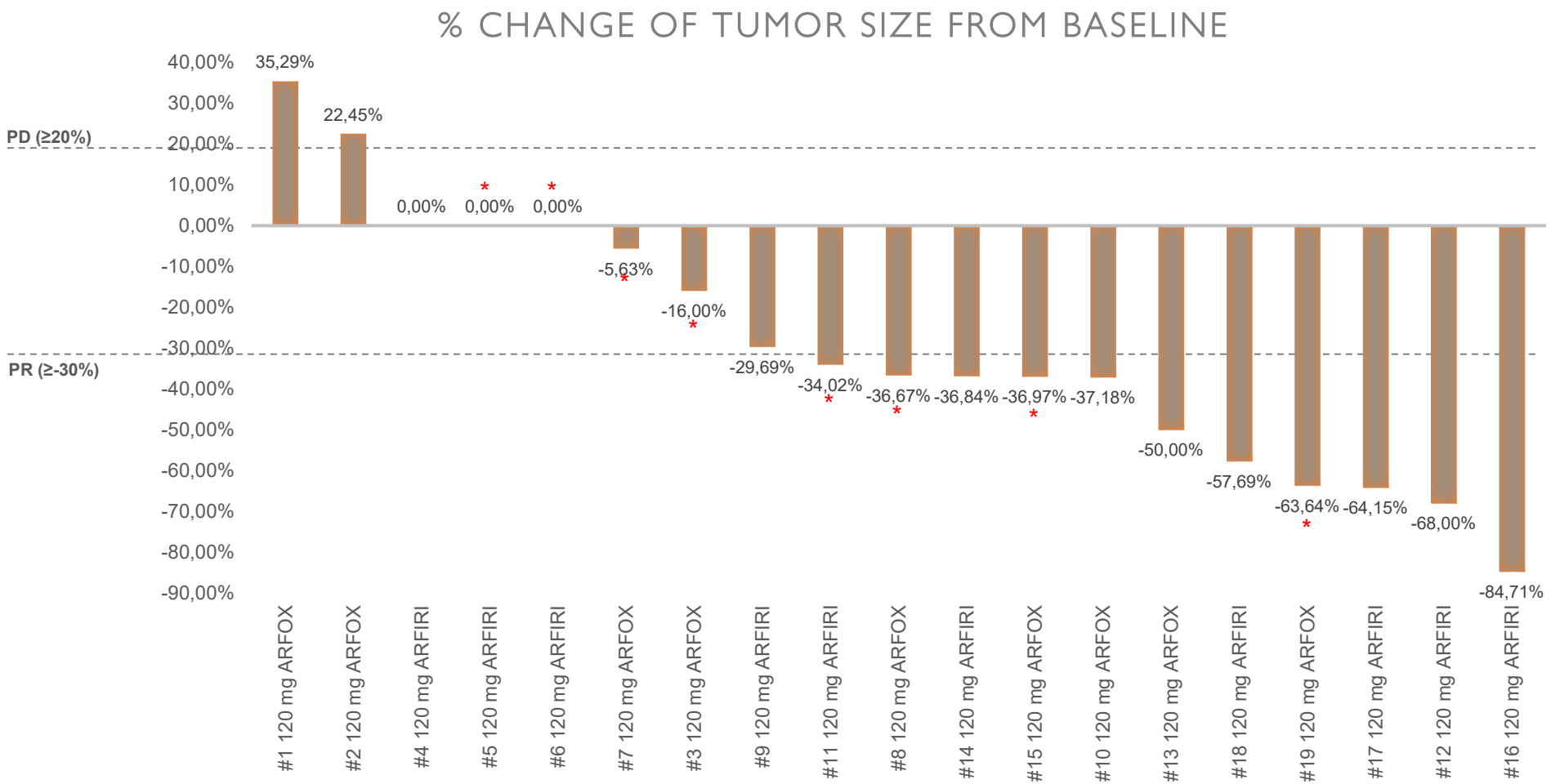


Based upon solid preclinical data, early clinical data, a favorable safety profile and a well understood MoA – FDA and EMA have endorsed the ongoing Phase 3 trial to form the basis for a future market registration

Source: ASCO 2018, Isofol Data on file

~60% Objective Response Rate in 19 1st line mCRC patients in ISO-CC-005

- some patients observed up to 32 weeks, treatment with 120 mg/m^2 Arfolitixorin + 5-FU + irinotecan or oxaliplatin (ARFIRI/ARFOX)



ORR according to RECIST 1.1

- 11 out of 19 patients had partial response, i.e. PR (≥-30%)
- ~60% ORR
- ~90% DCR

ORR= Objective Response Rate (CR; PR)
DCR= Disease Control Rate (CR, PR, SD)

* Patients received Avastin after 8 weeks of treatment

Source: Isofol Data on file

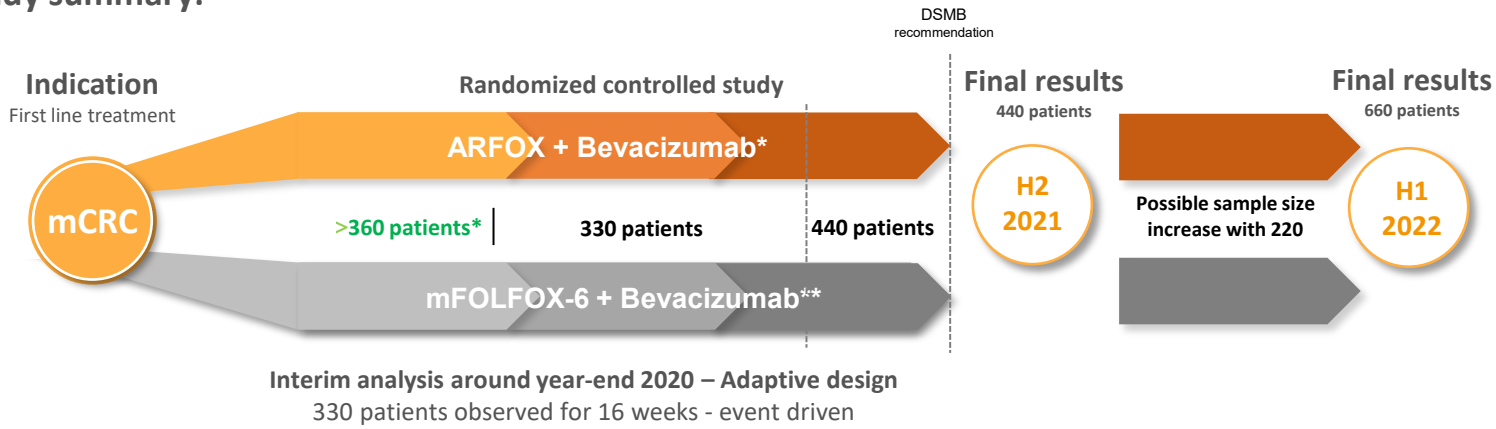
Strategic priorities

Strategies

- Ensure the success of the AGENT study in colorectal cancer
- Validate the gene expression
- Maximize benefit of the Solasia deal
- Secure a global commercial partner
- Establish a solid commercialization plan for a successful launch of arfolitixorin

AGENT study – Ongoing global Phase 3 study design

Study summary:



Interim analysis around year-end 2020 – Adaptive design
330 patients observed for 16 weeks - event driven

Primary Endpoint

ORR

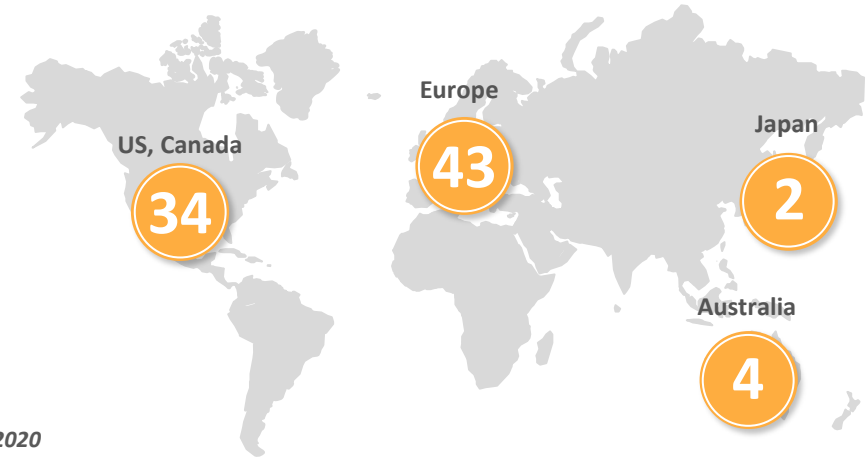
Objective response rate

Key Secondary Endpoints

PFS, DOR

Progression-free survival
Duration of Response

Study sites



Additionally sites in Japan and Australia are planned to be initiated

Coordinating Principal Investigator:

Prof Joseph Tabernero, MD, PhD

Vall d'Hebron Hospital

ESMO

Prof Heinz-Josef Lenz, MD, PhD

USC Norris Comprehensive Cancer Center
Part of Keck Medicine of USC

** As of August 2020*

*ARFOX (**Arfolitixorin** + 5-FU + Oxaliplatin) + bevacizumab
mFOLFOX-6 (Leucovorin** + 5-FU + Oxaliplatin) + bevacizumab

AGENT study – with Adaptive Design, a De-Risked Program

Regulatory requirement for marketing approval of arfolitixorin:

- FDA & EMA, TGA (Aus) and PMDA (Jpn)
- Primary Objective: **Response Rate, at least 10% increase above SOC**
- Secondary Objective: **Positive trend in PFS and DOR**
- Safety: **No deterioration in OS, at least maintained risk/benefit ratio**
- Required sample size: **440 patients**

Interim Analysis

- Basis for adaptive design
- When patient number 330 have been observed for at least 16 weeks (end 2020) the DSMB will review safety and efficacy (ORR and trend in PFS) and recommend based on outcomes;

1.

Stop recruitment at 440 patients

Carry on observing the 440 patients

2.

Sample size increase to 660 patients

Increase sample size to 660 patients to reach statistical significance on PFS

Clinical development 2020

Phase III AGENT study

- ✔ 330 patients recruited July 2020
- ✔ Expansion of the study in Japan have been initiated as a result of the Solasia Pharma K.K. deal
- ✔ Third DSMB meeting performed in June 2020 without any safety issues
- Interim analysis results around year-end of 2020
- Fully recruited (440 patients) by end of 2020
- Peer-reviewed publication on safety and dose finding data

Gene expression analysis in additional patient populations

- mCRC subpopulations
- Phase I/IIa patients

Breakthrough license agreement entered with Solasia to develop and commercialize arfolitixorin in Japan

Solasia

Solasia's proven capabilities to develop and commercialize oncology treatments in Japan and other Asian markets as well as their commitment to cancer patients make them the ideal partner to support our development and commercialization efforts in Japan

- Securing the Japanese market – the 2nd largest market for arfolitixorin
- Strong validation from a specialized innovative oncology partner
- Significant deal value – ~ USD 100 million as upfront and milestone payments
- Tiered royalties on net sales in solid double-digit figures
- Additional indications will be evaluated jointly by Solasia and Isofol

Route to the market – Commercial plan

Solid commercial forecast model established

- ✔ Favorable competitive environment
- ✔ Pricing and market access analysis
- ✔ Commercial uptake analysis

Partnering

- ✔ Japanese partner agreement secured August 2020
- ● Market preparations are initiated

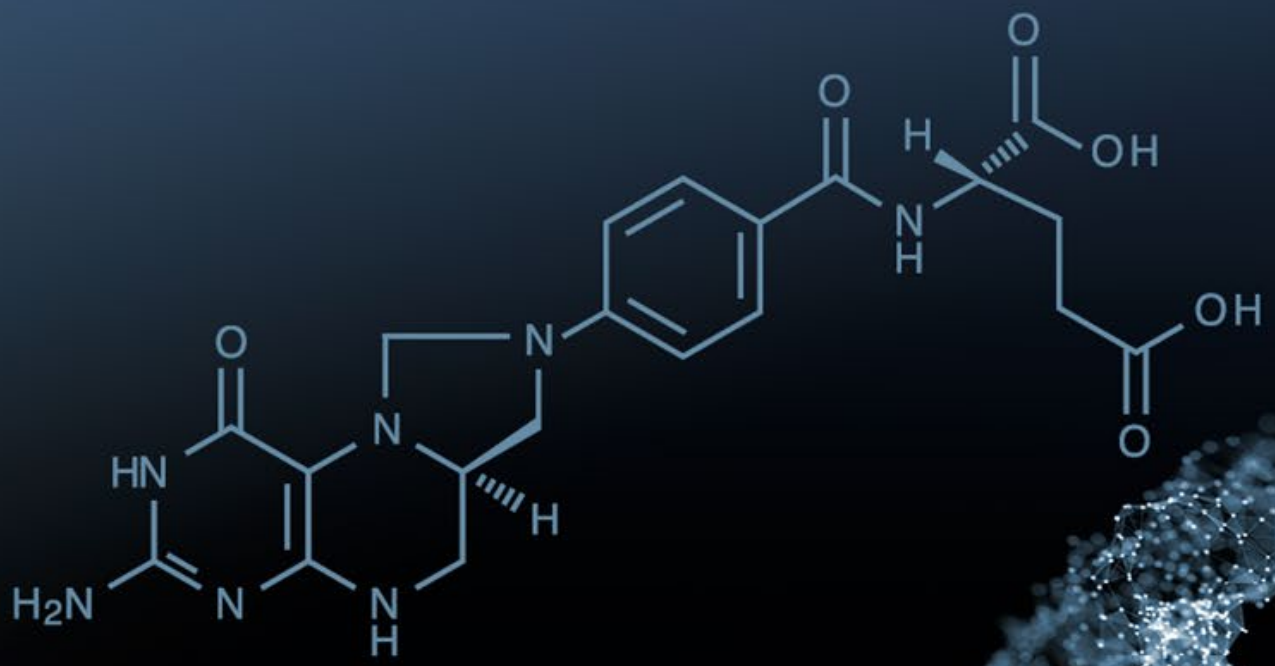
Global commercial plan in development

- ✔ Partnership with Syneos health to support in commercialization
- ● Medical affairs activities initiated in major markets and medical communication platform
- ● Global commercial plan including life cycle management plans

Active business development reach out to secure commercial partner
Focus on global partnering deal for RoW

Arfolitixorin – a de-risked late stage CRC opportunity

- AGENT study readout 2021 (440 patients)
- Global partner prior to NDA
- Global launch during 2023 (440 patients)
- Long IP protection US and Japan 2038, RoW 2034
- Blockbuster market potential - more than $1bn in annual sales in first line mCRC
- Excellent life cycle opportunity in other cancer indications



ISOFOL

Isofol Medical AB (publ)

Biotech Center
Arvid Wallgrens Backe 20
SE-413 46 Göteborg, Sweden

info@isofolmedical.com
www.isofolmedical.com