FivepHusion Corporate Summary

November 2022

FivepHusion is a private biotech company led by experienced executives and clinicians developing Deflexifol™*, a novel advanced clinical-stage drug reformulation that enhances chemotherapy for a range of adult and childhood cancers with significant unmet medical need. Our goal is to optimise chemotherapy to improve patient treatment outcomes and quality of life.

Deflexifol™ co-formulates the commonly used chemotherapy 5-fluorouracil (5-FU) with its biomodulator leucovorin (LV), a drug that improves 5-FU anti-cancer activity. Currently, due to the chemical incompatibility of standard formulations, oncologists serially administer these two agents, leading to side effects, sub-optimal tumour co-exposure and limited efficacy. Consequently, best clinical practice produces a tumour treatment response in only ~55% of metastatic colorectal cancer patients (mCRC), with a typical life expectancy of 20-30 months. The all-in-one Deflexifol™ formulation addresses significant limitations with current treatment, offering a "best in class" therapy by optimising co-administration of 5-FU and LV to enhance patient treatment via greater safety, tolerability and superior efficacy.

Deflexifol™ is in late-stage clinical development, having demonstrated very promising clinical results. Clinical trials have reported efficacy in end-stage solid tumour patients, of which the majority had previously failed standard 5-FU/LV. Fewer side effects led to greater tolerability, allowing for >40% higher 5-FU doses via the Deflexifol™ formulation compared with typical clinical practice. Independent surrogate data from multiple phase II trials also supports the potential for Deflexifol™ to achieve superior tumour response rates and survival for mCRC patients. A combination of improved tumour 5-FU/LV co-exposure together with higher tolerable 5-FU doses positions Deflexifol™ as an optimised anti-cancer formulation.

FivepHusion is developing Deflexifol™ via the FDA (505(b)(2)) and EMA Article 10b regulatory pathways as it incorporates two already approved, bioequivalent drugs. Having observed very promising efficacy in hard-to-treat patients, FivepHusion plans to exploit these pathways to rapidly progress Deflexifol™ into a global phase III pivotal trial commencing in 2023, with commercial launch projected for 2026. Deflexifol™ is protected by granted composition of matter patents in major markets, and existing commercial-scale manufacturing volumes of each formulation component can be exploited in its production.

FivepHusion's strategy is to replace standard 5-FU/LV formulations with Deflexifol™, as the new (gold) standard of care, prioritising mCRC (2020 market ~US$12.7B + 2.6% CAGR) as a first approved indication. A potential upside opportunity is use of Deflexifol™ in all cancers currently treated with standard 5-FU/LV, such as colorectal, breast, gastric and pancreatic cancers (~6M patient incidence). FivepHusion is also leveraging the unique attributes of Deflexifol™ to investigate new 5-FU/LV uses, including an upcoming multi-centre trial in paediatric brain cancers (2023 market ~US$1.65B + 4.1% CAGR).

FivepHusion is seeking strategic investment and co-development partnerships to support development and commercialisation of Deflexifol™.

To learn more, please contact Dr Christian Toouli, CEO & Managing Director: c.toouli@fivephusion.com

www.fivephusion.com

*Detsamma Investments Pty Ltd trades as "FivepHusion"; Deflexifol™ is a trademark of Detsamma Investments Pty Ltd.