FivepHusion Corporate Summary

January 2024

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 advanced development, having demonstrated promising clinical results. Two 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 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 US 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, and after December 2022 FDA feedback, FivepHusion plans to exploit these pathways to rapidly progress Deflexifol™ into a global phase III pivotal trial in 1st line mCRC patients in 2024. Deflexifol™ is protected by a growing portfolio of patents in major markets.

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 Deflexifol™ use 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 Deflexifol's unique attributes to investigate new 5-FU/LV uses, including in paediatric brain cancers (2030 market ~US$1.84B). A phase 1b/2a brain cancer trial involving all major Australian paediatric oncology centres launched in June 2023. Strategic collaborations with Syneos Health, Pfizer CentreOne and Allarity Therapeutics provide FivepHusion with access to the global expertise, resources, capabilities and technology to accelerate development of Deflexifol™.

FivepHusion is seeking investment and strategic global and regional 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

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