

ASX ANNOUNCEMENT

17 September 2019

Fujifilm Exercises License Option in GvHD

Melbourne, Australia; 17 September 2019: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that FUJIFILM Corporation (“Fujifilm”) has today exercised its license option in graft-versus-host disease (GvHD).

The exercise of the license option follows the successful completion of the Phase 1 clinical trial of CYP-001 in GvHD (announced to ASX on 30 August 2018), where all safety and efficacy endpoints were achieved.

Key highlights of the transaction

- **Fujifilm is granted an exclusive, worldwide license to develop and commercialise Cynata’s lead mesenchymal stem cell (MSC) product, CYP-001, for the prevention and treatment of GvHD in humans**
 - **Cynata will receive US\$3m cash** from Fujifilm as an upfront fee.
 - **Fujifilm** will bear responsibility for all costs of any further product development activities in relation to GvHD, along with responsibility for regulatory submissions and commercialisation.
 - The non-dilutive upfront payment of US\$3m will lengthen Cynata’s cash runway and support further investment in the upcoming Phase 2 trials in critical limb ischemia (“CLI”) and in osteoarthritis, along with other potential future clinical programs.
 - **Cynata will potentially receive additional future milestone payments from Fujifilm totalling up to US\$43m** based on successful attainment of certain industry standard product development and commercial milestones, the first of which is US\$2m on completion of the first Phase 2 clinical trial in USA, UK or Japan. Subsequent milestones are completion of Phase 3 clinical trials (US\$3m), submission of applications for regulatory approvals (US\$12m), acceptance of geographic marketing authorisations and first sales (US\$16m) and extending the indication (US\$10m).
 - **Cynata will receive a 10% royalty** on all future product sales if the licensed product is successfully commercialised in any country in which any licensed patents are granted or pending.
 - Having sub-licensed certain patent rights licensed-in from the Wisconsin Alumni Research Foundation (“WARF”) in respect of Cynata’s Cymerus™ technology to Fujifilm, Cynata will be required to make a one-off cash payment to WARF of US\$10,000. Cynata is also required to pay WARF a mid-single digit percentage royalty on Fujifilm product sales and 30% of other amounts received from Fujifilm, including in respect of milestone payments.
 - Both Fujifilm and Cynata have rights to terminate the license under certain conditions such as material breach and bankruptcy and failure to use reasonable efforts to achieve certain specified milestones. The agreement also includes limited mechanisms for potential royalty adjustment on termination of the WARF Head License, entry of a generic competitor or in-licensing third party enabling technology.



- Fujifilm and Cynata will enter into a separate agreement for the supply of product by Cynata for certain future product development activities at cost plus a moderate doubt digit manufacturing margin
- **The endorsement by Fujifilm of Cynata’s Cymerus platform supports the continued commercialisation of Cynata’s cell therapeutic products in other indications, including CYP-002 for critical limb ischemia (CLI) and CYP-004 for osteoarthritis**

To facilitate Cynata’s ongoing partnering efforts certain amendments have been made to the license agreement between Cynata and WARF, particularly in relation to sub-sublicensable sub-licenses under the WARF patents and extending certain interim development milestones, whilst not changing the current milestone for obtaining approval from the U.S. Food and Drug Agency (or an equivalent foreign agency) in 2026.

Dr Ross Macdonald, Cynata’s Chief Executive Officer, said, *“Fujifilm’s decision to exercise its license option in GvHD is a clear validation of our Cymerus platform technology solution for manufacturing MSCs at scale. We now look forward to Fujifilm taking this product through further clinical development activities and subsequently to market.”*

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale and without the limitation of multiple donors.

Cynata’s lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. Cynata plans to advance its Cymerus™ MSCs into Phase 2 trials for GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.