

Cynata Enters into a New Strategic Partnership with Fujifilm

Key highlights

- Cynata and Fujifilm have entered into a new strategic partnership which includes detailed and agreed core terms for Fujifilm to provide clinical and commercial manufacturing services for, and supply of, Cynata's Cymerus™ therapeutic mesenchymal stem cell (MSC) products
- Cynata and Fujifilm to negotiate in good faith a manufacturing services agreement incorporating the detailed and agreed core terms
- Cynata has regained all development and commercialisation rights to CYP-001 for graft-versus-host disease with US\$5m fee payable by Fujifilm to Cynata
- Cynata to immediately pursue GvHD product development strategy in the US, building on the existing US Orphan Drug Designation for CYP-001
- Fujifilm's shareholding in Cynata to be subject to a new voluntary escrow

Melbourne, Australia; 30 September 2021: Cynata Therapeutics Limited (ASX: "CYP" or "Cynata"), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced that it has entered into a new strategic partnership agreement ("SPA") with Fujifilm Corporation ("Fujifilm").

Under the SPA the parties agree to negotiate in good faith during a 90-day period a manufacturing services agreement ("MSA") incorporating the detailed and agreed core terms for Fujifilm to manufacture Cynata's Cymerus therapeutic mesenchymal stem cell ("MSC") products derived from induced pluripotent stem cells ("iPSC") for clinical trials and commercial applications.

Cynata has regained rights to CYP-001 for graft-vs-host-disease ("GvHD") and Fujifilm will pay Cynata US\$5m under the September 2019 licence agreement. The licence agreement has been terminated and Cynata will immediately implement a US development strategy for CYP-001 to capitalize on the unmet need and market opportunity for an effective and scalable MSC therapeutic for GvHD in the US market, for which it has already secured Orphan Drug Designation.

Cynata and Fujifilm intend to collaborate initially toward establishing at Fujifilm the current manufacturing process in place at Cynata's existing contract manufacturer, Waisman Biomanufacturing. In the meantime, Waisman will continue to manufacture product for Cynata's current clinical trials, which will continue as planned. The SPA sets out the core terms to be incorporated in the MSA for Fujifilm to undertake technology transfer, process validation and manufacturing under stage-by-stage, commercial, arms-length arrangements. Details of the initial stages of the process are presently being finalised and Cynata has made an initial in-principle expenditure commitment of US\$2m. Cynata and Fujifilm intend that Fujifilm will have first rights to manufacture clinical and commercial requirements for Cymerus therapeutic MSC products. In addition, and in recognition of the progress made by Fujifilm, Cynata will pay Fujifilm a proportion of any upfront licence fee



received by Cynata if Cynata approves main terms of a GvHD licence agreement with certain third parties within the next 6 months.

As part of the new partnership agreement, Fujifilm has agreed to a new voluntary escrow over the approximately 8.1 million shares it holds in Cynata. This escrow will be in place for 90 days and will be extended for up to a total of 15 months at the time of execution of an MSA.

Cynata has already secured Orphan Drug Designation from the U.S. Food and Drug Administration (“FDA”) for CYP-001 for the treatment of GvHD, potentially providing several commercially significant incentives, including seven years of marketing exclusivity, substantial tax credits and a waiver of FDA fees.

Cynata will now engage with the FDA on further clinical development of CYP-001 in the US via a Phase 2 clinical trial, using an iPSC master cell bank created by Fujifilm Cellular Dynamics, Inc. The previously completed Phase 1 clinical trial of CYP-001 in GvHD, results of which were published in *Nature Medicine*, met all safety and efficacy endpoints and broke ground by being the world’s first clinical trial of an allogeneic iPSC-derived product. A Phase 2 trial in GvHD will be an important late-stage addition to Cynata’s active pipeline, which also includes two clinical trials currently underway: the SCUpTOR Phase 3 trial in osteoarthritis and the MEND trial in respiratory distress, with a third trial, in diabetic foot ulcers (“DFU”), expected to commence later this calendar year.

In view of this broad and rich clinical pipeline and the current exposure to the diabetes therapy sector afforded through the planned DFU trial, Cynata will divert future activities around the currently on-hold critical limb ischemia indication toward partnering.

Dr Ross Macdonald, Cynata’s Chief Executive Officer, said:

“The execution of this new strategic partnership agreement with Fujifilm builds on a long and productive relationship between the two companies. Fujifilm Cellular Dynamics, Inc (a Fujifilm subsidiary) developed the original iPSC line used in Cynata’s Cymerus manufacturing process and we look forward to the extensive experience in cell therapy manufacture among the Fujifilm group being of significant long-term benefit to Cynata as we advance the development of our unique MSC therapeutic products. With Cynata having secured Orphan Drug Designation and regaining development and commercialisation rights to the GvHD indication we are excited to accelerate development in the important US market. This is especially so with our Cymerus technology addressing many of the complexities and challenges of manufacturing MSCs at commercial scale and with the FDA having shown its willingness to consider MSCs as a new treatment modality where the product has a scalable manufacturing process to maintain product consistency. Importantly, Fujifilm has also confirmed its strong commitment to the new product manufacturing partnership by agreeing to a further voluntary escrow over their shares in Cynata.”

Yutaka Yamaguchi, General Manager of the Life Sciences Business Division at FUJIFILM Corporation, said:

“Fujifilm has promoted development and manufacturing of cell therapies through collaborations with our partners, building on the strengths of FUJIFILM Cellular Dynamics, Inc. to produce therapeutic iPS cells in a stable and efficient way. The new strategic agreement builds on the partnership with Cynata to maximize the strengths and resources of both companies and further promote industrial application of iPS cell-derived regenerative medicine. We are confident that our significant, long-term investment in Cynata will reap rewards as it continues to meet its goals in developing the Cymerus technology.”

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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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 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. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and in patients with respiratory failure are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

About Graft-versus-host-disease

Graft-versus-host disease (GvHD) is a complication that can occur after a bone marrow transplant or similar procedure, when the donor's immune cells (from the "graft") attack the recipient of the transplant (the "host"). The only approved treatment for GvHD is corticosteroid therapy, which is typically only effective in about 50 percent of patients. When GvHD fails to improve or worsens despite steroid treatment, patients are described as having steroid-resistant GvHD. The prognosis for these patients is poor, with mortality rates in excess of 90 percent¹.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

¹ Westin JR, Saliba RM, De Lima M, et al. Steroid-Refractory Acute GVHD: Predictors and Outcomes. Adv Hematol. 2011; 2011:601953.