

November 7, 2022

## **Ono Exercises Option to HER2-targeted CAR T-Cell Product Candidate for Solid Tumors Generated from the Collaboration with Fate Therapeutics**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President and CEO: Gyo Sagara; “Ono”) announced that it has exercised its option to ONO-8250/FT825, iPSC cell-derived chimeric antigen receptor (CAR)-T cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors, created under the collaboration agreement with Fate Therapeutics, Inc. (San Diego, California, USA; President and Chief Executive Officer: Scott Wolchko; “Fate”) entered into in September 2018.

By exercising the option, Ono and Fate will jointly develop and commercialize ONO-8250/FT825 in the U.S. and Europe, and Ono will acquire the exclusive rights to develop and commercialize ONO-8250/FT825 in the rest of the world. Ono will make a milestone payment in connection with the option exercise. In addition, Ono will make milestone payments on the progress of clinical development and the achievement of certain net sales threshold in the rest of the world as well as tiered royalties on net sales outside of the United States and Europe. Fate retains manufacturing responsibilities for the products created from the collaboration on a global basis.

“We are encouraged by the compelling preclinical data package generated for ONO-8250/FT825 under our collaboration, which combines the antigen binder that Ono provides and Fate’s industry-leading iPSC product platform to overcome the challenges in solid cancer treatment,” said Toichi Takino, Senior Corporate Officer and Director, Research & Discovery HQ of Ono. “We look forward to initiating clinical development of the off-the-shelf, iPSC-derived CAR T-cell product candidate with the aim of delivering benefit to patients with some of the most difficult to treat cancers.”

“Over the past four years, we have worked closely with Ono to discover and integrate novel functional elements into our iPSC-derived CAR T-cell product platform that are specifically designed to address challenges in treating solid tumors, including cell trafficking and immune cell suppression in the tumor microenvironment,” said Scott Wolchko, President and Chief Executive Officer of Fate. “The preclinical data indicate ONO-8250/FT825 has a highly-differentiated therapeutic profile, including exhibiting anti-tumor activity against HER2-low tumor cells. We are excited to initiate IND-enabling activities under our collaboration with Ono with the goal of submitting an IND to FDA in 2023.”

Although CAR T-cell therapy has shown significant efficacy in treating hematologic malignancies, its wider application to solid tumors has been hampered by tumor-associated antigen heterogeneity, inefficient CAR T-cell trafficking to the tumor, and immunosuppression inherent to the tumor microenvironment. Fate’s multiplexed-engineered, iPSC-derived CAR T-cell product platform is designed to specifically address these challenges and enable the safe and effective treatment of solid tumors as monotherapy and in combination with monoclonal antibody therapy.

At the Society for Immunotherapy of Cancer (SITC) 37 Annual Meeting to be held from November 8-12, 2022 in Boston, Massachusetts, USA, the data from the ONO-8250/FT825 preclinical studies will be presented during a poster session on November 11, 9:00 AM to 9:00 PM (EST) (Abstract # 304).

Title: *“Off-the-shelf iPSC-derived CAR-T cells containing seven functional edits overcome antigen heterogeneity, improve trafficking and withstand immunosuppression associated with failed tumor treatment”*

#### About Fate Therapeutics' iPSC Product Platform

Fate's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, engineered, homogeneous cell products that are designed to be administered with multiple doses to deliver more effective pharmacologic activity, including in combination with other cancer treatments. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. Fate's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event and selecting a single engineered iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf for patient treatment. As a result, Fate's platform is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate's iPSC product platform is supported by an intellectual property portfolio of over 350 issued patents and 150 pending patent applications.

#### About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit [www.fatetherapeutics.com](http://www.fatetherapeutics.com).

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