

February 15, 2019  
Ohara Pharmaceutical Co., Ltd.

## **License Agreement on Novel Gliomas Treatment**

Ohara Pharmaceutical Co., Ltd. (Head office: Shiga, Japan; CEO: Seiji Ohara; hereinafter, "Ohara") has entered into a license, development and commercialization agreement in Japan dated January 29, 2019 concerning the novel compound ONC201 (Development No. OP-10) with Oncoceutics, Inc. (Head office: Philadelphia, PA, USA; CEO: Wolfgang Oster; hereinafter, "Oncoceutics").

In this agreement, Ohara has acquired not only the license for the development and commercialization of ONC201 in Japan, but also the right of first refusal of ONC 201 in China, Asia and West Africa, and the right of first refusal of next generation compound ONC 206 in Japan, China, Asia and West Africa. In return for the license and future rights, Ohara will make a multi-part payment to Oncoceutics including upfront payments, milestone payments, payment for purchase of the drug for re-sale, and royalties. In addition, Ohara will make a significant equity investment into Oncoceutics.

ONC 201 is a novel small molecule compound that acts as an antagonist to the dopamine D 2 receptor and leads to tumor cells to apoptosis. ONC201 has demonstrated anti-cancer activity and safety in preclinical models and in several ongoing clinical trials, including clinical trials in adult and pediatric patients with high grade gliomas\*<sup>1</sup>. In November 2018, the US Food and Drug Administration (FDA) has granted Fast Track Designation \*<sup>2</sup> to ONC 201 for the treatment of adult recurrent H3K27M-mutant high-grade glioma.

Ohara will advance clinical development in Japan so that ONC 201 can be delivered as a new treatment option to patients with H3 K27M-mutant high-grade glioma.

[About Ohara Pharmaceutical Co., Ltd.]

Ohara Pharmaceutical Co., Ltd. is one of the few Japanese pharmaceutical companies that engage in both the orphan drug and generic drug business. Its 3-year “Challenge 2020” business plan commenced in fiscal 2018, with one key objective of this plan being to challenge and address unmet medical needs. The company develops and markets orphan drugs mainly in the field of pediatric oncology and also operates an innovative generic drug business which takes careful consideration to prevent medical accidents. Ohara Pharmaceutical Co., Ltd. plans to further expand these businesses into emerging countries, primarily in the Asian region.

[About Oncoceutics, Inc.]

Oncoceutics, Inc. is a clinical-stage drug discovery and development company with a novel class of compounds, called “imipridones,” that selectively target G protein-coupled receptors for oncology. The first lead compound to emerge from this program is ONC201, an orally active small molecule DRD2 antagonist. The company is supported by grants from NCI, FDA, Musella Foundation, XCures, Cancer Commons, and a series of private and public partnerships.

For details, please visit: <http://oncoceutics.com/>

- \* 1 : Glioma is a generic term for tumors arising from numerous glial cells existing in the brain / spinal cord. The number of new annual patients in Japan is approximately 4,000 to 5,000 people. Among gliomas, Diffuse midline glioma, H3K27M-mutant is WHO grade IV and has a very low survival rate.
- \* 2 : Fast Track Designation is a system whereby FDA preferentially judges new drugs with high necessity.

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