

April 1, 2020

Ohara Pharmaceutical Co., Ltd.

Initiation of a Phase I/II Clinical Study of “OP-10” in Japan

Ohara Pharmaceutical Co., Ltd. (Head office: Shiga, Japan; CEO: Seiji Ohara; hereinafter, “Ohara”) announced that a Phase I/II Clinical Study of “OP-10,” an investigational drug for patients with recurrent or exacerbated glioma, has been initiated, and that the investigational drug “OP-10” has been administered to the first subject.

OP-10 (original development code: ONC201) is an antagonist of the dopamine receptor D2 (DRD2). It has been licensed from Oncoceutics, Inc. in the U.S.A. and is a novel small molecule compound that causes tumor cell apoptosis. Preclinical models and some ongoing clinical trials (including a clinical trial in adult and pediatric patients with high-grade gliomas^{*1}, etc.) in the U.S.A. have confirmed the anti-cancer activity and safety of OP-10. In November 2018, the US Food and Drug Administration (FDA) granted Fast Track Designation^{*2} to OP-10 for the treatment of adult recurrent H3K27M-mutant, high-grade glioma.

Ohara will advance clinical development in Japan so that OP-10 can be delivered as a new treatment option to patients with high-grade glioma.

[About Ohara Pharmaceutical Co., Ltd.]

Ohara Pharmaceutical Co., Ltd. is one of the unique Japanese pharmaceutical companies. It focuses on the development and distribution of orphan drugs mainly in the field of childhood cancer treatment as well as generic drugs taking the prevention of medical accidents into consideration. In the Midterm 3-year plan that started in FY2018, Ohara is committed to addressing medical issues under the theme, “To Challenge unmet medical needs,” applying the catch-phrase, “Challenge 2020.” Ohara is planning to further expand these activities into emerging countries mainly in Asia as well as other regions.

[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 OP-10, 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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