Press Release

OXFORD BIODYNAMICS JOINS ALS BIOMARKER STUDY SPONSORED BY MITSUBISHI TANABE PHARMA AMERICA

Proprietary Technology Platform to Assess Biomarker Panels in People with ALS

JERSEY CITY, N.J., May 3, 2019 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) today announced Oxford BioDynamics has joined the REFINE-ALS study, which was designed to identify and measure specific biomarkers in people with amyotrophic lateral sclerosis (ALS). Using an innovative technology platform to evaluate epigenetic and protein biomarkers, the company's analyses may offer insights on disease progression and treatment effect.

"ALS is a complex disease and the specific causes of disease onset and progression are not fully understood," said Stephen Apple, M.D., Senior Director of Medical Affairs, MTPA. "Through this biomarker study we are seeking to enhance our understanding of RADICAVA therapy in ALS. We are proud to announce Oxford BioDynamics has joined us in this effort and we look forward to seeing the data we gain from their technologies."

REFINE-ALS is sponsored by MTPA and led by Massachusetts General Hospital (MGH) Neurological Clinical Research Institute (NCRI). Biomarkers including oxidative stress, inflammation, neuronal injury/death and muscle injury, as well as clinical assessments, will be obtained from up to 300 patients prior to initiating treatment with edaravone, at start of treatment and at pre-specified time points for 24 weeks.

Oxford BioDynamics will evaluate biomarker panels utilizing **EpiSwitch™**. This proprietary technology platform assesses a novel class of epigenetic biomarkers known as chromosome conformation signatures, which are aimed at understanding the rate of disease progression.

"ALS is a challenging disease and we're excited to apply the EpiSwitch technology to uncover more information about its progression," said Alexandre Akoulitchev, Chief Scientific Officer, Oxford BioDynamics. "We are very pleased that OBD has been selected for this pivotal prospective trial led by the world leaders in ALS therapeutic development and patient care. As an extension of our previous work in ALS based on collaborations with ALS experts, this is an acknowledgment of the utility and value that EpiSwitch offers. We look forward to collaborating with our study partners to help disease understanding and clinical care for the entire ALS community."

At least 30 genes are believed to play a role in ALS, but more information is needed on their potential impact in ALS. This, combined with the lack of reliable laboratory tests to identify ALS, contributes to poor disease diagnosis, which may impact treatment.[1]

All participants in the prospective, observational, longitudinal, multicenter trial will be newly prescribed commercially available RADICAVA® (edaravone). Patient biomarker data and disease progression assessments will be compared to samples stored at biorepositories and progression models, respectively. The study is expected to begin in late spring of 2019, with early interim analyses planned for later in the year.

About Mitsubishi Tanabe Pharma America, Inc.

Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America, Inc. (MTPA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation's (MTPC) 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. MTPA is dedicated to delivering innovative products that address the unmet medical needs of patients in North America. It was established by MTPC to commercialize approved pharmaceutical products in North America with plans to expand its product line through collaborations with partners. For more information, please visit www.mt-pharma-america.com or follow us on Twitter and Facebook.

Overview of Mitsubishi Tanabe Pharma Corporation (MTPC)

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan.[2] In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 2016-2020. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. MTPC is the parent company of MTPA and the license holder of RADICAVA. For more information, go to http://www.mt-pharma.co.jp/.

About RADICAVA® (edaravone)

The U.S. Food and Drug Administration approved RADICAVA® (edaravone) on May 5, 2017 as a treatment for amyotrophic lateral sclerosis.[3] In a pivotal trial, people given RADICAVA experienced a 33 percent slower rate of decline in the loss of physical function, compared to placebo as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in people with ALS.[3,4,5]

Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) and commercialized in the U.S. by Mitsubishi Tanabe Pharma America, Inc. MTPC group companies began researching ALS in 2001 through an iterative clinical platform over a 13-year period. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. Marketing authorization was granted in Canada in October 2018 and Switzerland in January 2019.

IMPORTANT SAFETY INFORMATION

Before you receive RADICAVA, tell your healthcare provider about all of your medical conditions, including if you:

- have asthma.
- are allergic to other medicines.
- are pregnant or plan to become pregnant. It is not known if RADICAVA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RADICAVA passes into your breast milk. You and your healthcare provider should decide if you will receive RADICAVA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of RADICAVA?

- RADICAVA may cause serious side effects including hypersensitivity (allergic) reactions and sulfite allergic reactions.

- Hypersensitivity reactions have happened in people receiving RADICAVA and can happen after your infusion is finished.

- RADICAVA contains sodium bisulfite, a sulfite that may cause a type of allergic reaction that can be serious and life-threatening. Sodium bisulfite can also cause less severe asthma episodes in certain people. Sulfite sensitivity can happen more often in people who have asthma than in people who do not have asthma.

- Tell your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms: hives; swelling of the lips, tongue, or face; fainting; breathing problems; wheezing; trouble swallowing; dizziness; itching; or an asthma attack (in people with asthma).

- Your healthcare provider will monitor you during treatment to watch for signs and symptoms of all the serious side effects.

The most common side effects of RADICAVA include bruising (contusion), problems walking (gait disturbance), and headache.

These are not all the possible side effects of RADICAVA. Call your healthcare provider for medical advice about side effects. You may report side effects to Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, including full Prescribing Information and Patient Information, please visit **www.RADICAVA.com**.

Media inquiries:
Mitsubishi Tanabe Pharma America
Debbie Etchison
908-340-8578
Media_MTPA@mt-pharma-us.com

About Oxford BioDynamics

Oxford BioDynamics Plc (AIM: OBD) ("Oxford BioDynamics") is a biotechnology company focused on the discovery and development of epigenetic biomarkers for use within the pharmaceutical and biotechnology industry.

The Company's award-winning, proprietary technology platform, *EpiSwitch*™, aims to accelerate the drug discovery and development process, improve the success rate of therapeutic product development and take advantage of the increasing importance of personalised medicine.

In April 2019, Oxford BioDynamics received the Queen's Award for Enterprise: Innovation. The Queen's Awards for Enterprise are the most prestigious awards for UK businesses.

The Company is headquartered in the UK and listed on the London Stock Exchange's AIM under the ticker "OBD". For more information please visit www.oxfordbiodynamics.com.

---

[1] Mathis S, Goizet C, Soulages A, et al. (2019) Genetics of amyotrophic lateral sclerosis: A review. *J Neurol Sci,* 399, 217-226.

[2] Research by TOKYO SHOKO RESEARCH, LTD.

[3] RADICAVA® U.S. Prescribing Information. August 2018.

[4] Simon, N. G., Turner, M. R., Vucic, S., Al-Chalabi, A., Shefner, J., Lomen-Hoerth, C., & Kiernan, M. C. (2014). Quantifying Disease Progression in Amyotrophic Lateral Sclerosis. *Annals of Neurology*, 76(5), 643–657. http://dx.doi.org/10.1002/ana.24273.

[5] The Writing Group on behalf of the Edaravone (MCI-186) ALS 19 Study Group (2017). Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurology*. 16(7), 505-512.