MITSUBISHI TANABE PHARMA CANADA ANNOUNCES PUBLICATION OF REAL-WORLD DATA FOR RADICAVA® (EDARAVONE)

Findings of the analysis were published in eClinicalMedicine

TORONTO, ON August 15, 2022 – Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA), a subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA), today announced the publication of a paper entitled, "Intravenous edaravone treatment in ALS and survival: an exploratory, retrospective, administrative claims analysis," in *eClinicalMedicine*, part of *The Lancet*. Results from the analysis suggest that continued treatment with RADICAVA® (edaravone) in people with amyotrophic lateral sclerosis (ALS) was associated with prolonged survival compared to those not treated with the drug in a real-world setting based on a U.S. administrative claims database.

"Real-world data gives us the ability to bridge gaps in knowledge that exist between clinical trials and everyday medical practice," said Gustavo A. Suarez Zambrano, M.D., Vice President of Medical Affairs, MTPA. "While a randomized clinical trial is required to support the findings from this analysis, these data provide important insights from a real-life setting and deepen our understanding of RADICAVA's role in the treatment of ALS."

The retrospective, observational study utilized Optum's Clinformatics® Data Mart (CDM), a real-world de-identified database of administrative health claims across the U.S. for members with commercial or Medicare Advantage health plans, to assess overall survival among commercially insured ALS patients (≥18 years) who were treated continuously with RADICAVA® for at least 12 months, compared to a control group of patients not prescribed RADICAVA®. Implementing 1:1 propensity score matching,* the analysis compared 318 non-RADICAVA®-treated control patients with 318 patients who initiated RADICAVA® treatment between August 8, 2017, and March 31, 2020.

"ALS has been a clinically challenging disease to evaluate in a randomized clinical trial setting, especially for survival outcomes, due to its heterogeneity and average life expectancy," said Benjamin Rix Brooks, M.D., an ALS specialist and lead author of the study. "These real-world findings are encouraging and will help inform future research for this devastating disease."

Results from the analysis:

- Treatment with RADICAVA® over at least 12 months was associated with a six-month longer median survival compared with the non-RADICAVA® IV-treated patients.
    - Median survival was 29.5 months (95% CI, 25.4-35.9) for the RADICAVA®-treated patients and 23.5 months (95% CI, 20.0-28.0) for the non-RADICAVA®-treated patients.
- The risk of death during the study was 27% lower for the RADICAVA®-treated patients than for non-RADICAVA®-treated patients (hazard ratio [HR], 0.73; 95% CI, 0.59–0.91; P=.005).

* Matching on age, race, region, sex, pre-index disease duration, insurance, pre-index claims for cardiovascular disease and riluzole prescription, gastrostomy tube placement, artificial nutrition, non-invasive ventilation, and all-cause hospital.

- Between August 8, 2017, and March 31, 2021, 155 all-cause deaths (48.7%) were reported among RADICAVA®-treated patients vs. 196 (61.6%) among the non-RADICAVA®-treated patients.

It is important to note that real-world data studies ordinarily cannot determine definitive causal conclusions about the effects of treatment.[1] This study used real-world data, it was non-randomized, observational, exploratory and retrospective in nature, and may be subject to certain bias and confounding factors. The results of this type of analysis cannot be used to confirm the efficacy of drugs. Understanding the utility and limitations of real-world data is critical to proper application of insights.[2] RADICAVA® has not been authorized by Health Canada to prolong survival in patients with ALS.

This analysis was funded and conducted by MTPA.

About RADICAVA® (edaravone)
RADICAVA® (edaravone) is indicated to slow the loss of function in patients with amyotrophic lateral sclerosis (ALS), as measured by the ALS Functional Rating Scale - Revised (ALSFRSR).[ii.] Edaravone was discovered and developed for ALS by Mitsubishi Tanabe Pharma Corporation (MTPC) through an iterative clinical development platform over a 13-year period. In 2015, edaravone was approved for use as a treatment for ALS in Japan and South Korea. RADICAVA® was approved by the U.S. Food and Drug Administration in May of 2017. Marketing authorization was granted in Canada in October 2018 and Switzerland in January 2019.

About Mitsubishi Tanabe Pharma Canada, Inc.
Based in Toronto, Mitsubishi Tanabe Pharma Canada, Inc. (MTP-CA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma America, Inc. (MTPA) with a goal to provide therapies for some of the most difficult-to-treat diseases, including ALS. For more information, please visit www.mt-pharma-ca.com.

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. It was established by MTPC to commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com.

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[1] Berger ML, Sox H, Willke RJ, et al. Good practices for real-world data studies of treatment and/or comparative effectiveness: Recommendations from the joint ISPOR-ISPE Special Task Force on real-world evidence in health care decision making. Pharmacoepidemiol Drug Saf. 2017;26(9):1033-1039.
[2] U.S. Food and Drug Administration. Framework for FDA's Real-World Evidence Program. December 2018. https://www.fda.gov/media/120060/download.