NDA 209176/S-010

SUPPLEMENT APPROVAL

Mitsubishi Tanabe Pharma America, Inc.
Attention: Mr. Doug Dobak
Head of Regulatory Affairs
525 Washington Blvd., Suite 400
Jersey City, NJ 07310

Dear Mr. Dobak:

Please refer to your supplemental new drug application (sNDA) dated September 15, 2020, received September 15, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Radicava (edaravone) injection.

This Prior Approval supplemental new drug application updates sections 8 (Use in Specific Populations) and 12.3 (Pharmacokinetics) of the Radicava prescribing information with the study results from PMR-3208-3, as well as the following clinical studies conducted under IND 126396:

- MCI-186-J22, titled “An Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics of MCI-186 in Subjects with Mild or Moderate Renal Impairment Compared to Subjects with Normal Renal Function”

- MCI-186-J23, titled “A Multi-Center, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics of MCI-186 in Subjects with Mild or Moderate Hepatic Impairment Compared to Subjects with Normal Hepatic Function”

- MCI-186-E05, titled “An Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics of MCI-186 in Subjects with Severe Hepatic Impairment Compared to Subjects with Normal Hepatic Function”

In addition, this supplement proposes to update section 12.2 (Pharmacodynamics) of the prescribing information to add the following statement as requested in the Agency’s January 24, 2020, PMR Fulfilled/Supplement Request letter:

> **12.2 Pharmacodynamics**
> Cardiac Electrophysiology
> At a dose 5 times the recommended dose, RADICAVA does not prolong the QT interval to any clinically relevant extent.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, please contact Michelle Mathers, Regulatory Project Manager, at michelle.mathers@fda.hhs.gov or (240) 402-2645.

Sincerely,

{See appended electronic signature page}

Teresa Buracchio, MD
Deputy Director
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TERESA J BURACCHIO
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