

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

24 May 2019

**Subject: Withdrawal of Radicava, (edaravone), 30 mg solution for infusion -
EMEA/H/C/004938/0000**

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, Mitsubishi Tanabe Pharma GmbH (MTPD) has taken the decision to withdraw the application for Marketing Authorisation of Radicava, (edaravone), 30mg solution for infusion, which was intended to be used for the treatment of amyotrophic lateral sclerosis (ALS).

This withdrawal is based on the following reason:

-the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance.

The withdrawal does not have any impact on ongoing clinical trials with edaravone.

MTPD will continue to support the ongoing compassionate use program(s) pending further discussion with relevant local competent authorities which have granted approval for compassionate use.

MTPD remains fully committed to the ongoing development of edaravone in the treatment of ALS.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

MTPD would like to sincerely thank the (Co-) Rapporteurs and EMA for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,