

**Justification of premature termination to Competent Authority according to EOT form signed
20.09.2016**

D END OF TRIAL

D.1 Date of the end of the complete trial in all countries concerned by the trial?

D.1.1 (2016/09/15):

D.2 Is it an early termination?³

yes ☒ no ☐

¹ OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

² According to national legislation.

D.2.1 If yes, give date (2016/09/15):

D.2.2 Briefly describe in an annex (free text):

D.2.2.1 The justification for early termination of the trial;

D.2.3 AdCare was planned as single-centre trial, publicly funded by the university. Once the price for the IMP Carmustine had increased exponentially, there was a financial gap, which finally led to the decision that the trial cannot be conducted.

D.2.3.1 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

The trial was not initiated, no patients were included

D.2.3.2 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

Not applicable