

Declaration of the end of trial form

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt:	Competent authority registration number: Ethics committee registration number:
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To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE: UK

B TRIAL IDENTIFICATION

B.1 EudraCT number:	2007-006721-27
B.2 Sponsor's protocol code number:	CERE-120-06
B.3 Full title of the trial:	A Phase II, Multicenter, Randomized and Controlled Open-Label Trial Comparing the Safety and Efficacy of Bilateral Intraputamin (IPu) Administration of CERE-120 (Adeno-Associated Virus Serotype 2 [AAV2]-Neurturin [NTN]) Combined with Best Medical Therapy (BMT) versus BMT-alone in Subjects With Idiopathic Parkinson's Disease.

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1 DECLARATION FOR THE COMPETENT AUTHORITY	☒
C.1.1 Sponsor	☐
C.1.2 Legal representative of the sponsor	☐
C.1.3 Person or organisation authorised by the sponsor to make the application.	☒
C.1.4 Complete below:	
C.1.4.1 Organisation:	Quintiles
C.1.4.2 Name of person to contact:	[REDACTED]
C.1.4.3 Address:	The Pyramids Business Park Easter Inch, Bathgate Scotland, EH48 2EH UK
C.1.4.4 Telephone number:	[REDACTED]
C.1.4.5 Fax number:	[REDACTED]
C.1.4.6 E-mail	[REDACTED]
C.2 DECLARATION FOR THE ETHICS COMMITTEE	☐
C.2.1 Sponsor	☐
C.2.2 Legal representative of the sponsor	☐
C.2.3 Person or organisation authorised by the sponsor to make the application.	☐
C.2.4 Investigator in charge of the application if applicable ¹ :	
• Co-ordinating investigator (for multicentre trial):	☐
• Principal investigator (for single centre trial):	☐
C.2.5 Complete below:	
C.2.5.1 Organisation:	
C.2.5.2 Name:	
C.2.5.3 Address:	
C.2.5.4 Telephone number:	
C.2.5.5 Fax number:	
C.2.5.6 E-mail:	

¹ According to national legislation

D END OF TRIAL

D.1	Is it the end of the trial in this Member State?	yes ☒ no ☐
D.1.1	If yes, give date (YYYY/MM/DD):	2008-12-03
D.2	Is it the end of the complete trial in all countries concerned by the trial?	yes ☒ no ☐
D.2.1	If yes, give date (YYYY/MM/DD):	2008-12-03
D.3	Is it a premature ending of the trial?	yes ☒ no ☐
D.3.1	If yes, give date (YYYY/MM/DD):	2008-12-03
D.3.2	What is (are) the reason(s) for the premature ending? study, CERE-120-02, failed to demonstrate efficacy.	Initial data analysis of a US Phase II
D.3.2.1	Safety	yes ☐ no ☒
D.3.2.2	Lack of efficacy	yes ☐ no ☒
D.3.2.3	The trial has not commenced	yes ☒ no ☐
D.3.2.4	Other	yes ☒ no ☐
D.3.3	If yes to any of the above questions, briefly describe in an annex (free text):	
D.3.3.1	The justification for premature ending of the trial: Ceregene, Inc. has just completed the initial data analysis for the CERE-120-02 US Phase 2 study. Unfortunately, the study did not demonstrate an appreciable difference between patients treated with CERE-120 versus those in the control group. Therefore, Ceregene, Inc. has decided not to proceed with the CERE-120-06 clinical trial in Europe as it is currently designed. The reason for this withdrawal is not related to clinical safety.	
D.3.3.2	Number of patients still receiving treatment at time of premature termination in the MS concerned by the declaration and their proposed management:	0
D.3.3.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product: The potential benefit of CERE-120 on symptomatic management of Parkinson's Disease (defined by change in Unified Parkinson's Disease Rating Scale - motor off score at 12 months) could not be demonstrated in exploratory Phase II study.	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1	I hereby confirm that /confirm on behalf of the sponsor that (delete which is not applicable): - The above information given on this declaration is correct; and - That a summary of the clinical trial report will be submitted to the competent authority and ethics committee concerned as soon as available and within a 1 year deadline after the end of the trial in all countries.	
E.2	APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1)	☒
E.2.1	Date :	05 Dec 2008
E.2.2	Signature :	[Redacted]
E.2.3	Print name:	[Redacted]
E.3	APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) :	☐
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name:	