Date: 19 May 2022

Study Title:

A Phase II, 4 Week Randomized, Double-Blind, Parallel Group, Placebo Controlled Proof of Concept Study to Evaluate Efficacy, Safety and Tolerability of GRC 17536 in Patients with Painful Diabetic Neuropathy.

EudraCT Number:

2011-005879-16

Sponsor name:

Glenmark Pharmaceuticals S.A.

The sponsored hereby declares that the trail with the title "A Phase II, 4 Week Randomized, Double-Blind, Parallel Group, Placebo Controlled Proof of Concept Study to Evaluate Efficacy, Safety and Tolerability of GRC 17536 in Patients with Painful Diabetic Neuropathy" was cancelled and never initiated due to commercial purpose and no subjects were enrolled in the trail.

The above information was formally communicated to the competent authority via End of Trial notification.

Appendix: The declaration of the End of Trial Form.

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

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:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : United Kingdom

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2011-005879-16
B.2 Sponsor's protocol code number: GRC 17536-201
B.3 Full title of the trial : A Phase II, 4 Week Randomized, Double-Blind, Parallel Group, Placebo Controlled Proof of Concept Study to Evaluate Efficacy, Safety and Tolerability of GRC 17536 in Patients with Painful Diabetic Neuropathy.

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 : **Glenmark Pharmaceuticals Europe Ltd.**	
C.1.4.2	Name of person to contact : **Fiona Sellwood**	
C.1.4.3	Address : **C2 7600 The Quorum Oxford Business Park North Oxford, OX4 2JZ, UK**	
C.1.4.4	Telephone number : **+ 44 (0)7825 181 336**	
C.1.4.5	Fax number : **+ 44 (0)1865 711 986**	
C.1.4.6	E-mail : **fionas@glenmarkpharma.com**	

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[2]:	
	• 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 :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	(YYYY/MM/DD): **2012/06/12**

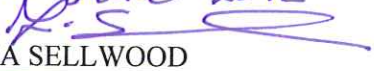
1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.

D.2	**Is it an early termination?**[3]	yes √ no ☐
D.2.1	If yes, give date (YYYY/MM/DD): **2012/06/12**	
D.2.1.1	Briefly describe in an annex (free text): **This study has not been started.**	
D.2.1.2	The justification for early termination of the trial; **For commercial reasons, it has been decided not to initiate this study.**	
D.2.1.3	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; **No subjects have been enrolled in this trial.**	
D.2.1.4	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. **None**	

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 the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	√
E.2.1	Date : 12th June 2012	
E.2.2	Signature : 	
E.2.3	Print name: FIONA SELLWOOD	

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:	

[3] Cf. Section 4.2. of the detailed guidance CT-1.

[4] Section 4.3. of the detailed guidance CT-1.