SCOPE INTERNATIONAL

SCOPE INTERNATIONAL AG • Konrad-Zuse-Ring 18 • D-68163 Mannheim

Bundesinstitut für Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn

13. März 2009

Klinische Studie OXN4501
Gesch. Z: 61 – 3910 – 4034617
EudraCT: 2008-003566-26

Sehr geehrte Damen und Herren,

hiermit möchten wir Ihnen mitteilen, dass der Sponsor sich entschlossen hat die o.g. Studie zu beenden. Der Antrag und die Begründung hierfür sind diesem Schreiben beigefügt.

Mit freundlichen Grüßen,

Dr. Michael Binder
- Clinical Research Associate -

Anlagen

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:

To be filled in by the applicant

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

B TRIAL IDENTIFICATION

B.1 EudraCT number:	**2008-003566-26**
B.2 Sponsor's protocol code number:	**OXN4501**
B.3 Full title of the trial:	**An exploratory, randomised, parallel-group, open-label, multicentre study to assess the post-operative management of moderate to severe pain in patients who underwent laparoscopic cholecystectomy, receiving oxycodone hydrochloride i.v. within 12 - 24 hours after surgery at first and then oxycodone / naloxone prolonged release tablets compared to patients receiving piritramide infusions.**

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:	Scope International AG
C.1.4.2	Name of person to contact:	Dr. Michael Binder
C.1.4.3	Address:	Konrad-Zuse-Ring 18 Mannheim 68163 Germany
C.1.4.4	Telephone number:	+49 621 429 39 65
C.1.4.5	Fax number:	+49 621 429 39 40
C.1.4.6	E-mail	mbinder@scope-international.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[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:	Address Line 1 Address Line 2 Address Line 3 Address Line 4
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):	13.03.2009	

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):	13.03.2009	

D.3	**Is it a premature ending of the trial?**		yes ☒ no ☐
D.3.1	If yes, give date (YYYY/MM/DD):	13.03.2009	
D.3.2	What is (are) the reason(s) for the premature ending?	Decision by Sponsor in response to the obligations requested by leading EC.	
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:	The resulting change of study design (requested by EC).	
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:	Not applicable since study has not commenced.	

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 :	13.03.2009	
E.2.2	Signature :		
E.2.3	Print name:	Dr. Michael Binder	

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:		

Annex 1: Reason for discontinuation of Trial

The decision for discontinuation of the clinical trial before recruitment start was made by the sponsor in respect to the new obligations requested by the leading EC in their letter from 27th February 2009.
In general these modifications would substantially change the study design which in consequence would impair patient recruitment and prolong the enrolment period. Furthermore the investigational sites would have to be evaluated another time for eligibility which consequently leads to an additional delay of study initiation.
Taking all aspects into account the economic efficiency as well as the feasibility of the clinical trial would become disproportionate to the sponsor. Therefore Mundipharma GmbH decided not to continue with this clinical trial.