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: The Netherlands

B TRIAL IDENTIFICATION

B.1 EudraCT number:	**2008-00404-92**
B.2 Sponsor's protocol code number:	**HOVON 92 AML / SAKK 30/08**
B.3 Full title of the trial:	**Randomized study to assess the added value of Laromustine in combination with standard remission-induction chemotherapy in patients aged 18-65 years with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPSS >= 1.5)**

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:	HOVON Data Center
C.1.4.2	Name of person to contact:	C. Korf
C.1.4.3	Address:	Groene Hilledijk 301 3075 EA Rotterdam The Netherlands
C.1.4.4	Telephone number:	+31 (0)10 704 15 60
C.1.4.5	Fax number:	+31 (0)10 704 10 28
C.1.4.6	E-mail	hdc@erasmusmc.nl

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:	HOVON Data Center
C.2.5.2	Name:	Prof. Dr. B. Löwenberg
C.2.5.3	Address:	Groene Hilledijk 301 3075 EA Rotterdam The Netherlands
C.2.5.4	Telephone number:	+31 (0)10 704 15 60
C.2.5.5	Fax number:	+31 (0)10 704 10 28
C.2.5.6	E-mail:	hdc@erasmusmc.nl

[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):	

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):	2010/02/16

D.3	**Is it a premature ending of the trial?**		yes ☒ no ☐
D.3.1	If yes, give date	(YYYY/MM/DD):	2010/02/12
D.3.2	What is (are) the reason(s) for the premature ending?		Vion Pharmaceuticals, Inc., will be withdrawing its Investigational New Drug Application for VNP40101M (with Laromustine). In accordance with the Data Safety Monitoring Committee's recommendation, HOVON placed the investigational arm B (with Laromustine) on hold effective December 23, 2009. As a result of Vion's withdrawal of the application, the DSMB's recommendation, and Vion's own Chapter 11 bankruptcy, the HOVON 92 AML / SAKK 30/08 study has been closed for entry as of 12 February 2010.
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:		see answer at D.3.2
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:		For 27 patients we have not yet received an off treatment form. All patients who are on study, will finish their treatments according to protocol (without Laromustine).
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:		Data may be evaluated and published after all CRFs have been completed. The IMP is no longer available because of the bankruptcy of the farmaceutical company Vion.

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 :	2010/02/22
E.2.2	Signature :	
E.2.3	Print name:	C. Korf

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☒
E.3.1	Date :	22 FEB 2010
E.3.2	Signature :	
E.3.3	Print name:	Prof. Dr. Löwenberg