Centre for Infections

Health Protection Agency

CTA Section
Clinical Trials Unit
MHRA
Market Towers
1 Nine Elms
London
SW8 5NQ

28 August 2007

Dear Sir/ Madam

Re: A Phase IV, single group study to evaluate the immune response to licensed seasonal influenza vaccine and relationship of this to cytomegalovirus-associated immunosenescence in UK older adults aged 50-80 years.

REC ref: 06/Q1704/169

EudraCT No: 2006-006563-23

Please find enclosed the completed notification form for the end of the trial.

We have closed the study early as the proportion of CMV negative individuals was not known at the start of the study but was estimated to be 20%. In the event it was closer to 30% which meant the essential 40 negative individuals were recruited within a smaller sample size than it was originally thought would be needed. As the study objective could be answered with this smaller sample size it was considered unethical to recruit further individuals, as detailed on the form.

Yours sincerely

Jo Southern
Immunisation Department, Centre for Infections

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: UK

B TRIAL IDENTIFICATION

B.1 EudraCT number:	**2006-006563-23**
B.2 Sponsor's protocol code number:	**CMVfluvaccinees**
B.3 Full title of the trial:	**A Phase IV, single group study to evaluate the immune response to licensed seasonal influenza vaccine and relationship of this to cytomegalovirus-associated immunosenescence in UK older adults aged 50-80 years**

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:	Health Protection Agency
C.1.4.2	Name of person to contact:	Jo Southern
C.1.4.3	Address:	Immunisation Department Centre for Infections Health Protection Agency 61 Colindale Ave, London NW9 5EQ
C.1.4.4	Telephone number:	0208 327 7681
C.1.4.5	Fax number:	0208 200 7868
C.1.4.6	E-mail	jo.southern@hpa.org.uk

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:	Health Protection Agency
C.2.5.2	Name:	Jo Southern
C.2.5.3	Address:	Immunisation Department Centre for Infections Health Protection Agency 61 Colindale Ave, London NW9 5EQ
C.2.5.4	Telephone number:	0208 327 7681
C.2.5.5	Fax number:	0208 200 7868
C.2.5.6	E-mail:	jo.southern@hpa.org.uk

[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):	2007/08/06

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):	2007/08/06

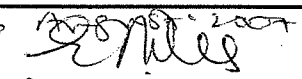
D.3	**Is it a premature ending of the trial?**	yes ☒ no ☐
D.3.1	If yes, give date (YYYY/MM/DD):	2007/08/06
D.3.2	What is (are) the reason(s) for the premature ending?	The proportion of CMV negative individuals was not known at the start of the study but was estimated to be 20%. In the event it was closer to 30% which meant the essential 40 negative individuals were recruited within a smaller sample size than it was originally thought would be needed. As the study objective could be answered with this smaller sample size it was considered unethical to recruit further individuals so the study was closed.
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 proportion of CMV negative individuals was not known at the start of the study but was estimated to be 20%. In the event it was closer to 30% which meant the essential 40 negative individuals were recruited within a smaller sample size than it was originally thought would be needed. As the study objective could be answered with this smaller sample size it was considered unethical to recruit further individuals so the study was closed.
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:	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 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 :	6 August 2007
E.2.2	Signature :	
E.2.3	Print name:	E. MILLER

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date :	6 August 2007
E.3.2	Signature :	
E.3.3	Print name:	E. Miller.