Annex 3: 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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2017-003193-14 **(..)**
B.2 Sponsor's protocol code number: 1819/2017 **(..)**
B.3 Full title of the trial : Therapie mit Aflibercept bei proliferativer diabetischer Retinopathie - eine prospektive, klinische Pilot-Studie.

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 : Department of Ophthalmology, Medical University Vienna	
C.1.4.2	Name of person to contact : PD Dr. Sonja Karst	
C.1.4.3	Address : Waehringerguertel 18-20, 1090 Vienna, Austria	
C.1.4.4	Telephone number : +43 1 40400 484700	
C.1.4.5	Fax number : +43 1 40400 78890	
C.1.4.6	E-mail sonja.karst@meduniwien.ac.at	

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: Department of Ophthalmology, Medical University Vienna	
C.2.5.2	Name : PD Dr. Sonja Karst	
C.2.5.3	Address : Waehringerguertel 18-20, 1090 Vienna, Austria	
C.2.5.4	Telephone number : +43 1 40400 484700	
C.2.5.5	Fax number : +43 1 40400 78890	
C.2.5.6	E-mail : sonja.karst@meduniwien.ac.at	

[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): 2021/09/18	

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): 2021/09/18	

D.3	**Is it a premature ending of the trial?**	yes ☒ no ☐
D.3.1	If yes, give date (YYYY/MM/DD): 2021/09/18	
D.3.2	What is (are) the reason(s) for the premature ending?	
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;	
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;	
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.	

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 :	
E.2.2	Signature :	
E.2.3	Print name:	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date : 29.09.2021	
E.3.2	Signature : Dr Sonja Karst	
E.3.3	Print name: PD Dr. Sonja Karst	

Annex:
The trial was ended prematurely due to the Covid-19 pandemic. Since our study patients are at risk of severe disease, we wanted to avoid monthly visits. Hence, all patients received treatment following standard of care in our subspecialty unit of diabetic retinopathy.