Aarhus, November 19, 2021

Danish Medicines Agency

Re: 'Adjunct effect of fluconazole in the treatment of Candida-associated refractory severe periodontitis. A single-center, placebo-controlled, triple blind, randomized clinical trial' (EudraCT number 2019-003541-15).

This letter is to inform that as the sponsor/principal investigator for this trial, I have decided to stop this study before any recruitment of participants is initiated.

Motivation: While the project had been approved by the local ethics committee and by the Danish Medicines Agency, the initiation meeting with the Good Clinical Practice unit (GCP) at the University Hospital in Aarhus never materialized due to the continued Coronavirus pandemic. Moreover, the corona situation has imposed a great deal of uncertainty regarding the possibilities for participant recruitment and actual conduct of the trial. As a result, the development and progress of the study has been stalled. Since the pandemic has also caused a considerable and unexpected increase in the already existing workload of the research group, we have to conclude that it is impossible for us to conduct the trial. I have therefore decided to stop this study before any recruitment of patients is initiated.
As the project did not start, no potential participant was contacted, no recruitments were done, and no data were collected.

Sincerely

Rodrigo López

Rodrigo López, Trial sponsor and principal investigator

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 :

B TRIAL IDENTIFICATION

B.1 EudraCT number: 2019-003541-15
B.2 Sponsor's protocol code number: 2019-Fungi
B.3 Full title of the trial: Adjunct effect of fluconazole in the treatment of Candida-associated refractory severe periodontitis. A single-center, placebo-controlled, triple blind, randomized clinical trial

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	**X**
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 Dentistry and Oral Health, Aarhus University**	
C.1.4.2	Name of person to contact : **Rodrigo López, sponsor/PI**	
C.1.4.3	Address : **Vennelyst Boulevard 9, 8000 Aarhus C, Denmark**	
C.1.4.4	Telephone number : **+45 61282078**	
C.1.4.5	Fax number : **none**	
C.1.4.6	E-mail : **rlopez@dent.au.dk**	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	**X**
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: **Department of Dentistry and Oral Health, Aarhus University**	
C.2.1.1	Name : **Rodrigo López, sponsor/PI**	
C.2.5.2	Address : **Vennelyst Boulevard 9, 8000 Aarhus C, Denmark**	
C.2.5.3	Telephone number : **+45 61282078**	
C.2.5.4	Fax number : **none**	
C.2.5.5	E-mail : **rlopez@dent.au.dk**	

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

D END OF TRIAL

D.1 Date of the end of the trial in this Member State? [3]	yes **X** no ☐
D.1.1. (**2021/11/19**):	

D.2 Date of the end of the complete trial in all countries concerned by the trial? [3]	yes **X** no ☐
D.2.1 (**2021/11/19): (this a single centre trial)**	

D.3 Is it an early termination?[4]	yes **X** no ☐
D.3.1 If yes, give date (**2021/11/19**):	
D.3.2 Briefly describe in an annex (free text):	
D.3.2.1 The justification for early termination of the trial;	
D.3.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;	
D.3.2.3 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:

- 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.[5]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1) ☐
E.2.1	Date : **2021/11/19**
E.2.2	Signature :
E.2.3	Print name: **Rodrigo López**

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:** ☐
E.3.1	Date : **2021/11/19**
E.3.2	Signature : 
E.3.3	Print name: **Rodrigo López**

[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the end of the trial in the individual Member State, section D1.1. shall be completed and submitted to the respective National Competent Authority.

2) At the global end of the trial, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted to all participating Member States in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

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

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