



262  
- 5 MAR. 2014

Celgene International Sarl  
Route de Perreux 1  
2017 Boudry  
Switzerland  
Tel: 0041 32 729 8500

## AMENDMENT #1 TO THE CLINICAL TRIAL AGREEMENT

Protocol No. ACE-011-BTHAL-001

### By and between;

The Azienda U.S.L. no. 8 in Cagliari (hereinafter called the "Azienda") TAX Code and VAT ID number no. 02261430926, with registered office in Selargius (Su Planu), Via Piero della Francesca, 1 represented by the General Manager Dr. Emilio Simeone

AND

The Company **Celgene International Sarl** (hereinafter the "Company"), tax code no. 34304, VAT number CH677334, located in Boudry, Switzerland, Route de Perreux 1, on behalf of Celgene Corporation, 86 Morris Avenue, Summit, NJ 07901, USA

### WITNESSETH

### WHEREAS:

1. The Parties entered into an Agreement on\*9 November 2012 (the "Agreement");
2. Due to the decease of the former Principal Investigator, Pr Renzo Galanello, and his replacement by Dr Rafaella Origa, the Principal Investigator, and
3. Due to the changes implemented by the Protocol Amendment 2,
4. The Parties now wish to amend the Agreement as per the terms and conditions of the present amendment ("Amendment");

### NOW, THEREFORE, the Parties agree as follows:

1. Capitalised terms used herein shall have the meanings set forth in the Agreement, unless otherwise defined in this Amendment.
2. Due to the decease of the Former Principal Investigator, Pr Renzo Galanello, the Institution proposed to Celgene to substitute the Former Principal Investigator by the Principal Investigator, Dr Rafaella Origa under this Amendment, through the Director of the II paediatrics Clinic Dr. Paolo Moi's written communication, with effective date 28 May 2013 based on the Local Ethics Committee approval. From such date the Principal Investigator is fully responsible under the Clinical Trial Agreement. For the avoidance of doubt, Principal Investigator hereby acknowledges that she has read and agrees to be bound by all terms and conditions under the Clinical Trial Agreement as from the date of her appointment as Principal Investigator as stated above.
3. The Parties agree to amend Article 6 to the Agreement with the following additional provisions which shall be added to the said Article:

a) Additional cycle will be paid at the rate of 700€ per cycle.

b) Hepatitis B&C (Not applicable for subjects that are transfusion independent) to be analysed locally during screening visit, will be paid at the rate of 100,24€. This is the total amount for the following tests

1. HBCAG IGM: 11,36
2. HBEAG 11.36
3. HBSAg: 11.36
4. HCV antibodies: 11.36
5. HCV RNA: 66.15

c) Start-up fees of 2000€ will be paid to the Azienda, to cover the start-up activities performed at the Azienda for the set-up of the protocol and its following amendments.

4. All terms and conditions not amended herein shall remain in full force and effect as per their current terms under the Agreement.

This Amendment shall become effective as from 27 August 2013.

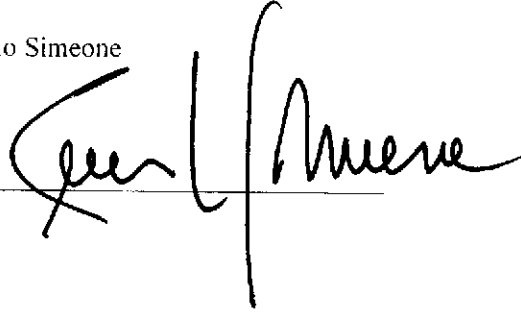
IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives.

**For the Azienda U.S.L. no. 8**

The General Manager

Dr. Emilio Simeone

Signed: \_\_\_\_\_

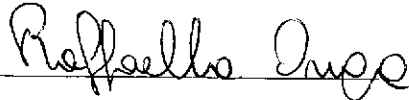


Date: \_\_\_\_\_

**The Principal Investigator (to consent)**

Dr Raffaella Origa

Signed: \_\_\_\_\_

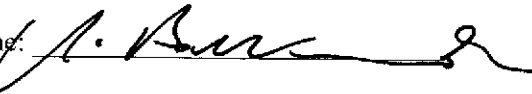


Date: \_\_\_\_\_

18 settembre 2013

**For the Sponsor Celgene International Sarl**

Name: \_\_\_\_\_



Signed: \_\_\_\_\_

Dr Michael Balkenohl  
Director Clinical Operations  
Celgene International  
Switzerland

Date: \_\_\_\_\_

10-SEP-2013

ALLEGATO ALLA DELIBERAZIONE

N. 262 DEL - 5 MAR. 2014  
IL DIRETTORE AMMINISTRATIVO (Dott. Sergio Salis) IL DIRETTORE SANITARIO (Dott. Ugo Spelli)  
IL DIRETTORE GENERALE (Dott. Emilio Simeone)

Il presente allegato è com-  
posto da n° 03 fogli  
di n° 03 pagine.



1. The first part of the document is a list of names and addresses of the members of the committee.

2. The second part of the document is a list of the names and addresses of the members of the committee who have been elected to the office of the chairperson.

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