PROGRESS & SAFETY REPORT

Protocol Title:	Evaluatie van de farmacokinetiek en pharmacodynamiek van intraveneus toegediende linezolid bij morbide obese, MRSA positieve, patiënten die lijden aan een pneumonie
Current Protocol version:	v1, 30/10/2012
Protocol number:	
EudraCT number:	2012-005127-33
EC Project number:	2012/788
Sponsor:	Pfizer
National Coordinating Investigator:	Dirk Vogelaers
Total number of sites in Belgium:	1
Reporting Period:	01/02/2013 – 30/9/2016

A. Trial Status

1. Have there been unexpected issues during the progress of the trial ?

   No

   If yes, which issues ?

2. Have there been amendments to the protocol ?

   No

   Please specify below:

Overview Amendments				
Amendment Number	Substantial Amendment	Non Substantial Amendment	Approval EC (dd/mmm/yyyy)	Approval FAGG (if applicable) (dd/mmm/yyyy)
Amendment 1	☐	☐		
Amendment 2	☐	☐		
Amendment 3	☐	☐		

3. Is the study still ongoing? (please complete below)

Study Overview						
Site	Not active yet?	Active?	Closed?	Number of Subjects included?	Date of first inclusion?	date of site closure (LPLV)
Ghent University Hospital	☐	☐	☒	0	-	30/9/2016
Parageorghiou General Hospital of Thessaloniki	☐	☐	☒	0	-	30/9/2016
University Hospital of Larissa	☐	☐	☒	6	-	30/9/2016
Naval & Veterans Hospital of Athens	☐	☐	☒	0	-	30/9/2016
University Hospital of Ionnina	☐	☐	☒	4	-	30/9/2016
General Hospital of Larissa	☐	☐	☒	0	-	30/9/2016
University Hospital of Herakleion	☐	☐	☒	5	-	30/9/2016

Remarks:

4. How many subjects will be, according to the approved protocol, included at the end of the study ?

   15

5. How many subjects were planned to be included at this time in the trial? Does the current accrual rate resembles the planned accrual rate?

We planned to include 20 patients but given the slow inclusion rate we decided to stop the study after 15 patient inclusions.

6. How many subjects have prematurely discontinued/completed the trial thus far?

Study Arm (if applicable)	Number of subjects completed	Number of subjects prematurely discontinued
15	15	0

Did any of the subjects discontinue the study prematurely due to safety issues? No

B. Safety

1. Have there been Serious Adverse Events/ Serious Adverse Reactions ?

No

If yes, what serious adverse events / serious adverse reactions ? (please complete below)

SAE Overview				
Subject ID	Study Arm (if applicable)	SUSAR (Y/N)	SAE Description	Outcome (ongoing, resolved, death, …)

Were all SAE's reported according to the applicable regulatory requirements?

Not applicable

Were any safety measures incorporated in the trial as a result of the occurred SAE's?

No

This report represents the state of the trial per (date): 1 Febr. 2017

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Signature National Coordinating Investigator:

Date: 1 Febr. 2017

After completion of this form, please return this form to Bimetra Clinics

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