Non Serious Adverse Drug Reactions Report

Start Date:2016-08-25 End Date:2016-08-26

Study :EMR700623-541	Investigator :Ying Zhong		Country of Investigator :China	SiteNo:C05		
Subject No :C05-0001	Subject Initials :XFZ	DOB :01/21/1988	Sex:Female	Race:Asian	Height:159cm	Weight:50kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	08/01/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/16/2015	08/18/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	None	Resolved		

Event Description:Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml，ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
oophorocystectomy	UK-Jul-2013	Not on treatment/medication	
salpingoplasty	UK-Feb-2014	Not on treatment/medication	
salpingitis after previous tubal occlusion	UK-Feb-2014	Not on treatment/medication	Ongoing

25-AUG-16

Ying Zhong/EMR700623-541/C05-0001

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-25 End Date:2016-08-26

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:001		
Subject No :001-0009	Subject Initials :	DOB :08/08/1960	Sex:Female	Race:Caucasian	Height:160(cm)	Weight:65(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	12/22/2014	44	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	12/22/2014	44	
Visit 1/ Baseline (Day 1)	12/22/2014	44	
Visit 4 (Month 9)	12/22/2014	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
injection site inflammation	12/22/2014	01/01/2015		Suspected	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	None	Resolved		

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
persistent flu-like symptoms	12/22/2014	UK-unk-2014		Suspected	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	None	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
acetaminophen	Uk-Feb-2015		Uk-Feb-2015	500	mg	per day

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
hypertension			Yes
dyslipidemia			Yes
acute bronchitis			No

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-25 End Date:2016-08-26

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:005		
Subject No :005-0007	Subject Initials :	DOB :05/06/1966	Sex:Female	Race:Caucasian	Height:165(cm)	Weight:70(kg)
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Visit 5 (Month12)/Early Termination						
Visit 1/ Baseline (Day 1)	03/05/2015		9			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
. 1.local erythema, pain	04/10/2015			Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Drug withdrawn	Led to study termination	Ongoing		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
induration local site injection	03/25/2015			Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Drug withdrawn	Led to study termination	Ongoing		
Event description:						
Subject received concomitant medications						
Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
caesarean section						No
uterine fibromas						Yes