Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0136	Subject Initials :Q-L	DOB :03/28/1984	Sex:Female	Race:Asian	Height:154cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/08/2015	06/12/2015		Related	Moderate

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

Event description:

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction incomplete	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0137	Subject Initials :YLF	DOB :11/01/1989	Sex:Female	Race:Asian	Height:153cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/09/2015	06/16/2015		Related	Moderate

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

Event description:

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0138	Subject Initials :TTJ	DOB :06/20/1990	Sex:Female	Race:Asian	Height:150cm	Weight:41.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/22/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		

Event description:

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Ectopic pregnancy laparoscopic surgery: the right fallopian tube embryo pelvic sticking points	Uk-Jan-2014	Not on treatment/medication	
Hysteroscopy: endometrial polyps.	Uk-Feb-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C04		
Subject No :C04-0087	Subject Initials :HZD	DOB :08/04/1983	Sex:Female	Race:Asian	Height:161cm	Weight:60kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	06/26/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	07/07/2015	07/21/2015		Related	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Dose reduced	None	Resolved		

Event description:none

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
spontaneous abortion	01/05/2010	Not on treatment/medication	
spontaneous abortion	05/18/2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C04		
Subject No :C04-0171	Subject Initials :SHL	DOB :08/17/1987	Sex:Female	Race:Asian	Height:154cm	Weight:40kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/30/2015	10/09/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose reduced	None	Resolved		
Event description:none						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-22 End Date:2016-03-23

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0014	Subject Initials :	DOB :09/02/1988	Sex:Male	Race:Caucasian	Height:181(cm)	Weight:69(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/29/2015	9	
Visit 3 (Month 6)	06/29/2015	9	
Visit 1/ Baseline (Day 1)	06/29/2015	9	
Visit 4 (Month 9)	06/29/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
flu-like symptoms	12/22/2015			Suspected	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Dose not changed	None	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Driptane	05/18/2015	Yes		5	mg	QD
Lioresal	05/18/2015	Yes		15	mg	TID
Acetaminophen	12/22/2015	Yes		500	mg	PRN

Does the subject have any relevant past or present medical conditions:No

Condition	Start Date	Related to study condition	Ongoing