Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :Fei Gong		Country of Investigator :China	SiteNo:C01		
Subject No :C01-0001	Subject Initials :TTW	DOB :05/13/1988	Sex:Female	Race:Asian	Height:157cm	Weight:41.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/16/2015		112.5			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	06/15/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Concomitant procedure**	Resolved		

Event Description:Nausea, vomiting, yellow urine with less volume, chest pelvic effusion,ascites puncture 10-Jun-2015,2200ml;ascites puncture 15-Jun-2015,2900ml;

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Bilateral fallopian tube obstruction	04/11/2014	Not on treatment/medication	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :Fei Gong		Country of Investigator :China	SiteNo:C01		
Subject No :C01-0068	Subject Initials :X-S	DOB :04/16/1989	Sex:Female	Race:Asian	Height:160cm	Weight:43kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	06/27/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	07/23/2015	08/04/2015		Related	Severe

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

Event Description:Abdominal distension, Nausea, yellow urine with less volume, chest pelvic effusion , Ascites puncture 23Jul2015,1000ml; 27Jul2015,2100ml; 30Jul2015,2500ml; 04Aug2015,2000ml ;

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
The left Hydrosalpinx and adhesions,less patency.Right fallopian tube partially blocked	03/22/2014	Not on treatment/medication	Ongoing
right fallopian tube resection because of Ectopic pregnancy	UK-Oct-2011	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0010	Subject Initials :Y-H	DOB :10/18/1985	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	05/11/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/29/2015	06/02/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication**(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description:Moderate OHSS occurs canceled transplant						
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:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0102	Subject Initials :HYD	DOB :10/14/1985	Sex:Female	Race:Asian	Height:163cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/19/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS risk				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			
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
Palace laparoscopy				Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0195	Subject Initials :J-L	DOB :08/15/1984	Sex:Female	Race:Asian	Height:156cm	Weight:48.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/28/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/14/2015	06/18/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	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 patency, pelvic adhesions.	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0200	Subject Initials :L-Z	DOB :12/17/1988	Sex:Female	Race:Asian	Height:155cm	Weight:70.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/28/2015		187.5			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	06/18/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	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 obstruction	Uk-Apr-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

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	Severe

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

06-APR-16

Ying Zhong/EMR700623-541/C05-0001

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-0059	Subject Initials :LKH	DOB :08/05/1981	Sex:Female	Race:Asian	Height:153cm	Weight:74kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	06/02/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	07/02/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
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:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-035	Subject Initials :PSS	DOB :01/19/1983	Sex:Female	Race:Asian	Height:161cm	Weight:56kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/11/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/23/2015	04/21/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
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:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/13/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
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:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-040	Subject Initials :LBH	DOB :03/05/1985	Sex:Female	Race:Asian	Height:164cm	Weight:61kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	04/06/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	04/15/2015	04/30/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
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:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-049	Subject Initials :PGR	DOB :02/20/1983	Sex:Female	Race:Asian	Height:168cm	Weight:62kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/02/2015	300	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/13/2015	05/29/2015		Related	Mild

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

Event Description:albumin treatment and resloved

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
laparoscopic ovary cystectomy	UK-UNK-2004	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-050	Subject Initials :KHG	DOB :04/22/1984	Sex:Female	Race:Asian	Height:150cm	Weight:46kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/03/2015	300	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/14/2015	05/29/2015		Related	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Dose not changed	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
ovary cystectomy	UK-Jan-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:006		
Subject No :006-0005	Subject Initials :	DOB :08/28/1965	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 2 (Month 3)	03/11/2015	8	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	03/11/2015	8	
Visit 1/ Baseline (Day 1)	03/11/2015	8	
Visit 4 (Month 9)	03/11/2015	8	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
increased liver enzimes	06/11/2015			Suspected	Mild

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:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
necrosis at injection site	06/30/2015			Suspected	Moderate

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

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
increased liver enzymes	12/20/2015			Suspected	Moderate

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

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
desloratadinum	08/22/2015		09/09/2015	5	miligrams	qd
liv 52	08/22/2015	Yes		275	miligrams	qd

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

Condition	Start Date	Related to study condition	Ongoing
thrombophilia			Yes
arterial hipertension			Yes

peripheral artheriopathy			Yes

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-06 End Date:2016-04-07

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0012	Subject Initials :	DOB :12/11/1988	Sex:Male	Race:Caucasian	Height:187(cm)	Weight:95(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/15/2015	9	
Visit 1/ Baseline (Day 1)	06/15/2015	9	
Visit 4 (Month 9)	06/15/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
elevated liver enzymes	01/07/2016			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	Concomitant medication	Ongoing		

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
trombocytopenia	03/28/2016			Suspected	Mild	
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:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
flu-like symptoms	03/30/2016			Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Concomitant medication	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Solu-Medrol	08/26/2015		08/28/2015	1000	mg	QD
Spironolactona	08/26/2015		08/28/2015	25	mg	QD
Controloc	08/26/2015		08/28/2015	40	mg	QD
Alanerv	08/28/2015		09/28/2015	1	tb	QD
Ibuprofenum	03/30/2016	Yes		400	mg	PRN
LIV52	03/28/2016	Yes		6	tb	TID

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

Condition	Start Date	Related to study condition	Ongoing