

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

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	
None(Othervalue:)	Not applicable	Led to study termination	Resolved			
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition	Start Date	Related to study condition	Ongoing			

09-MAY-16

NA/EMR700623-541/C02-0010

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0087	Subject Initials :XPT	DOB :06/15/1988	Sex:Female	Race:Asian	Height:158cm	Weight:57.0kg
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	05/30/2015	06/05/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Hysteroscopy normal				Uk-Mar-2015	Not on treatment/medication	

09-MAY-16

NA/EMR700623-541/C02-0087

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0142	Subject Initials :HMT	DOB :02/19/1988	Sex:Female	Race:Asian	Height:168cm	Weight:46.0kg
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	06/07/2015	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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
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 and hydrocephalus				Uk-Unk-2014	Not on treatment/medication	
Laparoscopy surgery: pelvic stars stick + fulguration of endometriosis foci, tubal plastic surgery				Uk-Unk-2014	Not on treatment/medication	

09-MAY-16

NA/EMR700623-541/C02-0142

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0210	Subject Initials :GLW	DOB :05/08/1983	Sex:Female	Race:Asian	Height:160cm Weight:55.0kg	
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/28/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/15/2015	09/20/2015		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: Moderate OHSS patients, improved canceled after embryo transfer.						
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: the right fallopian tube obstruction				Uk-Unk-2014	Not on treatment/medicatio n	

09-MAY-16

NA/EMR700623-541/C02-0210

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0215	Subject Initials :L-X	DOB :08/05/1989	Sex:Female	Race:Asian	Height:165cm	Weight:56.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/28/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/14/2015	09/18/2015		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: Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
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 occlusion				Uk-Unk-2014	Not on treatment/medication	
Under laparoscopy surgery to clear the fallopian tubes, pelvic adhesions dissection				Uk-Unk-2014	Not on treatment/medication	

09-MAY-16

NA/EMR700623-541/C02-0215

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-06 End Date:2016-05-09

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0249	Subject Initials :ZPY	DOB :09/13/1982	Sex:Female	Race:Asian	Height:162cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	09/07/2015	187.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/22/2015	09/28/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.						
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: incomplete right fallopian tube obstruction, left fallopian tube obstruction				Uk-Unk-2015	Not on treatment/medication	

09-MAY-16

NA/EMR700623-541/C02-0249

