Non Serious Adverse Drug Reactions Report

Start Date:2015-09-24 End Date:2015-09-25

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	06/16/2015		Related	Moderate

Causality Factors	**Action Taken with Study Treatment**	**Other action taken**	**Outcome**	**AE Special Interest**	**AE dose limiting toxicity**
None(Othervalue:)	Not applicable	Concomitant procedure**	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**
Bilateral fallopian tube obstruction	04/11/2014	Not on treatment/medication	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2015-09-24 End Date:2015-09-25

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	06/26/2015	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:

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:2015-09-24 End Date:2015-09-25

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:

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:2015-09-24 End Date:2015-09-25

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:2015-09-24 End Date:2015-09-25

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

Non Serious Adverse Drug Reactions Report

Start Date:2015-09-24 End Date:2015-09-25

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:2015-09-24 End Date:2015-09-25

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:2015-09-24 End Date:2015-09-25

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:2015-09-24 End Date:2015-09-25

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:2015-09-24 End Date:2015-09-25

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	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 **,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**
laparoscopic ovary cystectomy	UK-UNK-2004	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2015-09-24 End Date:2015-09-25

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	