Non Serious Adverse Drug Reactions Report

Start Date:2016-09-21 End Date:2016-09-22

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:001		
Subject No :001-0019	Subject Initials :	DOB :03/25/1988	Sex:Female	Race:Caucasian	Height:170(cm)	Weight:58(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/18/2015	9	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	06/18/2015	9	
Visit 1/ Baseline (Day 1)	06/18/2015	9	
Visit 4 (Month 9)	06/18/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
flu-like symptoms	06/18/2015	09/04/2015		Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Concomitant medication	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Acetaminophen	06/18/2015		09/04/2015	500	mg	occasionally

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:2016-09-21 End Date:2016-09-22

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:002		
Subject No :002-0002	Subject Initials :	DOB :08/13/1955	Sex:Male	Race:Caucasian	Height:180(cm)	Weight:84(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	02/16/2015	8	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	02/16/2015	8	
Visit 1/ Baseline (Day 1)	02/16/2015	8	
Visit 4 (Month 9)	02/16/2015	8	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
Injection site inflammation	11/11/2015	02/20/2016		Suspected	Moderate

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None(Othervalue:)	Drug withdrawn	Led to study termination	Resolved		

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
Blood hypertension			Yes
Cardiac ischemic heart disease			Yes
Diabetes mellitus type 2			Yes
Benign prostatic hyperplasia			Yes

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-21 End Date:2016-09-22

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:005		
Subject No :005-0001	Subject Initials :	DOB :08/27/1996	Sex:Female	Race:Caucasian	Height:169(cm)	Weight:65(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)	02/12/2015		5			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema and induration local site injection	04/28/2015	05/30/2015		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	Resolved		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
induration local site injection	04/28/2015	05/30/2015		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	Resolved		
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:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-21 End Date:2016-09-22

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
local erythema at site injection	04/10/2015	05/04/2015		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	Resolved		

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	05/04/2015		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	Resolved		

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

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-21 End Date:2016-09-22

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:005		
Subject No :005-0009	Subject Initials :	DOB :04/22/1992	Sex:Female	Race:Caucasian	Height:173(cm)	Weight:63(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)	03/26/2015		9			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema at site injection	06/09/2015	07/15/2015		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	Resolved		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
ecchymosis	06/09/2015	07/15/2015		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	Resolved		
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:No						
Condition				Start Date	Related to study condition	Ongoing