Non Serious Adverse Drug Reactions Report

Start Date:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0004	Subject Initials :	DOB :05/19/1987	Sex:Female	Race:Caucasian	Height:174(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 2 (Month 3)	12/22/2014	44	
Visit 3 (Month 6)	12/22/2014	44	
Visit 1/ Baseline (Day 1)	12/22/2014	44	
Visit 4 (Month 9)	12/22/2014	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
fever	02/17/2015	02/18/2015		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	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
shiver	02/17/2015	02/18/2015		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	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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0006	Subject Initials :	DOB :03/28/1975	Sex:Female	Race:Caucasian	Height:170(cm)	Weight:74(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 2 (Month 3)	01/12/2015	44	
Visit 3 (Month 6)	01/12/2015	44	
Visit 1/ Baseline (Day 1)	01/16/2015	44	
Visit 4 (Month 9)	01/12/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
pruritus	06/12/2015	06/13/2015		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	Resolved		

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema	06/12/2015	06/13/2015		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	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Methylprednisolone	04/04/2015		04/06/2015	500	mg	daily

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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0007	Subject Initials :	DOB :06/18/1983	Sex:Female	Race:Caucasian	Height:155(cm)	Weight:63(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	01/16/2015	44	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	01/16/2015	44	
Visit 1/ Baseline (Day 1)	01/16/2015	44	
Visit 4 (Month 9)	01/16/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
fever	03/31/2015	04/02/2015		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	Resolved		

Event description:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
shiver	03/31/2015	04/02/2015		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	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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0009	Subject Initials :	DOB :01/13/1971	Sex:Female	Race:Caucasian	Height:170(cm)	Weight:62(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 2 (Month 3)	02/04/2015	44	
Visit 3 (Month 6)	02/04/2015	44	
Visit 1/ Baseline (Day 1)	02/04/2015	44	
Visit 4 (Month 9)	02/04/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
fever	06/11/2015	06/12/2015		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	Concomitant medication	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Acetaminophen	06/11/2015		06/12/2015	500	mg	daily

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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0010	Subject Initials :	DOB :07/22/1970	Sex:Male	Race:Caucasian	Height:168(cm)	Weight:88(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 2 (Month 3)	02/04/2015	44	
Visit 1/ Baseline (Day 1)	02/04/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
flu-like illness	03/15/2015	03/16/2015		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	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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0011	Subject Initials :	DOB :07/08/1984	Sex:Female	Race:Caucasian	Height:167(cm)	Weight:57(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 2 (Month 3)	02/05/2015	44	
Visit 3 (Month 6)	02/05/2015	44	
Visit 1/ Baseline (Day 1)	02/05/2015	44	
Visit 4 (Month 9)	02/05/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
low fever	06/10/2015	06/12/2015		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	Concomitant medication	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema	06/10/2015	06/12/2015		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	Resolved		
Event description:						

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Acetaminophen	06/10/2015		06/12/2015	500	mg	daily

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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:003		
Subject No :003-0016	Subject Initials :	DOB :10/01/1976	Sex:Female	Race:Caucasian	Height:168(cm)	Weight:57(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 2 (Month 3)	02/06/2015	44	
Visit 3 (Month 6)	02/06/2015	44	
Visit 1/ Baseline (Day 1)	02/06/2015	44	
Visit 4 (Month 9)	02/06/2015	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local pain	04/17/2015	04/18/2015		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	Concomitant medication	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema	04/17/2015	04/18/2015		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	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local edema	04/17/2015	04/18/2015		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	Concomitant medication	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
pruritus	06/08/2015	06/09/2015		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	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
pruritus	09/05/2015	09/07/2015		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	Resolved		

Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema	09/05/2015	09/07/2015		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	Resolved		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
fever	09/05/2015	09/07/2015		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	Resolved		
Event description:						
Subject received concomitant medications:Yes						
Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
NSAIDs	04/17/2015		04/18/2015	200	mg	daily
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:2016-10-05 End Date:2016-10-06

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0010	Subject Initials :	DOB :03/25/1989	Sex:Male	Race:Caucasian	Height:179(cm)	Weight:63(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/08/2015	9	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	06/08/2015	9	
Visit 1/ Baseline (Day 1)	06/08/2015	9	
Visit 4 (Month 9)	06/08/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
elevated liver enzymes	07/24/2015	02/19/2016		Suspected	Moderate

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

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
LIV52	09/04/2015		01/26/2016	6	tb	TID
Acetaminophen	06/08/2015		06/08/2015	500	mg	PRN
Solu-Medrol	01/27/2016		01/29/2016	1000	mg	QD
LIV 52	01/27/2016		02/22/2016	3	tb	TID
Controloc	01/27/2016		02/03/2016	20	mg	QD
Rivotril 0.5mg	01/27/2016	Yes		500	mcg	BID
Milgamma	01/30/2016		02/08/2016	3	tb	TID

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:2016-10-05 End Date:2016-10-06

No Data between these 2016-10-05 and 2016-10-06