	Non Se	erious Adv	erse Drug	Reactions	s Report	
Start Date:2016-10	-05 End Date:2016-10-				•	
Study :EMR200136_583	Investigator :NA	Investigator :NA		SiteNo:003		
Subject No :003-0004	Subject Initials :	Subject Initials : DOB :05/19/1987		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	12/22/2014				
Visit 4 (Month 9)	12/22/2014	2/2014				
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:		1	-1	-1		1
Subject received co	oncomitant medications	<b>S</b>				
Name of medication	n Start Date	Ongoing	End Date	Dose	Unit	Frequency
Does the subject ha	ave any relevant past o	or present medical cond	itions:No			
Condition				Start Date	Related to study condition	Ongoing

	Non S	Serious Adv	erse Drug	Reactions	s Report		
Start Date:2016-10-							
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		
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:			1	1			
Subject received cor	ncomitant medication	ns: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 ha	ve any relevant past	or present medical cond	itions:No	1			
Condition				Start Date	Related to study condition	Ongoing	
						05-OCT-16	

	Non S	erious Adv	erse Drug	Reactions	s Report		
Start Date:2016-10-	05 End Date:2016-10				•		
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		
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:		ı			1		
Subject received cor	ncomitant medications	s					
Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency	
Does the subject ha	ve any relevant past o	or present medical cond	itions:No	1		ı	
Condition				Start Date	Related to study condition	Ongoing	
						05-OCT-1	

Study Drug		Non S	erious Adv	erse Drug	Reactions	s Report		
Investigator   Race:Caucasian   Height:170(cm)   Weight   Romania   Race:Caucasian   Height:170(cm)   Weight   Height:170(cm)   Weight   Race:Caucasian   Height:170(cm)   Weight   Race:Caucasian   Height:170(cm)   Weight   Height:170(cm)   Weight   Height:170(cm)   Weight   Race:Caucasian   Height:170(cm)   Weight   Height:170(cm)   Height:1	Start Date:2016-10-0	05 End Date:2016-10	)-06	_				
Study Drug		Investigator :NA		Investigator	Investigator			
Study Drug		Subject Initials :	DOB :01/13/1971	Sex:Female	Race:Caucasian	Height:170(cm)	Weight:62(kg)	
Visit 5 (Month12)/Early Termination         44           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 drug         Severity drug           fever         06/11/2015         06/12/2015         Suspected         Mild           Causality Factors         Action Taken with Study Treatment         Other action taken Outcome         AE Special Interest AE doxicil           None(Othervalue:)         Dose not changed         Concomitant medication         Resolved         Event description:           Subject received concomitant medications:Yes         Start Date         Ongoing         End Date         Dose         Unit         Frequence           Acetaminophen         06/11/2015         06/12/2015         500         mg         daily	First administration of	late of batch :		Batch number :	•			
(Month12)/Early Termination         description:           Visit 2 (Month 3)         02/04/2015         44         description:           Visit 3 (Month 6)         02/04/2015         44         description:           Visit 1/ Baseline (Day 1)         02/04/2015         44         description:           Visit 4 (Month 9)         02/04/2015         44         description:           Adverse Event         Start Date         End Date         Time related to study freatment of rug         Severity         description:           Causality Factors         Action Taken with Study Treatment         Other action taken         Outcome         AE Special Interest         AE do toxicity           None(Othervalue:)         Dose not changed         Concomitant medication         Resolved         Image: Concomitant medication         Resolved         Image: Concomitant medication         Prequitation         Prequitation </td <td>Study Drug</td> <td>Start Date</td> <td></td> <td>Dose</td> <td>Change in Dose</td> <td></td> <td>1</td>	Study Drug	Start Date		Dose	Change in Dose		1	
Visit 3 (Month 6)         02/04/2015         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44         44 <td< td=""><td>(Month12)/Early</td><td></td><td></td><td></td><td></td><td></td><td></td></td<>	(Month12)/Early							
Visit 1/ Baseline (Day 1)  Visit 4 (Month 9)  O2/04/2015  Adverse Event  Start Date  End Date  Time related to study treatment fever  O6/11/2015  O6/12/2015  Action Taken with Study Treatment  None(Othervalue:)  Dose not changed  Event description:  Suppected  Causality Factors  Outcome  AE Special Interest AE do toxicit Action Taken with Study Treatment  Concomitant medication  Resolved  Event description:  Suppected  Mild  AE Special Interest AE do toxicit Action Taken with Study Treatment  Pose not changed  Concomitant medication  Resolved  Concomitant medication  Resolved  Unit  Frequence Acetaminophen  O6/11/2015  O6/12/2015  O6/12/2015  O6/12/2015  O6/12/2015  O6/12/2015	Visit 2 (Month 3)	02/04/2015		44				
Visit 4 (Month 9)   O2/04/2015   244	Visit 3 (Month 6)	02/04/2015	02/04/2015					
Adverse Event Start Date End Date Time related to study treatment Suspected Mild  Causality Factors Action Taken with Study Treatment Study Treatment  None(Othervalue:) Dose not changed Concomitant medications: Yes  Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 Suspected Mild  Causality to study drug Severity Mild  Causality to study drug Severity Mild  Causality to study drug  Suspected Mild  Causality to study drug  Concomitant medication taken Outcome AE Special Interest AE do toxicity do toxicity for the study of the stud		02/04/2015		44				
fever 06/11/2015 06/12/2015 Suspected Mild   Causality Factors Action Taken with Study Treatment Other action taken Outcome AE Special Interest AE do toxicit   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 Frequence   Acetaminophen 06/11/2015 06/12/2015 500 mg daily	Visit 4 (Month 9)	02/04/2015		44				
Causality Factors Action Taken with Study Treatment Other action taken Outcome AE Special Interest AE do toxicit  None(Othervalue:) Dose not changed Concomitant medication  Event description:  Subject received concomitant medications:Yes  Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 500 mg daily	Adverse Event	Start Date	End Date		1 .	Severity		
Study Treatment toxicit  None(Othervalue:) Dose not changed Concomitant medication  Event description:  Subject received concomitant medications:Yes  Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 06/12/2015 500 mg daily	fever	06/11/2015	06/12/2015		Suspected	Mild		
Event description:  Subject received concomitant medications:Yes  Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 06/12/2015 500 mg daily	Causality Factors			Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
Subject received concomitant medications:Yes  Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 06/12/2015 500 mg daily	None(Othervalue:)		Dose not changed		Resolved			
Name of medication Start Date Ongoing End Date Dose Unit Frequence Acetaminophen 06/11/2015 06/12/2015 500 mg daily	Event description:		,L	1	1	L	1	
Acetaminophen         06/11/2015         06/12/2015         500         mg         daily	Subject received cor	ncomitant medication	is:Yes					
	Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency	
Does the subject have any relevant past or present medical conditions:No	Acetaminophen	06/11/2015		06/12/2015	500	mg	daily	
	Does the subject hav	ve any relevant past	or present medical cond	itions:No	1	<u> </u>	1	
Condition Start Date Related to study condition Ongo	Condition				Start Date		Ongoing	

	Non S	erious Adv	erse Drug	Reactions	s Report	
Start Date:2016-10-0	5 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 d	ate of batch :	· ·	Batch number :		-1	
Study Drug	Start Date		Dose	Change in Dose		I
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 con	comitant medication	3				
Name of medication	e of medication Start Date Ongoing		End Date	Dose	Unit	Frequency
Does the subject hav	e any relevant past	or present medical cond	itions:No	•	•	•
Condition				Start Date	Related to study condition	Ongoing
				•	•	05-OCT-16

	Non Se	erious Adv	erse Drug	Reactions	s Report		
Start Date:2016-10-0					•		
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 d	ate 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		
		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:				- I	- L	I	
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:		-1	1	1			
Subject received con	comitant 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 hav	e any relevant past o	r present medical cond	itions:No	•	•	•	
Condition				Start Date	Related to study condition	Ongoing	
						05-OCT-16	

		erious Adv	erse Drug	Reactions	s Report			
	05 End Date:2016-10	J-U6	1-	SiteNo:003				
Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania					
Subject No :003-0016	Subject Initials :	DOB :10/01/1976	Sex:Female	Race:Caucasian	Height:168(cm)	Weight:57(kg)		
First administration of	date of batch :	<b>'</b>	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	ausality Factors		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		
None(Othervalue:)		Dose not changed	None	Resolved			
Event description:		<u>'</u>			•		
Subject received con	comitant medication	ons: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 hav	e any relevant pas	t or present medical cond	itions:No			I.	
Condition				Start Date	Related to study condition	Ongoing	

	Non Se	erious Adv	erse Drug	Reactions	Report		
Start Date:2016-10-0	5 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 da	ate 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 con-	comitant 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 hav	e any relevant past o	r present medical cond	itions:No		ı		
				Start Date	Related to study condition	Ongoing	

05-OCT-16 NA/EMR200136\_583/007-0010

## 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