Non Serious Adverse Drug Reactions Report

Start Date:2016-09-24 End Date:2016-09-25

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	09/04/2015	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

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Start Date:2016-09-24 End Date:2016-09-25

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0012	Subject Initials :	DOB :12/11/1988	Sex:Male	Race:Caucasian	Height:187(cm)	Weight:95(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)	06/15/2015	9	
Visit 3 (Month 6)	06/15/2015	9	
Visit 1/ Baseline (Day 1)	06/15/2015	9	
Visit 4 (Month 9)	06/15/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
elevated liver enzymes	01/07/2016	06/20/2016		Suspected	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	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
trombocytopenia	03/28/2016	04/26/2016		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	
flu-like symptoms	03/30/2016			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	Ongoing		
Event description:						

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Solu-Medrol	08/26/2015		08/28/2015	1000	mg	QD
Spironolactona	08/26/2015		08/28/2015	25	mg	QD
Controloc	08/26/2015		08/28/2015	40	mg	QD
Alanerv	08/28/2015		09/28/2015	1	tb	QD
Ibuprofenum	03/30/2016	Yes		400	mg	PRN
LIV52	03/28/2016	Yes		6	tb	TID

Does the subject have any relevant past or present medical conditions:No

Condition	Start Date	Related to study condition	Ongoing