Non Serious Adverse Drug Reactions Report

Start Date:2016-09-19 End Date:2016-09-20

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None(Othervalue:)	Drug withdrawn	Led to study termination	Ongoing		

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None(Othervalue:)	Drug withdrawn	Led to study termination	Ongoing		

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

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Start Date:2016-09-19 End Date:2016-09-20

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:006		
Subject No :006-0005	Subject Initials :	DOB :08/28/1965	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 2 (Month 3)	03/11/2015	8	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	03/11/2015	8	
Visit 1/ Baseline (Day 1)	03/11/2015	8	
Visit 4 (Month 9)	03/11/2015	8	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
increased liver enzimes	06/11/2015	12/19/2015		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 with sequelae		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
necrosis at injection site	06/30/2015	09/09/2015		Suspected	Moderate	
Causality Factors		**Action Taken with Study Treatment**	**Other action taken**	**Outcome**	**AE Special Interest**	**AE dose limiting toxicity**
Protocol procedure(Othervalue:)		Not applicable	None	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
increased liver enzymes	12/20/2015			Suspected	Moderate	
Causality Factors		**Action Taken with Study Treatment**	**Other action taken**	**Outcome**	**AE Special Interest**	**AE dose limiting toxicity**
None(Othervalue:)		Not applicable	None	Ongoing		
Event description:						

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
desloratadinum	08/22/2015		09/09/2015	5	miligrams	qd
liv 52	08/22/2015	Yes		275	miligrams	qd

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
thrombophilia			Yes
arterial hipertension			Yes
peripheral artheriopathy			Yes