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Trial record **1 of 1** for: OBI-1-302
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Study of Modified Recombinant Factor VIII (OBI-1) in Subjects With Congenital Hemophilia A

This study has been terminated.

Sponsor:
Baxalta US Inc.

Information provided by (Responsible Party):
Baxalta US Inc.

ClinicalTrials.gov Identifier:
NCT01434511

First received: September 13, 2011
Last updated: June 26, 2015
Last verified: December 2014
History of Changes

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Results First Received: December 11, 2014

Study Type:	Interventional
Study Design:	Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hemophilia A
Intervention:	Biological: OBI-1

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Participant Flow: Overall Study

	OBI-1
STARTED	**1**
COMPLETED	**1**
NOT COMPLETED	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Baseline Measures

	OBI-1
Number of Participants [units: participants]	**0**
Age [1] [units: years] Mean (Standard Deviation)	
Gender [1] [units: participants]	
Female	
Male	
Region of Enrollment [1] [units: participants]	
United States	

[1] This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Outcome Measures

Hide All Outcome Measures

1. Primary: Proportion of Serious Bleeding Episodes Responsive to OBI-1 [Time Frame: 24 hours after initiation of treatment]

Measure Type	Primary
Measure Title	Proportion of Serious Bleeding Episodes Responsive to OBI-1
Measure Description	This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, the study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within the OBI-1-302 study (Congenital Hemophilia A).
Time Frame	24 hours after initiation of treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Proportion of Serious Bleeding Episodes Responsive to OBI-1	

No statistical analysis provided for Proportion of Serious Bleeding Episodes Responsive to OBI-1

2. Secondary: Overall Proportion of Serious Bleeding Episodes Successfully Controlled With OBI-1 Therapy, as Assessed by the Investigator. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Overall Proportion of Serious Bleeding Episodes Successfully Controlled With OBI-1 Therapy, as Assessed by the Investigator.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Overall Proportion of Serious Bleeding Episodes Successfully Controlled With OBI-1 Therapy, as Assessed by the Investigator.	

No statistical analysis provided for Overall Proportion of Serious Bleeding Episodes Successfully Controlled With OBI-1 Therapy, as Assessed by the Investigator.

3. Secondary: Proportion of Bleeding Episodes Responsive to OBI-1 Therapy at Designated Assessment Time Points After the Initiation of Therapy, as Assessed by the Investigator [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Proportion of Bleeding Episodes Responsive to OBI-1 Therapy at Designated Assessment Time Points After the Initiation of Therapy, as Assessed by the Investigator
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Proportion of Bleeding Episodes Responsive to OBI-1 Therapy at Designated Assessment Time Points After the Initiation of Therapy, as Assessed by the Investigator	

No statistical analysis provided for Proportion of Bleeding Episodes Responsive to OBI-1 Therapy at Designated Assessment Time Points After the Initiation of Therapy, as Assessed by the Investigator

4. Secondary: Frequency of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Frequency of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Frequency of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.	

No statistical analysis provided for Frequency of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.

5. Secondary: Total Dose of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Total Dose of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Total Dose of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.	

No statistical analysis provided for Total Dose of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.

6. Secondary: Total Number of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Total Number of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified,

study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Total Number of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.	

No statistical analysis provided for Total Number of Infusions of OBI-1 Required to Successfully Control Qualifying Bleeding Episodes.

7. Secondary: Correlation Between Response to OBI-1 Therapy at Specified Time Points and Eventual Control of Serious Bleeding Episodes. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Correlation Between Response to OBI-1 Therapy at Specified Time Points and Eventual Control of Serious Bleeding Episodes.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Correlation Between Response to OBI-1 Therapy at Specified Time Points and Eventual Control of Serious Bleeding Episodes.	

No statistical analysis provided for Correlation Between Response to OBI-1 Therapy at Specified Time Points and Eventual Control of Serious Bleeding Episodes.

8. Secondary: Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers, the Total Dose of OBI-1, the Outcome at 24 Hours and the Eventual Control of the Bleeding Episode. [Time Frame: Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary

Measure Title	Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers, the Total Dose of OBI-1, the Outcome at 24 Hours and the Eventual Control of the Bleeding Episode.
Measure Description	No text entered.
Time Frame	Frame: Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers, the Total Dose of OBI-1, the Outcome at 24 Hours and the Eventual Control of the Bleeding Episode.	

No statistical analysis provided for Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers, the Total Dose of OBI-1, the Outcome at 24 Hours and the Eventual Control of the Bleeding Episode.

9. Secondary: Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers and the Recovery of OBI-1. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers and the Recovery of OBI-1.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1

Number of Participants Analyzed [units: participants]	**0**
Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers and the Recovery of OBI-1.	

No statistical analysis provided for Correlation Between the Pre-infusion Anti-OBI-1 Antibody Titers and the Recovery of OBI-1.

10. Secondary: Recovery and Elimination Rate Parameters of OBI-1 in Subjects With Inhibitors Treated With OBI-1 Therapy. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Recovery and Elimination Rate Parameters of OBI-1 in Subjects With Inhibitors Treated With OBI-1 Therapy.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Recovery and Elimination Rate Parameters of OBI-1 in Subjects With Inhibitors Treated With OBI-1 Therapy.	

No statistical analysis provided for Recovery and Elimination Rate Parameters of OBI-1 in Subjects With Inhibitors Treated With OBI-1 Therapy.

11. Secondary: Efficacy Assessment of OBI-1 in Participants With Anti-human Factor VIII Titers >30 Bethesda Units (BU) [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Efficacy Assessment of OBI-1 in Participants With Anti-human Factor VIII Titers >30 Bethesda Units (BU)
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Efficacy Assessment of OBI-1 in Participants With Anti-human Factor VIII Titers >30 Bethesda Units (BU)	

No statistical analysis provided for Efficacy Assessment of OBI-1 in Participants With Anti-human Factor VIII Titers >30 Bethesda Units (BU)

12. Secondary: Anti-human Factor VIII Antibody Titer. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Anti-human Factor VIII Antibody Titer.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Anti-human Factor VIII Antibody Titer.	

No statistical analysis provided for Anti-human Factor VIII Antibody Titer.

13. Secondary: Anti-OBI-1 Antibody Titer. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Anti-OBI-1 Antibody Titer.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Anti-OBI-1 Antibody Titer.	

No statistical analysis provided for Anti-OBI-1 Antibody Titer.

14. Secondary: Anti-host Cell Protein Baby Hamster Kidney (BHK) Antibody Titer. [Time Frame: Through 90 days ± 7days following final OBI-1 dose]

Measure Type	Secondary
Measure Title	Anti-host Cell Protein Baby Hamster Kidney (BHK) Antibody Titer.
Measure Description	No text entered.
Time Frame	Through 90 days ± 7days following final OBI-1 dose
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This study was terminated early and only enrolled one participant. Due to concerns that the participant would be at risk of being re-identified, study results are not posted. The decision to terminate this study was not related to any safety and/or efficacy concern of OBI-1 in the indication described within this study (Congenital Hemophilia A).

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Measured Values

	OBI-1
Number of Participants Analyzed [units: participants]	**0**
Anti-host Cell Protein Baby Hamster Kidney (BHK) Antibody Titer.	

No statistical analysis provided for Anti-host Cell Protein Baby Hamster Kidney (BHK) Antibody Titer.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Serious Adverse Events

	OBI-1
Total, serious adverse events	
# participants affected / at risk	**0/1 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
OBI-1	OBI-1: intravenous infusion, up to every 2-3 hours for the first 24 hours of treatment

Other Adverse Events

	OBI-1
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/1 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial

results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Baxter's agreements with PIs may vary per requirements of individual PI, but contain common elements. For this study, PIs are restricted from independently publishing results until the earlier of the primary multicenter publication or 12 months after study completion. Baxter requires a review of results communications (e.g., for confidential information) ≥30 days prior to submission or communication. Baxter may request an additional delay of ≤30 days(e.g., for intellectual property protection)

Results Point of Contact:

Name/Title:
Organization:
e-mail:

Responsible Party:	Baxalta US Inc.
ClinicalTrials.gov Identifier:	NCT01434511 History of Changes
Other Study ID Numbers:	**OBI-1-302**
Study First Received:	September 13, 2011
Results First Received:	December 11, 2014
Last Updated:	June 26, 2015
Health Authority:	United States: Food and Drug Administration South Africa: Medicines Control Council United Kingdom: Medicines and Healthcare Products Regulatory Agency

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