**INSTITUTION Name/Logo**

**IND XXXXX**

**ANNUAL REPORT**

**DRUG TRADE NAME (GENERIC NAME, NAME OF ANTIBODY)**

**Reporting Period Covered in this Report: MM/DD/20YY to MM/DD/20YY**

Date of Report: MM/DD/20YY

Sponsor Name

Institution Name

Mailing Address

Mailing Address

Telephone

Email

**CONFIDENTIAL**

**TABLE OF CONTENTS**

Table of Contents

[1 Study INFORMATION 3](#_Toc134430512)

[1.1 Study Summary 4](#_Toc134430513)

[1.2 Enrollment Update 4](#_Toc134430514)

[1.3 Brief Description of Study Results 5](#_Toc134430515)

[2 Summary INFORMATION 5](#_Toc134430516)

[2.1 Adverse Events: Frequent and Serious 5](#_Toc134430517)

[2.2 Summary of IND Safety Reports 6](#_Toc134430518)

[2.3 Study Subject Deaths 6](#_Toc134430519)

[2.4 Study Subject Dropouts Due to an Adverse Drug Experience 7](#_Toc134430520)

[2.5 Understanding of the Drug’s Action 7](#_Toc134430521)

[2.6 List of Preclinical Studies 8](#_Toc134430522)

[2.7 Summary of Manufacturing or Microbiological Changes 8](#_Toc134430523)

[3 General Investigational Plan 8](#_Toc134430524)

[4 Investigator Brochure 9](#_Toc134430525)

[5 PHASE 1 Protocol Modifications 9](#_Toc134430526)

[6 Foreign Marketing Developments 9](#_Toc134430527)

[7 OUTSTANDING BUSINESS WITH RESPECT TO the IND 10](#_Toc134430528)

[8 Appendices 11](#_Toc134430529)

# Study INFORMATION

The original IND XXXXX was submitted to the FDA on MM/DD/202X. The ‘Study May Proceed’ notification was dated MM/DD/202X. This annual report summarizes data for all studies conducted under the IND from MM/DD/202X to MM/DD/202X. Table 1 presents an overview of all studies, completed and ongoing under this IND.

DRUG generic name (Trade Name®) is being evaluated under this IND for efficacy, safety, and tolerability in the treatment of disease or condition.

|  |  |
| --- | --- |
|  | **Table 1**. Clinical Studies Conducted Under IND# |
|  | **Protocol Number/ID** | **Study Title** | **Study Status** |
| 1 | AB0001 | To test the safety and efficacy of oral DRUG in children and adults with disease who have condition | Complete |
| 2 | AB0002 | To characterize the long-term use, safety, and efficacy of DRUG in children and adults with disease or condition in an observational study of AB0001 subjects | Complete |
| 3 | AB0003 | To investigate the safety and efficacy of oral DRUG in children and adolescents with disease or condition X-Y years of age | In progress |

##

## Study Summary

**Title of Study:** AB0003: Multi-center, Multi-national, Randomized, Placebo-Controlled Trial of DRUG in Subjects with Disease or Condition X-Y Years Old

**Study Design:** Multicenter double-blind randomized clinical trial

**Purpose:** To investigate the safety and efficacy of oral DRUG in children and adolescents with disease who have condition

**Patient Population:** Male and female subjects X years and ≤ Y years of age with a diagnosis of disease

**Treatment Regimen:** Trade Name® (generic name) 250 mg of DRUG taken orally three times a day

**Study Duration:** Total duration of the treatment period for each subject is XX weeks

**Study Status:** Active, not recruiting

**Clinicaltrials.gov**: NCT#

## Enrollment Update

The enrollment update as of MM/DD/202X is shown in **Table X** below. Table X presents an overview of enrollment, completed and ongoing.

|  |
| --- |
| **Table X. AB0003 Enrollment Update as of Date** |
| No. Planned | No. Enrolled | No. Completed Study | No. In Progress | No. Dropouts | Gender | Race | Ethnicity | Age Group (years) |
| 20 | 10 | 5 | 1 | 4 | F: | 5 | American Indian or Alaska Native: | 0 | Hispanic or Latino: | 3 | 2-11: | 0 |
|  |  |  |  |  | M: | 5 | Asian: | 1 | Not Hispanic, or Latino: | 6 | 12-17: | 0 |
|  |  |  |  |  |  |  | Black or African American: | 1 | Prefer not to answer: | 1 | 18-21: | 1 |
|  |  |  |  |  |  |  | Native Hawaiian or Other Pacific Islander: | 1 |  |  | 22-64: | 8 |
|  |  |  |  |  |  |  | White: | 5 |  |  | 65+: | 1 |
|  |  |  |  |  |  |  | Other: | 2 |  |  |  |  |

Include narrative as needed: *Recruitment for this study began Month 202X. We have enrolled 10 subjects with 5 subjects having fully completed the study and 1 subject in follow-up at this time.*

*In total, four subjects did not complete the study: two subjects were taken off treatment due to adverse events at Week 4 and Week 8 visits respectively, but completed all study visits for monitoring; one subject withdrew from the study prior to Week 4 due to an adverse event; and one subject was lost to follow-up after the Week 4 visit.*

## Brief Description of Study Results

No study results are available at this time.

# Summary INFORMATION

## Adverse Events: Frequent and Serious

# Option 1:

Appendix A contains the following tables of coded adverse event data for the AB0003 study, available as of Date:

* Most Frequently Occurring Treatment Emergent Adverse Events
* Incidence of Treatment Emergent Adverse Events
* Treatment Emergent Adverse Event Intensity
* Incidence of Treatment Emergent Serious Adverse Experiences - OR - Serious Adverse Experience (SAE) Narrative Summaries

The medical monitor sees no concerning trends in the adverse events (AEs) by severity or incidence. The AEs are similar to other disease or condition studies of similar duration.

Number SAE Reports were received during this reporting period. All were classified as unrelated to study drug by both the medical monitor and the site investigator.

**Option 2 (if the listing is short and can fit onto one page):**

Adverse events (AE) reported during this reporting period for the AB0003 study are presented in Table X below.

## Summary of IND Safety Reports

#

# Option 1:

During this reporting period, no serious adverse experiences resulted in the submission of an IND Safety Report in the AB0003 study.

#

# Option 2:

During this reporting period, a total of # SAEs resulted in the submission of an IND Safety Report. # follow-up Safety Reports (Serial No. ####; mm/dd/yyyy) was/were also submitted.

## Study Subject Deaths

#

# Option 1:

No subject deaths were reported for the AB0003 study during this reporting period.

# Option 2:

A summary of subject deaths for the AB0003 study during this reporting period is presented in Table X.

**Table X. Summary of Subject Deaths**

|  |  |  |  |
| --- | --- | --- | --- |
| **Subject ID** | **Date of Enrollment** | **Date of Death** | **Cause of Death** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Study Subject Dropouts Due to an Adverse Drug Experience

#

# Option 1:

No subjects were discontinued prematurely from the AB0003 study due to an adverse event during this reporting period.

# Option 2:

A summary of subjects who were discontinued prematurely from the AB0003 study due to an adverse event is presented in Table X.

**Table X. Summary of Drop-Outs**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Subject ID** | **Dose Level/Regimen** | **Date of Randomization** | **Date of First Dose** | **Date of Discontinuation** | **Cause of Discontinuation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Understanding of the Drug’s Action

# Option 1:

No new information regarding the action of DRUG name has been obtained during this reporting period.

# Option 2:

Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the mechanism of action of the drug products referred to in IND XXXXX:

NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets

IND ZZZZZ – Antibiotic Oral

## List of Preclinical Studies

# Option 1:

No preclinical studies were completed or in progress with DRUG name under the IND during this reporting period.

# Option 2:

"Enter number" preclinical studies were completed/are ongoing with DRUG name during this reporting period. They are summarized in Table X.

## Summary of Manufacturing or Microbiological Changes

# Option 1:

Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the manufacturing of the drug products referred to in IND XXXXX:

NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets

IND ZZZZZ – Antibiotic Oral

# Option 2:

There have “no changes” to manufacturing or microbiological changes

# General Investigational Plan

# Option 1 – study completed:

**AB0003 –** Enrollment was closed at all X active study sites as of Date. We anticipate all study visits will be completed by Date. We plan to lock the database by Date.

**Option 2 –** **study ongoing**:

The study is recruiting and enrolling subjects. Recruitment is expected to be completed (date) and all subjects are expected to complete the study by (date)

DMC Plan: During this reporting period the Data Monitoring Committee (DMC) conducted a planned comprehensive interim analysis involving data from all sites. Following the review the DMC Chair reported that the DMC sees no concerns regarding subject safety to date and approves the study to go forward without modification at this time.

The DMC will continue to review SAEs as they occur throughout the trial and may add additional analyses at any time.

# Investigator Brochure

The prescribing information for DRUG name is serving the function of an Investigator Brochure for the AB0003 study. The prescribing information was most recently revised in Month 202X.

# PHASE 1 Protocol Modifications

#

# Option 1:

No Phase 1 studies have been conducted under the IND during this reporting period.

# Option 2:

See Table X below for significant PHASE 1 study protocol updates submitted under the IND during this reporting period.

**Table X**. **AB0003 Significant Protocol Updates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Serial Number** | **Submission Type** | **Update** |
| *5/4/2023* | *0001* | *Protocol Amendment* | *The protocol changes reflect FDA Non-Hold comments, updated guidance from the CDC and clarification of inclusion/exclusion criteria as detailed in the attached summary of changes.* |
| *5/5/2023* | *0002* | *Protocol Amendment* | 1. *The enrollment design was revised as follows:*
2. *The inclusion criteria were expanded to include XXX, consistent with current XXX recommendations.*
3. *Clarified dosing cohort language.*
 |

# Foreign Marketing Developments

Not applicable.

# OUTSTANDING BUSINESS WITH RESPECT TO the IND

There is no outstanding business for which the FDA expects a reply, comment, or meeting.

# Appendices

**Appendix A. Adverse Events Listings for the (Study name) study**

**AEs Related to Study Drug or Study Participation**
*Includes related events: possibly, probably and definitely*

|  |  |  |
| --- | --- | --- |
| **AE Description** | **Grade** | **Number of subjects that experienced AE across all grades** |
| **1** | **2** | **3** | **4** | **5** |
| Anemia | X | X | X |  |  | 5 |
| Lymphocytopenia | X | X | X | X |  | 4 |
| Nausea | X | X |  |  |  | 2 |
| Neutropenia | X | X | X | X |  | 7 |
| Fatigue |  | X |  |  |  | 2 |

Related adverse events (AE) reported among study participants during this reporting period, with grade identified. A total of five adverse events (AE), anemia, lymphocytopenia, nausea, neutropenia, and fatigue, were reported during this reporting period for study participants.

**AEs Unrelated to Study Drug or Participation**

|  |  |  |
| --- | --- | --- |
| **AE Description** | **Grade** | **Number of subjects that experienced AE across all grades** |
| **1** | **2** | **3** | **4** | **5** |
| Fatigue | X |  |  |  |  | 1 |
| Anemia |  | X |  |  |  | 1 |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Unrelated adverse events (AE) reported among study participants during this reporting period, with grade identified. Only two adverse events (AE), fatigue and anemia, were reported during this reporting period for study participants.

**Serious Adverse Event (SAE) Table**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Subject ID** | **Event Start Date** | **SAE Description** | **Etiology:** relatedness to study participation or study drug(s) | **Outcome** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Etiology**: relatedness to study participation or study drug(s)

**1** – Unrelated; **2** – Possibly related; **3** – Probably related; **4** – Definitely related

**Outcome**:

**1** – Resolved without sequelae; **2** – Resolved with sequelae; **3** – Resolving;

**4** – Unresolved; **5** – Death