Sponsor

ESBA Tech, an Alcon Biomedical Research Unit LLC

Generic Drug Name

ESBA 105

Trial Indication(s)

Acute anterior uveitis

Protocol Number

ESBA105CRD04

Protocol Title

An Open-label Exploratory Study to Assess the Safety, Tolerability and Clinical Benefit of Topically Applied ESBA105 in Patients with Acute Anterior Uveitis

Clinical Trial Phase

Phase IIa

Study Start/End Dates

04 March 2009 to 27 October 2010

Reason for Termination (if applicable)

In December 2010, the Sponsor decided to terminate the study prematurely due to recruitment issues.

Study Design/Methodology

This was an interventional, open-label, exploratory, non-comparative proof-of-concept study with an equal focus on safety/local tolerability and clinical activity of topical ESBA105.

Centers

Subjects were recruited from 4 investigational sites located in Germany.

Objectives

- Evaluation of safety and local tolerability of topical ESBA105
- Evaluation of systemic exposure to ESBA105 following topical application to the eye

Test Product(s), Dose(s), and Mode(s) of Administration

Test product:
ESBA105 eye drops
Volume:
Single eye drops of 40 µL volume (10mg/mL = 1% ESBA105) with a dose level of 0.4 mg per single drop.
Dose Regimen:
Day 0 – Day 6 (first 7 days of treatment):

- Hourly drops (12-16 drops/day) during waking hours.
- Daily maximal dose: 6.4 mg.

Day 7 – Day 20 (8th to 21st treatment day):

- 5 drops per day during waking hours, applied in approximately 3- to 4-hourly dosing intervals.
- Daily dose: 2 mg.

Day 21 – Day 27 (22nd to 28th treatment day):

- 3 drops per day during waking hours, applied in approximately 6-hourly dosing intervals.
- Daily dose: 1.2 mg.

Mode of administration:
Topically to the affected eye

Statistical Methods

Per protocol no formal statistical hypothesis was tested in this exploratory trial. It was planned to record exploratory statistics as part of the trial assessment and to perform descriptive data analysis. In addition it was planned to present the clinical activity, individual patient disease courses, the percentage of patients requiring rescue medication, the safety data and the systemic exposure to ESBA105 as tables and figures.

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Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:

- Meets protocol-specified criteria for qualification and contraception
- Voluntarily consents to participate and provides written informed consent prior to any protocol-specific procedures

Exclusion criteria:

- Use of medications outside protocol-specified parameters
- Signs, symptoms or history of any condition that, per protocol or in the opinion of the investigator, might compromise:
  1. the safety or well-being of the participant or study staff
  2. the safety or well-being of the participant's offspring (such as through breast-feeding)
  3. the analysis of results

Disposition of Patients

A total of 10 patients were treated with ESBA105. 1 patient discontinued due to an Adverse Event.

Baseline Characteristics

There were 4 female and 6 male patients aged between 22 and 59 years enrolled in this study.

Summary of Efficacy

As per Sponsor’s decision, due to the limited number of patients, no descriptive data analyses were carried out and no data was presented as tables and figures and data were presented in raw data listings only.

Primary Outcome Measure

Evaluation of systemic exposure to ESBA105: There was no relevant or clinically significant systemic exposure to ESBA105 detected.

Secondary Outcome Measure

None to report

Summary of Safety

There were no deaths or SAEs reported within the study. Six patients experienced at least 1 adverse event (AE). There were 13 AEs reported in total. The majority of AEs were mild to moderate intensity.

Safety Results

Serious Adverse Events

There were no deaths or serious AEs.

Summary of Other Adverse Events

Category	Number (n) of Patients Experiencing Event
Any Adverse Events	6
Serious Adverse Events	0
Adverse Events Causing Discontinuation	1
Deaths	0

Other Relevant Findings

There are no other relevant findings to disclose.

Date of Clinical Trial Report

28 November 2011