Document: Study Protocol and Statistical Analysis Plan

Study: A Double-Masked, Placebo-Controlled, Randomized Phase II Clinical Trial to Assess The Efficacy of SCH1 in the Treatment of Acute Infectious Conjunctivitis

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Protocol Sasch-1

A Double-Masked, Placebo-Controlled, Randomized, Phase II Clinical Trial to Assess The Efficacy Of SCH1 in The Treatment Of Acute Infectious Conjunctivitis

Primary Investigator: Jacqueline Dauhajre (JD) MD

Sponsor: David Ritterband (DR) MD

Investigational Product: SCH1

Protocol Number: WIRB 20202223

Phase: II

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Abbreviations

AV	Adenovirus
AE	Adverse event
API	Active Pharmaceutical Ingredient
BCVA	Best corrected visual acuity
BP	Blood Pressure
CBC	Complete Blood cell Count
CRF	Case Report Form
CRO	Contract Research Organization
DR	David Ritterband MD (Co-investigator)
ECG	Electrocardiogram
ECC	Corneal Endothelial Cell Count
ETDRS	Early Treatment Diabetic Retinopathy Study
EW	Emily Waisbren (Principal investigator)
FDA	Food and Drug Administration
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonization
IND	Investigational New Drug
ITT	Intent-to-treat
PCR	Polymerase Chain Reaction
IRB	Institutional Review Board
QID	Four times daily
SAE	Serious Adverse Event
SCH-1	The investigation drug
SD	Standard Deviation
SPK	Superficial Punctate Keratitis
TOC	Test of Cure

Synopsis

Title	**SCH1 In The treatment of Acute Infectious Conjunctivitis**
Investigator	Jacqueline Dauhajre MD 82-11 37th Ave Suite 604 Jackson Heights, NY 11372
Sponsor	David Ritterband MD MEETH Ophthalmology 210 E. 64th Street New York, NY 10065
Indication	Treatment of acute infectious conjunctivitis, bacterial and/or viral.
Objective	The objective of this study is to evaluate the efficacy of Sasch1 in the treatment of acute infectious conjunctivitis.
Eligibility Criteria	Inclusion Criteria • Conjunctivitis (as defined below) within 72 hours of initial ocular symptoms. • At least 18 years of age. • Subjects capable of understanding the purpose and risks of the study, and able to give informed consent. • Conjunctivitis diagnosis defined as presence of the two cardinal signs of acute conjunctivitis- 1) bulbar conjunctival injection and 2) conjunctival discharge/exudates. • A three-point rating scale (0=absent, 1=mild, 2=moderate, 3=severe) will be employed to grade conjunctival discharge/exudates. • All patients will require a rating of 1(mild) or greater for conjunctival discharge/exudates. • Patients will require a rating of 1 (mild) for bulbar conjunctival injection.
	Exclusion Criteria • Conjunctivitis greater than 72 hours after initial ocular symptoms • Corneal ulcer, endophthalmitis, or any other confounding infection of the eye • Patients taking topical anti-inflammatory medications on a chronic basis • Known steroid glaucoma responders • Active herpes ocular infection • Pregnant women • Known allergy to chlorhexidine
Trial Design	This is a phase II single-center, prospective, placebo-controlled, randomized study of SCH1 in the treatment of acute infectious conjunctivitis. Study drug will be evaluated against vehicle.
Primary Endpoint	Clinical cure defined as rating of 0/3 for bulbar conjunctival injection and 0/3 for conjunctival exudates/discharge or clinical success defined as an overall decrease by 3 in the sum of both grades.

Secondary	• Patients will keep a self log of symptom score each of the 5 days of the study
Number of Subjects	• 30 (15 per treatment arm)
Target Population	• Patients with infectious conjunctivitis defined by bulbar conjunctival injection (rated at least 1 on 3 point grading scale) and conjunctival exudates / discharge (rated at least 1 on 3 point grading scale). • Patients greater than one year of age. • Patients of any race or ethnic group.
Length of Study	Enrollment period: 12 months Treatment period: 5 days Overall duration: 6 months 5 days
Study Drug	Subjects will be randomized to one of the following treatment arms: Treatment Arm A: SCH1 Treatment Arm B: Placebo (Vehicle only)
Assessment of Safety	• Incidence of SPK at day 1 • Incidence of SPK at Day 5 • Intraocular pressure at Day 5 VA loss of 4 or greater lines on Snellen VA Chart
Interim Analysis and Safety Monitoring	• Safety data will be reviewed by Dr. David Ritterband, Medical Monitor and Sponsor. A summary report of the safety points will be created every 3 months, as well as the end of the study, and reported to the IRB.
Statistical Analysis	The statistical analysis will evaluate: 1) The overall clinical success rate defined as the percentage of study participants achieving a clinical cure by Day 5 or an overall decrease in the sum of both grades by 3; 2) Microbiological cure rate defined as the percentage of study participants who demonstrate elimination of pre-treatment pathogen(s) by the Day 5 TOC exam. A statistical difference in clinical cure rate will be defined where the 95% confidence limit for the difference in the two study groups (SCH1 vs. Placebo) is greater than (+/-)15%. All data will be examined employing an “Intent to Treat” analysis for all patients. Mean outcome variables in the two study groups will be compared. Statistical means between both study groups will be analyzed by both parametric and non-parametric tests to allow for deviations of data from normal distributions.

Schedule of Visits and Assessments

	Screen / Visit 1	Visit 2	Visit 3
	Day 1	Day 3	Day 5
General Exams			
Informed consent	x		
Inclusion/exclusion criteria	x		
Medical history	x		
Vital signs	x		x
Physical Exam	x		
Patient comfort exam	x	x	x
AE assessment	x	x	x
Current meds	x	x	x
Ophthalmic exams			
BCVA	x		x
Visual acuity	x	x	x
Anterior segment slit lamp exam and tonometry	x	x	x
Dilated fundus exam	x		x

1.0 INTRODUCTION

This document is a protocol for a human clinical investigation. The study is to be conducted according to US and international standards of Good Clinical Practice (GCP), Food and Drug Administration (FDA) Title 21 part 312 and International Conference on Harmonization (ICH) Guidelines, applicable government regulations and institutional research policies and procedures.

2.0 BACKGROUND

2.1 Acute Infectious Conjunctivitis

Acute infectious conjunctivitis ("pink eye") is one of the most common and most contagious ocular infections in the US and the rest of the world. It is usually caused by either bacteria (both Gram-positive and Gram-negative) or more commonly, multiple serotypes of human adenovirus. In addition to the direct damage caused by the infection itself, the body's stereotyped immune response often overwhelms the delicate structures of the eye and leads to secondary, often permanent, inflammatory damage. While some combination antibiotic/anti-inflammatory drugs have been useful for routine bacterial conjunctivitis, all are suffering from increasing antibiotic resistance, and are contraindicated in the case of suspected viral infection due to their propensity to worsen the duration and severity of viral infections.

2.2 MEDICAL NEED IN ACUTE INFECTIOUS CONJUNCTIVITIS

Clinical differentiation of bacterial and viral conjunctivitis has depended on clinical signs, symptoms and history[1,2]. These factors are often accepted among practicing ophthalmologists as reliable indicators of etiology with little or no peer-reviewed literature substantiation. An evidence-based review by Rietveld *et al*[3] reviewed several databases, including the Cochrane Controlled Trials Register, along with standard ophthalmology texts and concluded that there is no evidence that signs and symptoms definitively differentiate viral from bacterial conjunctivitis. This lack of ability to clinically determine viral versus bacterial, combined with the known high prevalence of viral infections requires that physicians suspect virus in every case of acute conjunctivitis.

Although exact numbers are difficult to determine, estimates from a national survey of outpatient health encounters[4,9], comparison with epidemiological surveys completed in other countries[5,6,7] and studies of incidence in military recruits[8] suggest that the number of cases of viral conjunctivitis may be as high as 15-20 million per year in the United States. Experts estimate the socioeconomic impact (in terms of lost work hours) from this disease is in the billions of US dollars. There is no FDA approved drug available to treat these cases: there are no antibiotics, anti-inflammatories or combination products FDA-approved for the treatment of viral conjunctivitis. This represents a massive unmet need in ophthalmology.

2.3 SCH1

SCH1 is a novel combination anti-infective / steroid eye drop with *in vitro* efficacy against many bacteria, yeasts, fungi and human adenovirus. The product contains two FDA-approved active pharmaceutical ingredients (Pred Forte, or prednisolone acetate 1%, application #017011, approved May 30, 1973; chlorhexidine gluconate, approved Decmeber 28, 1995). The combination is formulated as a 0.2% chlorhexidine 1% prednisolone acetate ophthalmic suspension. In preclinical evaluation, it demonstrated antimicrobial efficacy on contact with ocular isolates of *S.aureus, P. aeruginosa, E. coli, C. albicans, and A. brasiliensis* A review of preclinical studies is provided in the investigators brochure.

2.4 Study Rationale

Acute infectious conjunctivitis is a leading cause of ocular morbidity, epidemic eye infection, lost productivity, patient discomfort and in some cases permanent visual compromise. The infectious agent is frequently viral in origin and frequently bacterial in origin with very little to reliably distinguish one from the other. Concomitant inflammatory damage often occurs and can lead to long term ocular morbidity. No current treatments are capable of treating both viruses and bacteria. Additionally no current combination antibiotic/steroid combinations can safely be administered in suspected viral infections. The objective of this study is to assess the efficacy of SCH1

as a first-line treatment for ocular inflammation and infection in the setting of an acute viral or bacterial conjunctivitis infection.

2.5 Dose Rationale
Each drop of SCH1 (approx. 80-110 microliters) contains 0.2% chlorhexidine gluconate and 1% prednisolone acetate. To adequately treat both the inflammatory and infectious components of acute conjunctivitis, frequent dosing is employed early in the course of infection which can be tapered rapidly as symptoms resolve. We will employ a regimen of 1 drop every two hours while awake in affected eyes on Day 1 followed by 1 drop four times a day for the remaining four days of treatment.

3.0 Objective
The objectives of this study are to evaluate the effectiveness of SCH1 in the treatment of infectious conjunctivitis.

4.0 Endpoints

4.1 Primary Endpoints
The primary endpoint will be the achievement of a clinical cure defined as a rating of 0/3 for bulbar conjunctival injection and 0/3 for conjunctival exudates/discharge or clinical success defined as an overall decrease by 3 in the sum of both scores.

4.2 Secondary Endpoint
Patients will keep a log and rate their symptoms on a pre-determined scale each of the 5 days of the study.

4.3 Analysis Unit
The primary analysis will be performed on one eye of each subject. If both eyes qualify, the eye with the worse grade will be designated as the study eye. If both eyes have equal grade, the eye with more recent onset of symptoms will be designated as the study eye. If both eyes experienced onset of symptoms at the same time, the right eye will be designated as the study eye.

5.0 Trial Design
This is a Phase II single-center, double-masked, placebo controlled, randomized study of SCH1 for the treatment of infectious conjunctivitis. Approximately 30 subjects will be enrolled, who will be randomized in a 1:1 ratio between SCH1and placebo. Subjects will be assessed at day 1, day 3, and day 5 for efficacy and safety.

5.1 Randomization and Masking
Approximately 30 patients will be randomized in a 1:1 ratio to either SCH1 or placebo. Randomization will be administered through “block randomization” (blocks of 4). The code will be kept by DR, who will not be involved in examining or grading patients.

Each investigator will receive a sealed envelope containing the description of the study medication assigned to each patient number. Investigators will be instructed not to open the envelope unless a medical emergency requires identification of the study medication.

5.2 Treatments

The test article consists of one 3mL bottle of SCH1 ophthalmic suspension. Doses will be administered directly from the bottle. See section 8.0 for storage, handling and administration. The placebo, which consists of the vehicle for SCH1, will be supplied in an identical 3mL bottle the placebo will.

5.3 Duration

Enrollment for the study is expected to require twelve months. Patients will be followed for five days.

6.0 Selection and Withdrawal of Subjects

6.1 Inclusion Criteria

Subjects must meet all of the following criteria to be included in the study:

- A documented history of symptoms consistent with infectious conjunctivitis
- Onset of symptoms in most recently affected eye less than 72 hours prior to visit
- At least 18 years of age
- Women of childbearing age must have a negative urine pregnancy test prior to starting the study drug and must not be lactating.
- Female subjects of non-childbearing potential must meet at least one of the following criteria:
    1. Premenarche females, defines as:
        a. Females who have not had onset of menstrual cycle
    2. Postmenopausal females, defined as:
        a. Females over 60
        b. Females between 45 and 60 of age who are amenorrheic for at least 2 years
    3. Females who have had a hysterectomy and/or bilateral oophrectomy.

  All other female subjects will be considered to be of childbearing potential.
- Subjects or their guardians must be capable of understanding the purpose and risks of the study; able to give informed consent (and assent by pediatric subjects, if required) and to comply with the study requirements

6.2 Exclusion Criteria

Subjects with any of the following will be excluded from the study:

- Conjunctivitis in which the most recently affected eyes had onset of symptoms greater than 72 hours prior to visit
- History of chronic allergic conjunctivitis, including vernal or atopic keratoconjunctivitis
- Presence of corneal ulcer, endophthalmitis, or other confounding ocular infectious process
- Active herpes virus ocular infection

- Patient with ocular conditions potentially interfering with conjunctival or corneal grading (e.g. chronic conjunctival injection after multiple surgeries, pseudophakia, or bullous keratopathy, etc.)
- Known steroid-responder (steroid-response glaucoma)
- Patient taking topical anti-inflammatory drops on a chronic basis
- Pregnant women
- Any current or history of substance abuse, psychiatric disorder or a condition that, in the opinion of the investigator, may invalidate communication or compliance with the protocol or return to study visits
- Known allergy to chlorhexidine gluconate or prednisolone acetate

6.3 Subject Withdrawal Criteria

Subjects will be removed from the study for the following reasons:

- Subjects meet criteria for rescue (see section 6.4)
- Subjects withdrawal of consent
- Investigator decides it is in best interest of subject to withdraw from the study due to safety or efficacy issues
- Subject lost to follow up
- Study discontinuation by JD
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An excessive rate of withdrawals can render the study uninterpretable: therefore unnecessary withdrawal of subjects should be avoided. A subject who withdraws for any reason should be encouraged to return to have the End of Treatment assessments performed. If a subject is lost to follow-up at any point during the study, attempts to contact the subject should be documented, and Subjective Symptoms Score should also be obtained. The reason for withdrawal from the study must be documented in the CRF by the Investigator.

If the subject withdraws from the trial and also withdraws consent for disclosure of future information, no further evaluation should be performed and no additional data should be collected. JD or DR may retain and continue to use any data collected before such withdrawal of consent.

6.4 Subject Rescue Criteria and Procedures

Subjects who experience onset of a corneal infiltrate, intraocular inflammation, or glaucoma are to receive rescue therapy. Dosing with SCH1/placebo is to be stopped at the time of administration of rescue therapy. All evaluations scheduled for visit 3/End of Treatment should be performed at this time.

7.0 Treatment of Subjects

Subjects meeting all the inclusion criteria and none of the exclusion criteria will be accepted into the study. Each subject must read and sign an informed consent form (or assent provided for pediatric subjects) prior to any screening procedures being performed. Subjects will be randomized either to placebo or SCH1, and will be followed in an outpatient setting. After their initial visit, subjects will come to the study center on day 3 and Day 5. Safety and efficacy measurements will be taken on these visits.

Potential risks and benefits to subjects participating in this study are detailed in the Subject Informed Consent Form.

7.1 Screening Prior To Randomization

A screening examination is performed on the initial visit. Screening procedures will include:

Informed consent
Inclusion/exclusion criteria
Complete medical history and demographic information
Best corrected visual acuity
Slit lamp examination and tonometry
Graded assessment of conjunctival inflammation and cornea
Dilated fundus examination or Optos Fundus photography
Conjunctival culture swab (A pre-packaged swab (*Visufarma Adenoplus)* to obtain a viral culture from the eye)
Documentation of the subject's fulfillment of the entry criteria for all subjects considered for the study and subsequently included or excluded is to be completed by the Investigator or designee. Documentation of screening failure details will be recorded in the source documentation.

7.2 Study Procedures/Assessments

The second visit has a +/- 1 day window. The third visit has a +/-1 day window.

Visit 1

Perform the following activities on Visit 1 (baseline)

- Review
- BCVA
- SLE and tonometry
- DFE
- Grading of injection / discharge
- Dispense study medication

Visit 2

Perform the following activities on Visit 2

- Record AEs
- Review of current medications
- Visual acuity
- SLE
- Grading of injection / discharge

Visit 3

Perform the following activities on Visit 3

- Record AEs
- Review of current medications
- Visual acuity

SLE
Grading of injection / discharge
DFE

8.0 Study Treatment
DR will provide SCH1 (the study drug) and identically packaged placebo (vehicle only). The SCH1 test article is an eyedrop suspension.

8.1 Storage and Handling
Study drug and placebo can both be safely stored at room temperature and ambient conditions for the duration of the trial. Study drug and placebo storage will be in locked cabinet with 24 hour alarmed temperature monitoring. Central storage and study package delivery will be coordinated by DR in concert with contract research and manufacturing organizations.

8.2 Study Drug Administration
The study drug is administered as one drop to the affected eye every two hours while awake on Day 1, four times per day while awake for Day 2 through Day 5. The drugs are administered by the patient.

8.3 Compliance
Compliance will be assessed by maintaining adequate drug dispensing and return logs. Patients will also keep written record of when treatments were given.

9.0 Assessment of Efficacy
Efficacy will be assessed by objective clinical score and microbiological culture.

9.1 Graded Measure of Conjunctival Discharge / Exudates
A three-point rating scale (0=absent, 1=mild, 2=moderate, 3=severe) will be employed to grade conjunctival discharge/exudates. Clinical efficacy will be defined as reduction in score by 2 grades (i.e. 3->1, 2->0) or a score of 0.

9.2 Graded Measure of Conjunctival Injection
A three-point rating scale (0=absent, 1=mild, 2=moderate, 3=severe) will be employed to grade conjunctival injection. Clinical efficacy will be defined as reduction in of each score to 0 or an overall reduction by 3 in the sum of both scores.

9.3 Other Assessments of Efficacy
Patients will keep a record of their own subjective symptom score from 1-5.

10.0 Assessment of Safety
The safety population is defined as all subjects who received one or more doses of SCH1. Standard summary and/or analysis techniques will be used for the evaluation of AEs, vital sign measurements, clinical laboratory results and physical examinations, and these are to be detailed within the body of the report. The safety data will be presented in individual listings and summary tables where appropriate.

10.1 Best Corrected Visual Acuity
BCVA will be measured using ETRDRS method at each visit.

10.2 Corneal Epithelium Grading
Corneal epithelium grading, including the presence of SPK, will be recorded at each visit.

10.3 Intraocular Pressure
Intraocular pressure will be measured by tonometry at screening and at each visit.

10.4 Cataract Assessment
Cataract grading will be recorded at each visit.

10.5 Vital Signs
Vital signs will be recorded at each visit.

10.6 Adverse Events
10.6.1 Definition of Adverse Events
An adverse event is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

10.6.2 Relationship to Study Drug
Relationship to study drug will be determined by the Investigator and so reported to the medical monitor.

10.6.3 Adverse Event Intensity Grading
The intensity of all AEs will be graded according to the following table:

Mild: AE requiring no special treatment and not requiring deviation from the usual activities
Moderate: AE that impairs usual activities but are ameliorated by simple therapeutic interventions
Severe: AE which impairs usual activities and requiring intervention

10.6.4 Eliciting Adverse Events
At each study visit the subject will be questions about AEs. All AEs, whether observed by the Investigator, elicited by the Investigator or designee, or spontaneously reported by the subject will be documented in the subject's chart and the Adverse Event Reporting Form. The investigator must assess whether or not the AE is related to the study drug, and to determine whether to continue or discontinue the study drug.

10.6.5 Serious Adverse Events
Each AE is to be classified by the Investigator as SERIOUS or NON-SERIOUS.

10.6.6 Serious Adverse Event Reporting

If an SAE or a clinically significant AE occurs, the Investigator must verbally and/or in writing (via fax) notify EW or its designee within 24 hours of the occurrence of the SAE. Report the SAE to:

Contact Information for SAE Reporting:

Isha Mehta (IM) DO
MEETH Ophthalmology
210 E. 64th Street 7th Floor
New York, NY 10065
Mobile 1-302-983-0280

David Ritterband MD
MEETH Ophthalmology
210 E. 64th Street 7th Floor
New York, NY 10065
W 212-702-7313

Medical Monitor: David Ritterband, MD

The initial SAE report must be followed by a written report, signed by the Investigator, and received by DR or his designee via fax within two working days. The Investigator must provide written follow-up reports until the SAE or clinically significant AE has resolved or until a stable clinical endpoint is reached. Notification of an SAE or clinically significant AE must also be submitted to the IRB in accordance with its requirements.

11.0 Statistical Considerations

The clinical success rate is expected 50%-75% higher in the treatment group than in the placebo group. The microbiological cure rate is expected to be 60%-80% higher in the treatment drug arm compared to the placebo arm. Based on these estimates of efficacy, statistical and clinical significance will be demonstrable with 30 patients in each group to assure an outcome analysis with a power of >80% to detect the difference between the two groups at the 95% confidence interval.

12.0 Direct Access to Source Documents

Source data includes all information, original records of clinical findings, observations, or other activities in the clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these include but are not limited to: hospital records, clinical and office charts, laboratory notes, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, photographs,

13.0 Quality Control and Quality Assurance

A site visit will be held prior to initiation of subject enrollment. The protocol, CRFs, study drug supplies, and relevant procedures will be explained in detail at the site visit.

Subsequent to subject enrollment, a study site monitor from JD or its designees will review the CRFs and source documents to ensure that the study is conducted according to the protocol and GCP/ICH guidelines.

To ensure compliance with GCP/ICH guidelines and all applicable regulatory requirements, DR or its designee may conduct a quality assurance audit. Regulatory agencies may also conduct a regulatory inspection of this study. Such audits or inspections can occur at any time during or after completion of the study. If audits or inspections occur, the Investigator and the Institution agree to allow the auditor/inspector direct access to all relevant documents and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any relevant issues.

14.0 Ethics

This study will be conducted in accordance with local regulations, GCP, ICH guidelines and, where applicable, the Declaration of Helsinki. The Investigator at each site will be responsible for the overall conduct of the clinical trial for the site and will be responsible for ensuring the trial is conducted according to the protocol and all regulatory requirements and IRB/EC regulations.

15.0 Subject Informed Consent

Subjects (or their legal guardian) will sign written informed consent document. A copy of the document is attached.

16.0 Institutional Review

The protocol and informed consent form for the study must be approved by an appropriately constituted IRB as defined by local requirements. The list of the IRB voting members, their titles and/or occupations, and their institutional affiliations and/or the IRB general assurance number, if applicable, must be submitted to the Sponsor or its designee prior to shipment of study drug to the investigator.

A copy of the Letter of the Approval from the IRB which also contains the study's protocol title, number, and protocol version date, must be received by JD or (DR) or its designee prior to shipment of drug supplies to the Investigator.

Significant changes to the protocol by JD must also be approved by the IRB and documentation of this approval must be submitted to JD or its designee prior to implementation of any changes. Records of IRB annual review, if applicable, and approval of all documents pertaining to this study must be sent to DR or his designee and kept on file by the Investigator. These documents are subject to regulatory authority or the Sponsor or its designee inspection at any time during the study.

Periodic status reports and adverse drug events must be submitted to the IRB according to the IRB's reporting requirements. The IRB must also be notified of completion of the study and a final report must be submitted to the IRB in accordance with the IRB's reporting requirements. A copy of these reports should be sent to DR or his designee. The

Investigator must maintain an accurate and complete record of all communication, reports and submissions to the IRB.

17.0 General Information
All study records including CRFs, signed Form FDA 1572, originals of test results, informed consent forms, IRB approval letters, correspondence, and all other documents pertaining to the conduct of the study must be kept on file by the Investigator.

Changes to the protocol can be made only by written amendment agreed upon by EW and the Investigator. The IRB must be informed of all changes and must approve all changes that may increase risk to the subjects.

A new FDA 1752 form must be prepared and signed for any of the following circumstances: if there is any addition or name/address changes of the Investigator, a sub-Investigator, laboratory, facilities or IRB. This form and a copy of any additional CVs, laboratory license and certificates, and/or IRB membership list/assurance number, if applicable, must be sent to JD or its designee. A copy must also be retained in the Investigator's file. JD or its designee must be notified, in writing, when an Investigator leaves the institution where the study has been conducted. The Investigator must assign a designee to assume his/her study-related responsibilities.

18.0 Data Handling and Record Keeping
18.1 Confidentiality
The sponsor (DR) will preserve the confidentiality of all subjects taking part in this trial. The data in this trial may be used in company publications and regulatory submissions. Information about study subjects will be kept confidential in accordance with guidelines established by the HIPPA.

18.2 Case Report Forms
The sponsor (DR) will provide CRF's for each subject. Each subject will be identified by study identification number and subject's initials. All data reported on CRFs will be supported by source documents. The source documents must be made available to the Sponsor clinical monitors during scheduled monitoring visits, auditors during any audits requested by the Sponsor and to regulatory agencies during inspections. When a subject discontinues the study, the CRF must be completed in a timely manner and signed by the Investigator.

18.3 Record Keeping
All study records are subject to inspection by regulatory agencies or the Sponsor or the Sponsors designees at any time. Records must be kept for two years following written notification by the Sponsor of either regulatory approval or discontinuation of the development program.

18.4 Financial
As required by US Federal Regulation 21 CFR 54, each listed investigator who is involved in the treatment or evaluation of research subjects must disclose certain

financial arrangements with the Sponsor. To ensure compliance, each investigator listed on Form FDA 1572 must complete a financial disclosure form prior to the shipment of study drug and one year after the completion of the study. If any relevant changes in this information occur during this interval, a new or updated financial disclosure must be provided.

18.5 Publication

The first publication or disclosure of study results shall be a publication or disclosure coordinated by the Sponsor. Thereafter, all subsequent publications will reference the original publication(s).

References

1. Mahajan VM. Acute bacterial infections of the eye: their aetiology and treatment. *Br J Ophthalmol* 1983;**67**:191– 4.

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4. Nash, EA, et. al. Patterns of emergency department visits for disorders of the eye and ocular adnexa *Arch Ophthalmol,* 1998; **116**: 1222-1226.

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6. Ishii K. et al. Comparative studies on aetiology and epidemiology of viral conjunctivitis in three countries of East Asia--Japan, Taiwan and South Korea. *Int Journal of Epidemiology* 1987; **16**: 98-103.

7. Aoki, K. et. al. A twenty-one year surveillance of Adenoviral Conjunctivitis in Sapporo, Japan.*Int Ophthalmol Clinics*. 2002; **42**:49-54.

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Statistical Analysis Plan

Statistical and Analytic Plans

Chi-Square tests of homogeneity or Fisher exact tests (depending on validity of normality assumptions) were performed to assess if the distribution of the categorical outcome of clinical cure (i.e. score of zero on both conjunctival injection and conjunctival discharge) varied by treatment with either SCH-1 or placebo.

Descriptive statistics (i.e. mean and standard deviations [SD] for normally distributed data, median with interquartile ranges [IQR] for non-normally distributed data) were calculated for all relevant measures. Percentage breakdowns will be used for categorical variables (ie: gender, age). All P-Values will be two-sided with statistical significance evaluated at the 0.05 alpha level.

All analyses were performed in SAS Version 9.4 (SAS Institute, Inc. Cary, NC).

Determination of Sample Size

The determination of sample size was derived from clinical experience, in which we expected the clinical cure rates at day 5 to be approximately 20% and 80 % in the placebo and SCH-1 groups respectively. A sample of 15 patients per group will yield 87% power to detect a difference between 20% and 80%, based on a Fisher's exact test with a 0.05 significance level.

Changes in the Conduct of the Study or Planned Analyses

There were no changes in the conduct of the study or planned analysis.