STATISTICAL ANALYSIS PLAN

Protocol Number: A-101-WART-202

A RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED, PARALLEL GROUP STUDY OF A-101 TOPICAL SOLUTION APPLIED ONCE A WEEK IN SUBJECTS WITH COMMON WARTS

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Approval

A-101-WART-202 STATISTICAL ANALYSIS PLAN, FINAL

TITLE: **A RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED, PARALLEL GROUP STUDY OF A-101 TOPICAL SOLUTION APPLIED ONCE A WEEK IN SUBJECTS WITH COMMON WARTS**

C. Powala 12-1-2017

Christopher Powala
Chief Operating Officer, Aclaris Therapeutics, Inc.

Date

Mark H. Bradshaw 11/21/2017

Mark H. Bradshaw
Statistician

Date

Approval

A-101-WART-202 STATISTICAL ANALYSIS PLAN, FINAL

TITLE: **A RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED, PARALLEL GROUP STUDY OF A-101 TOPICAL SOLUTION APPLIED ONCE A WEEK IN SUBJECTS WITH COMMON WARTS**

Christopher Powala
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1. SYNOPSIS

Protocol Number A-101-WART-202 Synopsis	
Protocol Number:	**Protocol Title:** A Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study of A-101 Topical Solution Applied Once a Week in Subjects with Common Warts
Sponsor: Aclaris	**Phase of Development:** **Phase 2**
Study Drug Description: A-101 Solution (45%) is a hydrogen peroxide solution that will be supplied in a glass ampule with an applicator to be applied to common warts (verruca vulgaris) on the trunk or extremities. The study drug, A-101 (hydrogen peroxide) 45% Topical Solution (hereafter referred to as A-101) is a colorless solution that must be stored at room temperature (15-25° C or 59 -77 ° F). The blinded vehicle solution is packaged to match the active study drug and will be stored under the same conditions.	
Study Objectives: **Primary:** The main objective of this study is to evaluate the clinical effect of A-101 45% vs Vehicle when applied to 1 common Target Wart (verruca vulgaris) on the trunk or extremities. **Secondary:** The secondary objectives of this study include: • Evaluate the clinical effect of A-101 45% when applied to all treated Warts (Target plus Non-Target Warts) • Duration of response in all treated Warts (Target Warts plus Non-Target Warts) • Safety of A-101 45%	
Study Design: This is a phase 2, randomized, multicenter study to evaluate the safety and efficacy of A-101 45% vs Vehicle in subjects with common warts on the trunk or extremities. Subjects may have up to a total of 4 treated common warts located on their trunk or extremities. Investigators will be required to identify 1 Target Wart for treatment with A-101 study medication. An additional 3 Non-Target Warts may be treated and followed throughout the study protocol therapy. All identified Common Warts will be treated once a week for 8 weeks. Subjects will be followed for 3 months after the last weekly treatment. Approximately 120 evaluable subjects will be randomized to one of 2 treatment arms in a 1:1 ratio. The duration of study participation is anticipated to be up to a maximum of 155 days per subject. All subjects will be followed for at least 12 weeks after the last study medication treatment. Safety will be evaluated based on clinical laboratory studies (hematology and clinical chemistry), vital signs, assessment of local skin reactions (LSRs), assessment of adverse events (AEs), and concomitant medication review.	

Efficacy will be evaluated based on assessment of each Target and Non-Target Wart according to the Physician Wart Assessment (PWA). Sites will be required to take standardized color photographs of each Target and Non-Target Wart to assist with the documentation of the location of each of the wart throughout the study.

Number of Patients to be Enrolled:

Approximately 120 evaluable subjects will be randomized to the study.

Number of Study Sites:

This study will be conducted in the US only at approximately 15 treatment centers.

Inclusion Criteria:

Subjects must meet all of the following criteria to be considered for participation in this study.

1. Subject is able to comprehend and is willing to sign an informed consent/assent for participation in this study.
2. Male or female ≥ 8 years old.
3. Subject has a clinical diagnosis of common warts.
4. Subject has up to 1 Target Wart and up to 3 additional Non-Target Warts located on the trunk or extremities. The identified Target and Non-Target Warts must meet the requirements as defined below:
    a. Each wart must have a longest axis that is ≥ 3mm and ≤ 8 mm and have a thickness of ≤3mm
    b. Each wart must be a discrete lesion
    c. Each wart must be present for at least 4 weeks
    d. Not be covered with hair which, in the investigator's opinion, would interfere with the study medication treatment or the study evaluations
    e. Not be in an intertriginous fold
    f. Be the only common wart present when the circular cutout template is centered over the wart
5. The Target and Non-Target Warts must have a PWA ≥ 2.
6. Subject chemistry and complete blood count results are within normal limits. If any of the laboratory values are outside normal range, the treating investigator must assess the value/s as NOT clinically significant and document this in the subject's medical chart in order for the subject to be eligible for randomization.
7. Woman of childbearing potential (WOCBP) must have a negative urine pregnancy test within 14 days of the first application of study drug and agree to use an active method of birth control for the duration of the study.
8. Subject is non-pregnant and non-lactating.
9. Subject is in good general health and free of any known disease state or physical condition which, in the investigator's opinion, might impair the evaluation of any Target or Non-Target Warts or which exposes the subject to an unacceptable risk by study participation.
10. Subject is willing and able to follow all study instructions and to attend all study visits.

Exclusion Criteria:

Subjects are excluded from this study if any 1 or more of the following criteria is met:

1. Subject has clinically atypical warts on the trunk or extremities.
2. Subject is immunocompromised (e.g., due to chemotherapy, systemic steroids, genetic immunodeficiency, transplant status, etc.).
3. Subject has periungual, subungual, genital, anal, mosaic, plantar, flat, or filiform wart as a Target

or Non-Target Wart.

4. Subject has a history of Human Immunodeficiency Virus (HIV) infection.
5. Subject has had any Human Papilloma Virus (HPV) vaccine within 1 year prior to Visit 2
6. Subject has used any of the following intralesional therapies within the specified period prior to Visit 2
    - Immunotherapy (e.g., *Candida* antigen, mumps antigen, *Trichophyton* antigen); 8 weeks
    - Anti-metabolite therapy (e.g., bleomycin, 5-fluorouracil); 8 weeks
7. Subject has used any of the following systemic therapies within the specified period prior to Visit 2:
    - Immunomodulatory/immunosuppressant therapy (e.g., etanercept, alefacept, infliximab); 16 weeks
    - Glucocorticosteroids (inhaled and intra-nasal steroids are permitted); 28 days
8. Subject has used any of the following topical therapies within the specified period prior to Visit 2 on, or in a proximity to any Target or Non-Target Warts, that in the investigator's opinion interferes with the study medication treatment or the study assessments:
    - LASER, light or other energy based therapy (e.g., intense pulsed light [IPL], photo-dynamic therapy [PDT]; 180 days
    - Immunotherapy (e.g., imiquimod, squaric acid dibutyl ester[SADBE], etc); 12 weeks
    - Liquid nitrogen, electrodesiccation, curettage; 60 days
    - Hydrogen peroxide; 90 days
    - Anti-metabolite therapy (e.g., 5-fluorouracil); 8 weeks
    - Retinoids; 90 days
    - Over-the-counter (OTC) wart therapies; 28 days
9. Subject currently has or has had any of the following within the specified period prior to Visit 1 on or in a proximity to any Target or Non-Target Warts that, in the investigator's opinion, interferes with the study medication treatment or the study assessments:
    - Cutaneous malignancy; 180 days
    - Sunburn; currently
    - Pre-malignancy (e.g., actinic keratosis); currently
10. Subject has a history of sensitivity to any of the ingredients in the study medications.
11. Subject has any current skin disease (e.g., psoriasis, atopic dermatitis, eczema, sun damage), or condition (e.g., sunburn, excessive hair, open wounds) that, in the opinion of the investigator, might put the subject at undue risk by study participation or interfere with the study conduct or evaluations.
12. Participation in another therapeutic investigational drug trial in which administration of an investigational study medication occurred with 30 days prior to Visit 1.

Duration of Treatment

The duration of the study participation is anticipated to be a maximum of 155 days per subject. The final visit (Visit 13) has a maximum allowable visit window of 7 days: Study visits are:

- Visit 1 (Day -13 to 0) screening
- Visit 2 (Day 1) randomization; study medication treatment
- Visit 3 (Day 8) study medication treatment
- Visit 4 (Day 15) study medication treatment
- Visit 5 (Day 22) study medication treatment
- Visit 6 (Day 29) study medication treatment
- Visit 7 (Day 36) study medication treatment
- Visit 8 (Day 43) study medication treatment
- Visit 9 (Day 50) study medication treatment

- Visit 10 (Day 57) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 11 (Day 78) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 12 (Day 106) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 13 (Day 134) follow up evaluations, no Target or Non-Target Wart retreatment; end of study

Criteria for Evaluation

Efficacy:

The investigator will evaluate the severity of each Target and Non-Target Wart using the Physician Wart Assessment (PWA)

Safety:

Safety will be evaluated by following adverse events, clinical laboratory exams, vital signs, concomitant medications, as well as through skin examinations and general physical exams.

Study Drug Administration

Study drug medication will be applied to each Target and Non-Target Wart meeting the requirements for treatment/retreatment during Visits 2 through 9. The study drug will be applied by the subject in the presence of the treating physician or a member of the investigational site staff who is a trained healthcare professional. Subjects between the ages of 8 and 17 years of age will have their A-101 study medication applied by the investigational research staff.

Study medication must be applied to each of the Target and Non-Target Warts for approximately 15 seconds. The treated warts must remain undisturbed for approximately 15 seconds. This treatment cycle may be repeated up to 3 times to each Target and Non-Target Wart.

Statistical Methods

Efficacy Analysis

The primary efficacy analysis will be a comparison between treatment groups based on the mean change in Target Wart PWA from Baseline (Visit 2) to Visit 10, using Analysis of Covariance with Baseline PWA as the covariate. Secondary efficacy analyses will include comparisons between treatment groups based on the following: the proportion of subjects with the Target Wart Clear (PWA = 0) at Visit 10 using Fisher's Exact Test; the proportion of subjects with all treated warts Clear at Visit 10 using a Cochran-Mantel-Haenszel test stratified by number of treated warts; and the mean of per-subject percentages of all treated warts that are clear at Visit 10 using Analysis of Variance. Durability of response in the Active treatment group will be evaluated by calculating the proportion of those treated warts achieving a PWA status of Clear at Visit 10 which continue to maintain a PWA status of Clear at Visit 13. This analysis will be performed separately for Target Warts, and for all treated warts. The 95% confidence limits around the calculated proportions will also be calculated in order to estimate the population lower limit value of the observed sample proportions.

Safety Analysis

Safety endpoints for adverse events (AEs) include the following: incidences of all treatment-emergent AEs (TEAEs) and all serious AEs (SAEs); by severity, by relationship to study drug and discontinuation of patients from study due to AEs. Safety endpoints for AEs, clinical laboratory tests, vital signs, and physical examinations and local skin reactions will be specified in the statistical analysis plan (SAP). All safety endpoints will be summarized using descriptive statistics.

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Term
AE	Adverse Event
ANCOVA	Analysis of Covariance
°C	Degrees Centigrade
CMH	Cochran-Mantel-Haenszel
CRA	Clinical Research Associate
CRO	Contract Research Organization
CS	Clinically Significant
e.g.	for example, (Latin; *exempla gratia*)
EC	Ethics Committee
eCRF	Electronic Case Report Form
°F	Degrees Fahrenheit
FDA	Food and Drug Administration
5FU	5 Fluorouracil
G	Gram
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
H_2O_2	Hydrogen Peroxide
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
i.e.	that is (Latin; *id est*)
IPL	Intense Pulsed Laser
IRB	Institutional Review Board
ITT	Intent to Treat
LOCF	Last Observation Carried Forward
LSR	Local Skin Reactions
MedDRA	Medical Dictionary for Regulatory Activities
mL	Milliliter

Abbreviation	Term
Mm	Millimeter
NCS	Not Clinically Significant
OTC	Over-The-Counter
PDT	Photodynamic Therapy
PP	Per Protocol
PWA	Physician Wart Assessment
SAE	Serious Adverse Event
SI	Subject Identifier
SK	Seborrheic Keratosis
SOP	Standard Operating Procedure
US	United States
WOCBP	Women of childbearing potential

2. STUDY OBJECTIVES

2.1. Study Objectives

2.1.1. Primary Objective

The primary objective of this study is to evaluate the effectiveness of A-101 45% compared to vehicle when applied to 1 common target wart on the trunk or extremities.

2.1.2. Secondary Objective

The secondary objectives of this study include:

- Evaluate the clinical effect of A-101 45% when applied to all treated warts (Target plus Non-Target Warts)
- Duration of response in all treated warts (Target Warts plus Non-Target Warts)
- Safety of A-101 45%

3. STUDY DESIGN

This is a phase 2, randomized, multi-center, study designed to evaluate the safety and efficacy of A-101 45% compared to Vehicle in subjects with common warts on the trunk or extremities.

During the study, the investigator will identify 1 eligible Target Wart and up to 3 additional Non-Target Warts on each subject on the trunk or extremities. All Target and Non-Target Warts will be treated weekly for 8 weeks.

Subjects will be required to complete a total of 13 study visits. The protocol defined study visits are:

- Visit 1 (Day -13 to 0) screening
- Visit 2 (Day 1) randomization; study medication treatment
- Visit 3 (Day 8) study medication treatment
- Visit 4 (Day 15) study medication treatment
- Visit 5 (Day 22) study medication treatment
- Visit 6 (Day 29) study medication treatment
- Visit 7 (Day 36) study medication treatment
- Visit 8 (Day 43) study medication treatment
- Visit 9 (Day 50) study medication treatment
- Visit 10 (Day 57) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 11 (Day 78) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 12 (Day 106) follow up evaluations, no Target or Non-Target Wart retreatment
- Visit 13 (Day 134) follow up evaluations, no Target or Non-Target Wart retreatment; end of study

Refer to Section 4 for a complete list of protocol required study assessments.

A completed evaluable subject is a subject that completes all required treatment Visits (Visits 2-9), completes Visit 13 (end of study visit), has had all Target Warts assessed at these visits and has not had a protocol violation documented during the study.

3.1. Number of Subjects and Study Centers

Approximately 120 evaluable subjects will be randomized to one of two treatment arms at approximately 15 investigational centers in the US.

3.2. Duration of Study

The anticipated time for study enrollment is 3 months. The duration of study participation is anticipated to be a maximum of 155 days per subject. Subjects will have a total of 13 study visits. The maximum anticipated duration for the study is approximately 8 months.

4. STUDY PROCEDURES

The schedule of study activities (including assessments, tests, exams, disease assessments, and study drug administration) beginning with screening and continuing through the end of study are outlined in Table 1. A written, signed informed consent form (ICF)/assent must be obtained from each subject prior to performing any study related procedure (e.g., vital signs, clinical laboratory sampling, urine pregnancy test or photography).

Table 1: Study Procedures

Visit	V1 Screening	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
Treatment Day	-13 to 0	1	8	15	22	29	36	43	50	57	78	106	134
Treatment Window	N/A	N/A	±1 day	±4 days	±4 days	±4 days	±4 days	±4 days	±4 days	+4 days	±7 days	±7 days	+7 days
Study Procedures													
Informed Consent/Assent	X												
Inclusion Criteria/Exclusion Criteria	X	X[1]											
Subject Identifier	X[2]												
Medical history/demographics	X												
Fitzpatrick Skin Type Assessment	X[3]												
Vital Signs	X[4]								X				X
Prior Medications/Therapies	X[5]												
Clinical Chemistry and CBC[6]	X								X				X
Urine Pregnancy Test[7]	X	X							X				X
Target Wart Identification[8]	X												
Physician's Wart Assessment[9]	X	X	X	X	X	X	X	X	X	X	X	X	X
Target Wart Dimensions[10]	X	X	X	X	X	X	X	X	X	X	X	X	X
Standardized Photography[11]	X	X		X					X	X			X
Subject Randomization		X[12]											
Local Skin Reactions		X[13]	X[13]	X[13]	X[13]	X[13]	X[13]	X[13]	X	X	X	X	X
Study Medication Application[14]		X	X	X	X	X	X	X	X				
Weighing of Study Medication Applicators[15]		X	X	X	X	X	X	X	X				
Subject Instructions	X	X	X	X	X	X	X	X	X	X	X	X	

Concomitant therapies[16]		X	X	X	X	X	X	X	X	X	X	X	X
Adverse Events[17]		X	X	X	X	X	X	X	X	X	X		

[1]Subject inclusion/exclusion criteria will be re-assessed prior to randomization during Visit 2.

[2]Investigational sites will assign a unique five-digit subject identifier to each subject at Visit 1. This subject identifier will be used in all study documentation for the duration of the study.

[3]Each subject's skin must be assessed during Visit 1 using the Fitzpatrick Skin Type Assessment. Refer to Section **Error! Reference source not found.** for the scale.

[4]Vital signs [including temperature, pulse, respiratory rate, blood pressure, height and weight (Visit 1 only)] will be measured by a qualified staff member at Visit 1, Visit 9 and Visit 13.

[5]Prior medications/therapies will be collected for a time-period of 13 days prior to Visit 2. Refer to Section **Error! Reference source not found.** for a list of permitted and restricted concomitant medications.

[6]A complete blood count (including hematocrit, hemoglobin, platelet count, red blood cell count and morphology, white blood cell count and differential (absolute and %) including basophils, eosinophils, lymphocytes, monocytes and neutrophils and a clinical chemistry panel including albumin, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN), bicarbonate, calcium, chloride, creatinine, glucose, lactate dehydrogenase (LDH), phosphorus, potassium, sodium, total bilirubin, total protein, and uric acid.

[7] Woman of child bearing potential will be required to have a urine pregnancy test at Visit 1, at Visit 2 prior to randomization, Visit 9 and Visit 13.

[8]The treating investigator will identify 1 Target Wart and up to 3 additional Non-Target Warts on the trunk and extremities.

[9] The investigator will use the Physician Wart Assessment (PWA) to assess each Target and Non-Target Warts. The investigator must assess the Target and Non-Target Warts prior to application of the study medication at Visit 2-Visit 9. In order to be eligible for randomization at Visit 2, the subject must have a PWA grade $\geq$ 2.

[10] The investigator will measure the dimensions (longest diameter and thickness) of the Target and Non-Target Warts at Visit 1 and prior to randomization at Visit 2. In order for the subject to be randomized at Visit 2 each Target and Non-Target Wart must have the specific dimensions outlined in Section 5.1. At Visits 3-13 the investigator will measure the diameter of each Target and Non-Target Wart.

[11] At Visits 1, Visit 2 (prior to study medication application), Visit 4 prior to study medication application, Visit 9, Visit 10 and at Visit 13, a qualified investigational center staff member will take a photograph of each Target and Non-Target Wart using the Aclaris supplied camera. All photographs will be sent to a central imaging laboratory.

[12] Subjects will be randomized at Visit 2 prior to application of study medication. Investigational study staff will re-confirm subject eligibility prior to randomization.

[13] The investigator and subject will assess each Target Wart for local skin reactions associated with irritation at Visits 2-13. At Visit 2-Visit 9, the investigator and subject will assess the Target and Non-Target Warts for LSRs prior to the application of the study medication. The subject will assess LSRs 10 ($\pm$4) minutes after the application of A-101 study medication and the investigator will assess for LSRs 20 ($\pm$ 4) minutes after application of A-101 study medication. Refer to Section 6.1 for the complete list of Local Skin Reaction signs and symptoms.

[14]The investigator will apply the A-101 study medication to subject 8 to 17 years of age. Subjects 18 years of age and older will apply their A-101 study medication in the presence of the treating physician or a member of the investigational study staff that has been trained on the protocol. All Target and Non-Target Warts will be treated with study medication following randomization at Visit 2. If a Target or Non-Target Wart meets the criteria for re-treatment as defined in Section **Error! Reference source not found.** the lesion will be re-treated at Visit 3-9. Following application of study medication, subjects must NOT wash/submerge the Target or Non-Target Warts for at least 6 hours and they must NOT apply any topical products to the Target or Non-Target Warts for at least 6 hours.

[15]Sites will be required to weigh all A-101 study medication applicators before and after treatment and document the weight of each applicator in the subject's eCRF.

[16]All concomitant therapies including (topical and oral) prescription medications, over the counter medications and natural supplements and non-drug therapies including chiropractic, physical therapy, and energy based therapy must be documented in the subject CRF. Subjects must not apply any topical products (e.g., moisturizers, sunscreen, etc.) to their Target or Non-Target Warts within 12 hours prior to any study visit.

[17]The reporting period for Serious Adverse Events (SAEs) begins when the subject signs the informed consent and continues through Visit 11. Refer to Section **Error! Reference source not found.** for instructions on the reporting of SAEs. Non-serious clinical adverse events will be collected following the application of the study medication at Visit 2. Non-serious adverse events that occur between the time of consent and study medication application will be documented as medical history. All safety reporting (AEs and SAEs) will conclude at Visit 11 (approximately 28 days after last study medication application) except for clinical adverse events related to local skin reactions.

5. ASSESSMENTS OF CLINICAL EFFICACY

5.1. Target and Non-Target Wart Identification

At Visit 1, the investigator will identify one Target Wart and up to 3 additional Non-Target Warts on the trunk or extremities for each subject for treatment and evaluation.

For this study, the trunk and extremities are defined as:

- The front and back of the torso from the clavicle to the hips, including the buttocks and excluding the genitals and anus
- The arms from the shoulder to the fingertips, excluding periungual and subungual areas
- The legs from the hip to the ankles (including the dorsal side of the foot).

At Visit 1, each Target and Non-Target Wart must:

- Have a longest axis that is ≥3mm and ≤8mm
- Have a thickness ≤3mm
- Be a discrete lesion
- Be, when centered in the circular cutout of the provided template, the only common wart present (Refer to Figure 1)
- Not be periungual, subungual, genital, anal, mosaic, plantar, flat or filiform.
- Not be covered with hair which, in the Investigator's opinion, would interfere with the study medication treatments or the study evaluations
- Not be in an area that may be occluded (*e.g.*, by clothing or footwear or in a skin fold).

Record the location of the Target and Non-Target Wart on the body charts in the CRFs indicating landmarks and distances to assist with confirming the location of the Target and Non-Target Warts at subsequent visits.

At Visit 1, the Investigator and an investigational staff member will identify each Target and Non-Target Wart by placing 2 identification (ID) stickers approximately 180 degrees opposite each other with the identified wart in the center of the area outlined by the provided circular template (diagram not to scale):

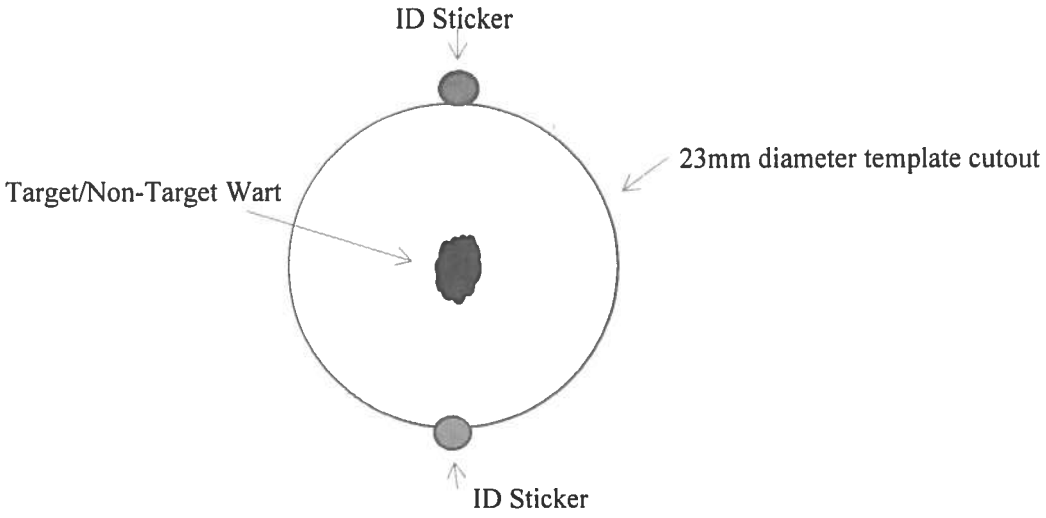

Figure 1 Target/Non-Target Wart Identification

At Visits 2-13, an investigational staff member (other than the evaluating investigator) will confirm the location of each Target/Non-Target Wart using an appropriate combination of the Visit 1 hard-copy reference prints, Visit 2 photographs and the body charts. The staff member will identify the Target/Non-Target Warts by placing 2 appropriately colored ID stickers, with the Target/Non-Target Wart number written on one sticker, approximately 180 degrees opposite each other with the identified wart in the center of area outlined by the provided circular template.

5.2. Standardized photography

At Visits 1, 2, 4, 9, 10, and 13 a qualified investigational center staff member will take standardized color photographs of each Target and Non-Target Wart.

The photographs are to document the appearance and location of the subjects' Target and Non-Target Warts. The subject's identity will not be revealed in the study photographs.

At Visit 2, the photographs must be taken prior to the study medication application.

Care must be taken to ensure the same lighting, background, subject positioning relative to the camera and camera settings are used for each photograph.

Sites will be provided with photography equipment and supplies necessary for obtaining the Target Lesion photographs. Detailed instructions for obtaining and managing the photographs will be documented in the study specific Photography Manual and provided to the site at the study initiation visit.

5.3. Physician's Wart Assessment (PWA)

The Physician's Wart Assessment (PWA) is the Investigator's assessment of the severity of each Target and Non-Target Wart at a particular time point. The Investigator should NOT refer to any other assessments to assist with this evaluation. This evaluation IS NOT a comparison with the PWA at any other visit.

At every study visit, the Investigator will assess the Target and Non-Target Warts and report the one integer that best describes the Target and Non-Target Wart severity using the following scale. At any visit where a study medication treatment is performed, the PWA must be completed prior to the treatment.

Physician's Wart Assessment	
Grade	**Descriptor**
0	Clear: No visible wart. No further treatment is indicated
1	Near Clear: A visible wart that is less than 3mm in maximal diameter (or length)
2	A visible wart ≥ 3mm and <6 mm in maximal diameter (or length)
3	A visible wart ≥ 6mm in maximal diameter (or length)

At Visit 1 for the subject to be enrolled and at Visit 2 for the subject to be randomized each Target and Non-Target Wart must have a PWA grade ≥ 2.

At Visits 3-9, Target and Non-Target Warts must have a PWA > 0 to be retreated. If the Investigator cannot assess the PWA for a Target or Non-Target Wart (*e.g.*, the Target /Non-Target Wart cannot be visualized because of an LSR such as edema, scabbing, etc.) she/he must report the reason in the subject's CRFs. The Target/Non-Target Wart must not be retreated at that visit, and the subject should be seen at the next scheduled visit.

5.4. Subject Instructions

An investigational center staff member will dispense a Subject Instruction Sheet to each subject at Visit 1 (Refer to Appendix **Error! Reference source not found.**).

Throughout the study, the subjects should:

- Continue their routine cleansing regimen except they should avoid vigorous scrubbing of the Target/Non-Target Warts (*e.g.*, loofah, back brushes, scrubbing straps, abrasive washcloths, sponges and cleansing pads, etc.)
- Continue their routine cosmetics and skin care products

- Avoid exposing the Target/Non-Target Warts to excessive natural or artificial ultraviolet radiation (*e.g.*, sunlight, tanning beds) and use sunscreen on the Target/Non-Target Warts, if excessive exposure cannot be avoided
- Avoid activities that might irritate the Target/Non-Target Wart
- Avoid the use of self-tanning lotions and spray tans.
- Bring the subject instruction sheet with them to each visit.

On study visit days, the subjects should:

- When appropriate for the Target/Non-Target Wart location wear loose fitting clothing to the visit (Note: clothing that comes in contact with the study medication may be bleached)
- Starting with Visit 2, not apply any topical products to the Target/Non-Target Wart within **12 hours** prior to the visit (Note: routine cleansing products are allowed)
- After the completion of any study visit where a study medication treatment was performed DO NOT:
    - Wash/submerge the Target or Non-Target Warts for at least **6 hours**
    - Apply any topical products to the Target or Non-Target Warts for at least **6 hours**.

5.5. Other Study Supplies

Aclaris Therapeutics, Inc. will provide:

- An appropriate ruler, or other instrument, for measuring the thickness of all Target/Non-Target Warts dimensions
- Templates for use when identifying Target/Non-Target Warts
- Supplies and instructions for collecting, labeling, shipping and result reporting for the clinical laboratory tests and urine pregnancy tests from a third party
- Equipment, supplies and training for taking standardized photographs
- Scales to weigh all treatment applicators
- Eyewash kits.

6. ASSESSMENT OF SAFETY

In addition to reporting adverse events throughout the study the investigator, a designated and appropriately trained staff member or the subject, will perform the following safety assessments according to the schedules noted below.

The investigational staff member performing the LSR evaluations must not participate in the study medication treatment for the subject being evaluated.

6.1. Local Skin Reactions (LSR)

The LSR assessment is the Investigator's assessment of the signs and the subject's assessment of the symptoms associated with irritation at the Target/Non-Target Wart site (*i.e.*, the Target/Non-Target Wart and the skin immediately surrounding the Target/Non-Target Wart exposed to study medication). The Investigator may refer to previous photographs to assist with these assessments only after the PWA has been performed.

The Local Skin Reaction signs to be assessed are:

- Erythema
- Edema
- Erosion
- Ulceration
- Vesicles/bullae
- Excoriations
- Scabbing.

The Local Skin Reaction symptoms to be assessed (by the Subject) are:

- Stinging/burning
- Pruritus (itch).

At Visits 2-13, the Investigator will evaluate the LSR signs at the Target/Non-Target Wart site(s) as follows:

- At visits where a study medication treatment or retreatment is performed:
  - Perform an LSR assessment prior to any study medication application
  - For treated Target and Non-Target Warts perform an LSR assessment 20 (±4) minutes after the Treatment Completion Time.

At Visits 2-13, the Subject will assess the LSR symptoms at the Target/Non-Target Wart site(s) as follows:

- At visits where a study medication treatment or retreatment is performed:
  - Perform an LSR assessment prior to any study medication application
  - For every treated Target and Non-Target Wart site, 10 (±4) minutes after the Treatment Completion Time, report the average of the severity of the LSR for all symptoms since completion of the study medication treatment.

- At visits where no study medication treatment is performed:
  - Perform an LSR assessment.

The Investigator and subject should report the one integer that best describes the severity of each LSR sign or LSR symptom for the Target and Non-Target Wart sites using the scale below.

Local Skin Reactions	
Grade	**Descriptor**
0	None
1	Mild
2	Moderate
3	Severe

6.2. Other Evaluations

At Visit 1, the investigator must determine each subject's Fitzpatrick skin type and document appropriately on the subject's CRF.

Table 2 Fitzpatrick Skin Type Scoring System

Skin Type Classification	Description
Type I	always burns, never tans (pale white; blond or red hair; blue eyes; freckles)
Type II	usually burns, tans minimally (white; fair; blond or red hair; blue, green, or hazel eyes)
Type III	sometimes mild burn, tans uniformly (cream white; fair with any hair or eye color)
Type IV	burns minimally, always tans well (moderate brown)
Type V	very rarely burns, tans very easily (dark brown)
Type VI	Never burns, never tans (deeply pigmented dark brown to darkest brown)

(Fitzpatrick 1988)

Medical history information will be recorded including all medical conditions and disease states that, at Visit 1:

- Are ongoing
- Require concomitant therapy
- Are, in the opinion of the investigator, relevant to the subject's study participation.

7. STATISTICAL CONSIDERATIONS

7.1. Sample Size and Power Consideration

Based on efficacy results from the previous study and the active study medication specified in the current protocol for the same indication, sample size for the current study is anticipated to provide greater than 90% power to achieve statistical significance in the primary efficacy analysis.

7.2. General Statistical Considerations

In general, all listings, summaries and analyses will be done and presented by treatment group. Data listings will be produced for all relevant parameters. Summaries of quantitative variables will include the sample size, mean, median, standard deviation, minimum, and maximum. Ordinal variables will be treated as continuous for analysis purposes. For non-ordinal categorical variables, the summaries will include the number and percent of subjects for each outcome. Unless otherwise indicated, for inferential comparisons, statistical significance will be declared if the two-sided p-value is ≤ 0.05. No alpha adjustments will be made.

7.3. Analysis Populations and Disposition of Subjects

7.3.1. Analysis Populations

The Safety Population is defined as all subjects who received at least one application of study medication.

The Intent-to-Treat (ITT) population is defined as all subjects who were randomized, received at least one application of study medication and had at least one post-baseline efficacy evaluation. No data imputation will be used for missing data.

The Per-Protocol (PP) population includes all ITT subjects who completed Visit 10 with no major protocol violation and who missed no more than 3 treatment visits. For the Visit 13 analysis, the PP population must also have had a Visit 13.

7.3.2. Subject Disposition

Disposition of subjects will be presented by treatment group for each population. These presentations will include the number of subjects who completed the study and the number who discontinued, as well as the reason for study discontinuation.

7.4. Analyses of Demographics, Baseline Characteristics

Demographic and other baseline variables including age, sex, ethnicity, height, weight, vital signs, and all safety and efficacy parameters related to the subject's condition at Baseline, and including laboratory-based evaluations, will be summarized. Summary statistics (N, mean, SD, median, minimum, maximum, proportions, as appropriate) will be presented by treatment group. Baseline PWA scores will be summarized to show comparability among treatment groups before the start of study medication.

7.5. Treatment Compliance

Study medication use and accountability will be presented in a listing. Overall study medication use will be summarized by treatment group.

8. PRESENTATIONS OF SAFETY INFORMATION

Descriptive statistics by treatment group will be calculated on the safety parameters collected on or after Visit 3 using the Safety Population, defined as subjects who received at least one application of study medication. Safety summaries will include listings of clinical laboratory values and abnormal values, adverse events incidences within each Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class, and changes from pre-dose values in vital signs. Adverse event summaries will be presented showing the proportion of patients experiencing adverse events, both overall and by MedDRA System Organ Class.

8.1. Treatment-Emergent Adverse Events

The proportion of subjects with treatment-emergent adverse events (TEAEs) will be tabulated by treatment group and presented by MedDRA Preferred Terms within System Organ Class. The number and percent of subjects with treatment emergent adverse events, premature discontinuations due to adverse event, adverse events classified by their highest relationship to study drug, and adverse events classified by their maximum severity, will be summarized by MedDRA preferred term. A summary of all serious adverse events by treatment group will also be prepared.

A summary of the incidence of serious adverse events (SAEs) will be presented by MedDRA Preferred Terms within System Organ Class, and by treatment group.

8.2. Concomitant Medications

The use of concomitant medications will be listed.

8.3. Vital Signs

Vital sign data (systolic blood pressure, diastolic blood pressure, pulse, respiration rate, temperature, and body weight) will be summarized by treatment group and by visit, including mean changes from baseline.

8.4. Clinical Laboratory Results

Central clinical laboratory data will be summarized by treatment group and laboratory parameter, showing the proportion of subjects with abnormal values.

8.5. Local Skin Reactions

Local Skin Reaction (LSR) scores will be summarized by frequency distributions for each symptom, by treatment group and visit. The proportion of subjects with with Severity > 0, and similarly for subjects with Severity > 1 will be presented for each symptom, by visit.

9. STATISTICAL ANALYSIS METHODS

9.1. Statistical Analysis of Efficacy Data

Primary and secondary efficacy analyses will be performed on the Per-Protocol population, defined as all randomized subjects who missed no more than 3 treatment visits, completed Visit 10 (and Visit 13 for purposes of the Visit 13 analysis), and who have not had a major protocol violation over that time period including the use of a clinically relevant quantity of a prohibited medication as determined by the study Medical Monitor. No missing data imputation will be used for these analyses.

Visit 10 is considered to be the primary efficacy endpoint. In addition, some analyses will also be conducted at earlier and subsequent visits, and treated as exploratory analyses. Some sensitivity efficacy analyses may also be re-performed on the Intent to Treat population, defined as those randomized subjects who have at least one post-baseline visit with required efficacy data collection and who completed Visit 10 with required collection of efficacy data. For those analyses, missing efficacy data for intermediate visits may be imputed using the last observation carried forward (LOCF) procedure. A determination as to the performance of such analyses using the Intent to Treat population will be based on the number and pattern of visits missed by randomized subjects. Exploratory analyses using models specified below may also be performed for separate sub-groups, depending on enrollment outcomes.

For all analyses, two-tail alpha will be set to 0.05 unless otherwise specified, with no adjustment for multiple comparisons. ANOVAs and ANCOVAs will include Site in the model only if doing so improves the sensitivity of the model for comparing treatment groups.

After the last randomized subject has completed Visit 10 the efficacy data captured to date in the database will be validated, locked through Visit 10 and unblinded for the purpose of analyzing efficacy data through Visit 10. Those analyses are not considered to be interim analyses as the results will be final. Data will continue to be collected through Visit 13 for all subjects, and the full database will subsequently be locked for efficacy analysis (including durability of response) beyond Visit 10, and for the analysis of safety and all other clinical data.

The primary efficacy analysis will be a comparison between treatment groups based on the mean change in Target Wart PWA from Baseline (Visit 2) to Visit 10, using Analysis of Covariance with Baseline PWA as the covariate.

Secondary efficacy analyses will include comparisons between treatment groups based on the following: the proportion of subjects with the Target Wart Clear (PWA = 0) at Visit 10 using a one-tail Fisher's Exact Test; the proportion of subjects with the Target Wart Clear or Near-Clear (PWA = 0 or 1) at Visit 10 using a one-tail Fisher's Exact Test; the proportion of subjects with all treated warts Clear at Visit 10 using a Cochran-Mantel-Haenszel test stratified by number of treated warts; the proportion of subjects with all treated warts Clear or Near-Clear at Visit 10 using a Cochran-Mantel-Haenszel test stratified by number of treated warts; the mean of per-subject percentages of treated warts that are Clear at Visit 10 using Analysis of Variance; the

mean of per-subject percentages of treated warts that are Clear or Near-Clear at Visit 10 using Analysis of Variance; and the mean of per-subject percent change from baseline PWA for treated warts using Analysis of Variance.

Durability of response in the Active treatment group will be evaluated by calculating the proportion of those treated warts achieving a PWA status of Clear at Visit 10 which continue to maintain a PWA status of Clear at Visit 13. This analysis will be performed separately for Target Warts, and for all treated warts. The 95% confidence limits around the calculated proportions will also be calculated in order to estimate the population lower limit value of the observed sample proportions.

Exploratory analyses may be conducted using a subset of the above analysis models, based on lesion sub-groups including body location, age, time to clearance, and also the following baseline wart classification: warts that are determined to be treatment-naive vs. recalcitrant.

9.2. Statistical Analysis of Safety Data

Descriptive statistics will be calculated on the safety parameters using the ITT population. The proportion of subjects with treatment-emergent adverse events will be tabulated and presented by treatment and Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class. Vital signs, LSR scores and clinically relevant abnormal laboratory results will also be tabulated and presented by study medication. No inferential testing will be performed.

Data from all randomized subjects will be presented and summarized. Safety summaries by study medication group will include listings by study medication of adverse events incidences within each MedDRA System Organ Class, and changes from pre-application values in vital signs. Adverse event summaries will be presented by study medication showing the proportion of subjects experiencing adverse events, both overall and by MedDRA System Organ Class.

9.3. Interim Analysis

An interim Analysis will not be conducted for this study.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.1. Protocol Amendments

No changes from the final approved (signed) protocol will be initiated without the prior written approval or favorable opinion of a written amendment by the IEC/IRB, except when necessary to eliminate immediate safety concerns to the study subjects or when the change involves only logistics or administration. The principal investigator and the sponsor will sign the protocol amendment.

10.2. Protocol Deviations, Violations and Exceptions

A **protocol deviation** is non-adherence to protocol-specific study procedures or schedules that does not involve inclusion/exclusion criteria, primary objective variable criteria, and/or GCP

guidelines. Deviations are considered minor and do not impact the study. Deviations include study procedures that occurred outside the treatment windows (except for treatment application days).

A **protocol violation** is defined as any divergence from the protocol-specific inclusion/exclusion criteria, subject is administered a prohibited medication, primary objective variable criteria, and/or GCP guidelines. Protocol violations will be identified and recorded, by study center personnel, on the CRF.

As a matter of policy, sponsor/CRO will not grant **exceptions** to protocol-specific entry criteria to allow patients to enter a study. If under extraordinary circumstances such action is considered ethically, medically, and scientifically justified for a particular patient, prior approval from sponsor/CRO and the responsible IRB/IEC, in accordance with the Sponsor/CROs Standard Operating Procedure (SOP), is required before the patient will be allowed to enter the study. If investigative center personnel learn that a patient who did not meet protocol eligibility criteria was entered in a study (a protocol violation), they must immediately inform sponsor/CRO. Such subjects will be discontinued from the study, except in a rare instance following review and written approval by sponsor/CRO and the responsible IRB/IEC, according to the applicable SOP.

10.3. Data Management

Data will be collected using eCRFs that are specifically designed for this study. The data collected on the eCRFs will be captured in a clinical data management system (CDMS) that meets the technical requirements described in US 21 Code of Federal Regulations (CFR) Part 11. The CDMS will be fully validated to ensure that it meets the scientific, regulatory, and logistical requirements of the study before it is used to capture data from this study. Before using the CDMS, all users will receive training on the system and study specific training. After they are trained, users will be provided with individual system access rights.

The handling of data, including data quality assurance, will comply with regulatory guidelines, including ICH and GCP, and the sponsor/CRO SOPs and working instructions. Data management and control processes specific to this study will be described in a data management plan. At the end of the study, the database will be locked and the data will be released for reporting and statistical analysis

10.4. Quality Assurance

The study is conducted under the sponsorship of Aclaris Therapeutics, Inc. in compliance with the applicable regulatory requirements as well as applicable ICH guidelines, Helsinki Declaration, and in respect of the Aclaris Therapeutics, Inc. and/or sub-contractor SOPs for study conduct and monitoring.

Audits may be carried out by the Aclaris Therapeutics, Inc. or Aclaris Therapeutics, Inc.'s representatives and inspections may be performed by regulatory authorities or IRB/ECs before, during or after the study. The investigator will provide the auditing/inspecting group direct access to all study records (*e.g.*, CRFs, subject medical records, study medication dispensing records) and the investigational center study facilities. The investigator and study staff will be available and will assist the auditing/inspecting groups as appropriate.

11. TABLES AND LISTINGS: TITLES

Note: Mock tables and listings are provided in a separate document. They are intended to illustrate the format, layout and content of each table and listing. Final tables and listings may differ as appropriate. The mock tables and listings may include data from a previous study but will be superseded by data from the present study. Study identifier will be changed to A-101-WART-202. Treatment groups will be changed to A-101 Solution 45% and A-101 Solution Vehicle. Table numbers may be re-defined by the Medical Writer. Titles and Footnotes will be modified as required.

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Table 14.3.5.3	Treated Wart Local Skin Reactions (Evaluated by Subject), Number and % of Subjects for Each Symptom and Visit, With Target Wart Severity > 0 (None)

Table 14.3.5.4	Treated Wart Local Skin Reactions (Evaluated by Investigator), Number and % of Subjects for Each Symptom and Visit, With Target Wart Severity > 0 (None)
Table 14.3.5.5	Treated Wart Local Skin Reactions (Evaluated by Subject), Number and % of Subjects for Each Symptom and Visit, With Target Wart Severity > 1 (Mild)
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