CLINICAL STUDY REPORT

Study Title

Investigator

1. Title Page

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| **Study Title** |  | | |
| **Test Drug/Investigational Product:** |  | | |
| **Indication Studied** |  | | |
| **Study Description** |  | | |
| **Study Sponsor** |  | | |
| **Study Phase** |  | | |
| **Study ID** |  | **ClinicalTrials.gov NCT #** |  |
| **Study Initiation Date**  **(First subject enrolled)** |  | | |
| **Date of Early Termination** | *(if any)* | | |
| **Study Completion Date (Last subject completed)** |  | | |
| **Investigator(s)** |  | | |
| **Sponsor Signatory** | *(the person responsible for the study report within the sponsor. The name, telephone number, and email of the sponsor contact person for questions arising during review of the study report should be indicated on this page)* | | |
| **Commercial Supporter** | This study was supported with a medical grant in the form of funding and/or study product from Galderma Laboratories, L.P. | | |
| **Good Clinical Practices (GCP) Statement** | This study was performed in compliance with ICH Good Clinical Practices (GCP), including the archiving of essential documents. | | |
| **Date of Report** |  | | |

1. Synopsis

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| **Title of Study** |  | |
| **Investigator(s)** |  | |
| **Study Site(s)** |  | |
| **Study Period (years)** | *From: (First subject enrolled)*  *To: (Last subject completed)* | *Phase:* |
| **Objectives** | *Primary:* | |
| *Secondary:* | |
| *Other:* | |
| **Study Design & Methodology** |  | |
| **Number of Subjects** | *Planned:* | *Analysed:* |
| **Subject Selection Criteria** | *Main Criteria for Inclusion:* | |
| *Main Criteria for Exclusion:* | |
| **Test Product, Dose, and Route of Administration** |  | |
| **Duration of Treatment** |  | |
| **Reference Product, Dose, and Route of Administration** |  | |
| **Criteria for Evaluation** | *Efficacy:* | |
| *Safety:* | |
| **Statistical Methods** |  | |

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| **Conclusions** | *Efficacy:* |
| *Safety:* |
| *Conclusions:* |
| **Report Date** |  |

Investigator’s Signature

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| Study Title: |

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| Author(s): |

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| *I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.* |
| **Investigator:** |
| **Signature:** |
| **Date:** |

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1. List of Abbreviations and Definition of Terms

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| **Abbreviations** | **Definitions** |
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1. Ethics

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| Institutional Review Board |
| Ethical Conduct of the Study |
| Subject Information and Consent |

1. Investigators and Study Administrative Structure

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1. Introduction

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1. Study Objectives

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1. Investigational Plan

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| Overall Study Design |
| Discussion of Study Design |
| Selection of Study Population |
| Treatments |
| Efficacy and Safety Variables |
| Data Quality Assurance |
| Statistical Methods Planned in the Protocol and Determination of Sample Size |
| Changes in the Conduct of the Study or Planned Analyses |

1. Study Patients

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| Disposition of Patients |
| Protocol Deviations |

1. Efficacy Evaluation

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| Data Sets Analyzed |
| Demographic and Other Baseline Characteristics |
| Treatment Compliance |
| Efficacy Results and Tabulations of Individual Subject Data |

1. Safety Evaluation

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| Extent of Exposure |
| Adverse Events (AEs) |
| Deaths, Other Serious Adverse Events, and Other Significant Adverse Events |
| Clinical Laboratory Evaluation |
| Vital Signs, Physical Findings, and Other Observations Related to Safety |
| Safety Conclusions |

1. Discussion and Overall Conclusions

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1. Tables, Figures and Graphs (referred to but not included in the text)

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1. Reference List

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1. Appendices

## 16.1 Study Information

## 16.2 Patient Data Listings

## 16.3 Case Report Forms for Deaths, Other Serious Adverse Events and Withdrawals for AEs

## 16.4 Individual Patient Data Listings for Safety Data