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Active, not recruiting ⓘ

Study to Evaluate the Safety and Efficacy of BF-200 ALA (Ameluz®) and BF-RhodoLED® in the Treatment of Superficial Basal Cell Carcinoma (sBCC) With Photodynamic Therapy (PDT).

ClinicalTrials.gov ID ⓘ NCT03573401

Sponsor ⓘ Biofrontera Inc.

Information provided by ⓘ Biofrontera Inc. (Responsible Party)

Last Update Posted ⓘ 2026-01-14

Study Details Tab

Study Overview

Brief Summary

The aim of this study is to test the safety and efficacy of photodynamic therapy (PDT) with the medication Ameluz® performed with the PDT-lamp BF-RhodoLED® in comparison to the respective placebo treatment for superficial basal cell carcinoma (BCC).

Detailed Description

The study will be conducted as randomized, double blind and vehicle-controlled (4:1 ratio of verum (BF-200 ALA; Ameluz®) to vehicle (placebo)) clinical trial at 15 sites in the United States of America (US). Each site should randomize between 10 and 20 subjects.

Each subject will complete a clinical observation period that will last for up to 7 months (up to 4 weeks screening and pre-randomization period, and up to 6 months clinical observation period) followed by a 5-year follow-up (FU) period after the completion of the first PDT cycle.

Feedback

The treatment of superficial BCC lesion(s) comprises of up to two PDT cycles each with two PDT sessions one to two weeks apart of each other. 12 weeks after the first PDT of the first cycle lesion(s) will be assessed clinically and only subjects with remaining BCC lesion(s) will be retreated in the second PDT cycle starting the same day. For clinically completely cleared subjects the clinical observation period of the study will end and these subjects will enter the FU part of the study.

For each subject a Main Target Lesion will be defined that will be excised either 12 weeks after the first PDT of the first cycle, if clinically cleared, or at the end of the clinical observation period in order to histologically confirm the clinical assessment. Additional Target Lesions will be assessed clinically, only. Randomization will be stratified by the number of lesions (1 vs ≥ 2 Lesion(s)).

Definitions of complete responders comprise of:

1. Complete response of the Main Target Lesion which is assessed 12 weeks after the start of the last PDT cycle that included treatment of the Main Target Lesion and is defined as a Main Target Lesion that is completely clinically and histologically cleared.
2. In general, clinically complete responders are categorized 12 weeks after the start of the last PDT cycle according to clinical assessment only and are defined as subjects with all lesions (Main plus Additional Target Lesions) clinically cleared.

Verum and vehicle are indistinguishable. However, treatment is accompanied with typical adverse events (AEs). In order to guarantee the blind status of the investigator assessing efficacy after each PDT cycle, a second investigator or delegated person will perform drug application and light treatment as well as all safety evaluations at visits where PDT is applied and during the phone call 1 week after each PDT cycle, respectively. Both investigators (delegated person(s)) are not entitled to exchange information about the study outcome and side effects.

Official Title

A Randomized, Double Blind, Vehicle-controlled Multicenter Phase III Study to Evaluate the Safety and Efficacy of BF-200 ALA (Ameluz®) and BF-RhodoLED® in the Treatment of Superficial Basal Cell Carcinoma (sBCC) With Photodynamic Therapy (PDT).

Conditions ⓘ

Superficial Basal Cell Carcinoma

Intervention / Treatment ⓘ

- Combination Product: Photodynamic therapy (PDT) (ALA-PDT, Ameluz®-PDT)
- Combination Product: Placebo Photodynamic therapy (PDT) (vehicle to BF-200 ALA containing no active ingredient)

Other Study ID Numbers ⓘ

- ALA-BCC-CT013

Study Start (Actual) ⓘ

2018-09-25

Primary Completion (Actual) ⓘ

2024-03-19

Study Completion (Estimated) ⓘ

2029-02

Enrollment (Actual) ⓘ

187

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

This study has 18 locations

United States

Arizona Locations

 **Phoenix, Arizona, United States, 85006**
Medical Dermatology Specialists

 **Phoenix, Arizona, United States, 85032**
Alliance Dermatology & Mohs Center

California Locations

 **Fountain Valley, California, United States, 92708**
First OC Dermatology

 **San Diego, California, United States, 92121**
Cosmetic Laser Dermatology

Colorado Locations

 **Greenwood Village, Colorado, United States, 80111**
AboutSkin Research, LLC

Florida Locations

 **Delray Beach, Florida, United States, 33445**
Dermatology Associates PA of the Palm
Beaches

 **Gainesville, Florida, United States, 32606**
University of Florida Dept of Dermatology

Indiana Locations

 **Indianapolis, Indiana, United States, 46260**
Laser and Skin Surgery Center of Indiana

Michigan Locations

 **Detroit, Michigan, United States, 48202**
Henry Ford Health System

New Hampshire Locations

 **Lebanon, New Hampshire, United States, 03756**
Dartmouth-Hitchcock Medical Center

New York Locations

 **Brooklyn, New York, United States, 11209**
The Narrows Institute for Biomedical Research
and Education, Inc.

 **Rochester, New York, United States, 14623**
Skin Search of Rochester, Inc

 **Victor, New York, United States, 14564**

Rochester Dermatologic Surgery

South Carolina Locations

 **Charleston, South Carolina, United States, 29407**

Clinical Research Center of the Carolinas

Texas Locations

 **Houston, Texas, United States, 77056**
Austin Institute for Clinical Research Inc.

 **Pflugerville, Texas, United States, 78660**
Austin Institute for Clinical Research Inc.

Utah Locations

 **West Jordan, Utah, United States, 84088**
Jordan Valley Dermatology

Virginia Locations

 **Norfolk, Virginia, United States, 23502**
Virginia Clinical Research, Inc.

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Willingness and ability to sign the informed consent form and Health Insurance Portability and Accountability Act (HIPAA) form. A study-specific informed consent form and a HIPAA form must be obtained in writing for all subjects prior to starting any study procedures.
- Men or women ≥ 18 years of age.
- Presence of ≥ 1 naïve sBCC lesion in the treatment areas face/forehead, bald scalp, extremities and/or neck/trunk, all of which are, according to the clinical judgement of the investigator, likely to be histologically confirmed as sBCCs. Lesions should not be within the embryonic fusion planes (H-zone), especially within 2 cm of the hair zone or on the ears. In case of multiple lesions, one lesion is defined as Main Target Lesion which will be excised at the end of the clinical observation period. Only eligible naïve sBCCs, confirmed by histology taken at screening, are allowed to be included in the study as Main or Additional Target Lesions. Thus, eligible sBCCs must lack any histological evidence of aggressive growth patterns (e.g. severe squamous metaplasia, infiltrative/desmoplastic features or basosquamous features). BCCs assessed as non-naïve (e.g. previously treated or recurrent) or non-eligible by biopsy taken at screening (and in a distance >5 cm from the next lesion included in the study) should be excised by surgery or removed by cryotherapy in a timely manner. Other treatments for these lesions are not allowed during the study.
- The diameter of each eligible lesion should be ≥ 0.6 cm, and the entire treatment field must not exceed ~ 20 cm². The treatment field is defined as the field to which IMP is applied, usually including the target lesions and margins surrounding the lesions of up to 1 cm. For the Main Target Lesion, the maximal lesion size should be such that surgical excision without a skin transplant is feasible according to the investigator's judgement.
- Target BCC lesions must be discrete and located within 1-2 illumination areas (the illumination area is defined by the effective illumination area of the BF-RhodoLED® device with approximately 6 x 16 cm).
- Willingness to receive up to 4 PDTs within 3.5 months and excision of the Main Target Lesion either at Visit 5, if clinically cleared, or at the end of the clinical observation period 12 weeks after the start of the last PDT cycle (Visit 8), irrespective of whether the treated Main Target Lesion was clinically cleared or not.
- Free of significant physical abnormalities (e.g. tattoos, dermatoses) within the potential treatment field plus a 5 cm radius surrounding the target lesion(s) as they may interfere with examination or final evaluation.
- Willingness to stop the use of moisturizers and any other cosmetics within the treatment field plus a 5 cm radius surrounding the target lesion(s) 48 hours prior to an office visit and 48 hours after each PDT session. Sunscreen will be allowed, but should not be applied to the treatment field plus the 5 cm radius surrounding the target lesion(s) within approximately 24 h prior to a clinical visit.

- Acceptance to abstain from extensive sunbathing and the use of a solarium during the clinical observation period. Subjects with sunburn within treatment areas cannot be included until fully recovered.
- Healthy subjects and subjects with clinically stable medical conditions, including, but not limited to controlled hypertension, diabetes mellitus type II, hypercholesterolemia, and osteoarthritis, will be permitted to be included in the study if their medication is not prohibited by this protocol.
- Women of childbearing potential are permitted to participate in this study only if they have a negative serum pregnancy test at screening and are willing to use a highly effective method of contraception during the clinical observation period of the study.

Exclusion Criteria:

- History of hypersensitivity to 5-ALA or any ingredient of BF-200 ALA which includes soybean phosphatidylcholine.
- Hypersensitivity to porphyrins.
- Current treatment with immunosuppression therapy.
- Presence of photodermatoses.
- Presence of porphyria.
- Presence of clinically significant inherited or acquired coagulation defect.
- Evidence of clinically significant (CS) unstable medical conditions, such as:
 - Metastatic tumor or tumor with high probability of metastasis.
 - Cardiovascular disease class III, IV (New York Heart Association [NYHA]).
 - Immunosuppressive condition.
 - Hematologic, hepatic, renal, neurologic, or endocrine condition.
 - Collagen-vascular condition.
 - Gastrointestinal condition.
- Clinically relevant cardiovascular, hepatic, renal, neurologic, endocrine, or other major systemic diseases that complicate implementation of the protocol or interpretation of the study results.
- Gorlin Syndrome or Xeroderma pigmentosum.
- Presence and/or physical treatment of skin tumors other than (naïve) sBCC (e.g. malignant melanoma, squamous cell carcinoma (SCC), Bowen's disease, aggressive BCC or nBCC diagnosed at the screening visit by clinical assessment) within a distance of ≤ 5 cm from the nearest target lesion within 4 weeks prior to PDT (Visit 2) until the end of the clinical observation period. However, biopsied lesion(s) that were not confirmed eligible at screening and which are located at a distance of > 5 cm from any lesion(s) that will be included in the study can be surgically removed. Treatment by PDT or topical medication during the course of the clinical observation period of the study triggers exclusion of the subject.
- If lesion(s) are assessed as non-eligible by biopsy during initial screening and these lesions are localized within a distance of 5 cm from an otherwise suitable lesion, this suitable

lesion must be excluded from the study.

- Any AK lesions within the treatment field (lesion area including margin of 0.5 to 1.0 cm).
- Any topical medical treatment of AK, other non-melanoma skin cancers (NMSC), or melanoma (except for IMP treatment of the target lesion(s)) starting 12 weeks prior to Visit 2 (PDT-1) and lasting until the end of the clinical observation period.
- Any other topical medical treatment of the skin 12 weeks prior to Visit 2 (PDT-1) until the end of the clinical observation period, with the exception of:
 - Topical treatments with corticosteroids (allowed throughout the clinical observation period of the study).
 - Topical non-steroidal anti-inflammatory drugs (NSAIDs such as diclofenac) (allowed throughout the clinical observation period of the study with the restriction of 7 days prior to and 7 days after PDTs).
- Start of intake of medication with hypericin or systemically acting drugs with phototoxic or photoallergic potential within 8 weeks prior to screening.
- Any of the systemic treatments listed below, within the designated period prior to PDT and during the clinical observation period.
 - Interferon - 6 weeks
 - Immunomodulators or immunosuppressive therapies - 12 weeks
 - Cytotoxic drugs - 6 months
 - Investigational drugs - 8 weeks
 - Drugs known to have major organ toxicity - 8 weeks
 - Corticosteroids (oral or injectable) - 6 weeks
 - MAL or ALA - 12 weeks
- Systemic treatment with NSAIDs is not to be used 7 days prior to and 7 days after PDT. ASA (e.g. Aspirin®) up to 100 mg/ day, ibuprofen up to 200 mg/ day, and acetaminophen (e.g. Tylenol®) is allowed during this period.
- Presence of tattoos, skin inflammation, wounds, etc. in the treatment field(s) plus a 5 cm radius surrounding the target lesion(s).

Ages Eligible for Study ⓘ

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

- Primary Purpose** ⓘ : Treatment
- Allocation** ⓘ : Randomized
- Interventional Model** ⓘ : Parallel Assignment
- Masking** ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm 	Intervention/Treatment 
Experimental: BF-200 ALA Topical application of BF-200 ALA containing 7.8% 5-ALA (5-aminolevulinic acid). Photodynamic therapy (PDT)	Combination Product: Photodynamic therapy (PDT) (ALA-PDT, Ameluz®-PDT) - The Main Target Lesion will be marked by at least 3 ink marks prior to PDT to enable precise excision for histopathological assessment 12 weeks after the first or second PDT cycle dependent on the clearance status of the lesion. All target lesions should be prepared prior to drug application by degreasing, removal of all scabs and crusts, and roughening of the surface, if appropriate. Bleeding should be avoided. The formulations will then be applied to the lesions (maximal combined lesion area incl. margin is 20 cm²) located in 1 to 2 illumination areas. The medication should be applied to the entire lesion(s) plus a 0.5 - 1.0 cm margin surrounding each lesion at a thickness of 1 mm, allowed to dry (for approximately 10 minutes), covered with occlusive dressing, and incubated for approximately 3 h. Thereafter, any remnants of the IMP will be removed carefully and the PDT illumination will be administered using the light emitting diode (LED) red light device BF-RhodoLED®. - Other Names: - ALA-PDT, Ameluz®-PDT
Placebo Comparator: Vehicle	Combination Product: Placebo Photodynamic therapy (PDT) (vehicle to BF-200 ALA containing no

Topical application of vehicle to BF-200 ALA containing no active ingredient. Photodynamic therapy (PDT)	active ingredient) The Main Target Lesion will be marked by at least 3 ink marks prior to PDT to enable precise excision for histopathological assessment 12 weeks after the first or second PDT cycle dependent on the clearance status of the lesion. All target lesions should be prepared prior to drug application by degreasing, removal of all scabs and crusts, and roughening of the surface, if appropriate. Bleeding should be avoided. The formulations will then be applied to the lesions (maximal combined lesion area incl. margin is 20 cm²) located in 1 to 2 illumination areas. The medication should be applied to the entire lesion(s) plus a 0.5 - 1.0 cm margin surrounding each lesion at a thickness of 1 mm, allowed to dry (for approximately 10 minutes), covered with occlusive dressing, and incubated for approximately 3 h. Thereafter, any remnants of the IMP will be removed carefully and the PDT illumination will be administered using the light emitting diode (LED) red light device BF-RhodoLED®.
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What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Composite Clinical and Histological	Each subject had one Main Target Lesion. The composite clinical and histological response rate of the subjects' Main Target Lesions is the	12 weeks after

Response of the Subject's Main Target Lesion as Assessed 12 Weeks After the Start of the Last PDT Cycle That Included Treatment of the Main Target Lesion.	percentage of subjects with a clinically and histologically cleared Main Target lesion 12 weeks after the start of the last PDT cycle that included treatment of the Main Target Lesion (Visit 5 or Visit 8).	the start of the last PDT cycle that included treatment of the Main Target Lesion
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Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Main Target Lesion Clinical Response Rate (According to Clinical Assessment Only) Assessed 12 Weeks After the Start of the Last PDT Cycle	1. Key secondary endpoint: Percentage of Main Target Lesions with complete clinical clearance (i.e. according to clinical assessment only) 12 weeks after the start of the last PDT cycle.	12 weeks after the start of the last PDT cycle
Main Target Lesion Histological Response Rate (According to Histological Assessment	2. Key secondary endpoint: Percentage of Main Target Lesions with complete histological clearance (i.e. according to histological assessment only) 12 weeks after the start of the last PDT cycle.	12 weeks after the start of the last

Only) Assessed 12 Weeks After the Start of the Last PDT Cycle		PDT cycle
Subject Complete Clinical Response (Complete Clearance of All Target Lesions According to Clinical Assessment Only) Assessed 12 Weeks After the Start of the Last PDT Cycle.	3. Key secondary endpoint: Percentage of subjects with complete clinical clearance of all Target Lesions (i.e. according to clinical assessment only) 12 weeks after the start of the last PDT cycle.	12 weeks after the start of the last PDT cycle
Subject Complete Response (Clinically and Histologically Cleared Main Target Lesion (See Above) and Complete Clinical Remission of All Additional Target Lesions) Assessed 12 Weeks After the Start of the Last PDT Cycle.	4. Key secondary endpoint: Percentage of subjects with complete clinical and histological clearance of the Main Target Lesion and complete clinical clearance of all Additional Target Lesions 12 weeks after the start of the last PDT cycle	12 weeks after the start of the last PDT cycle

Lesion Complete Clinical Response Rate Per Treatment Arm (Complete Clearance of Individual Lesions (Main and Additional Target Lesions)) According to Clinical Assessment Only, Assessed 12 Weeks After the Start of the Last PDT Cycle.	Further secondary endpoint: Percentage of Individual Target Lesions that are completely clinically cleared per treatment arm 12 weeks after the start of the last PDT cycle.	12 weeks after the start of the last PDT cycle
Main Target Lesion Complete Response (Clinically and Histologically Cleared) Assessed 12 Weeks After PDT-1.	Further secondary endpoint: Percentage of Main Target Lesions that are clinically and histologically cleared 12 weeks after PDT-1.	12 weeks after PDT-1
Main Target Lesion Clinical Response (According to Clinical Assessment	Further secondary endpoint: Percentage of Main Target Lesions that are clinically cleared 12 weeks after PDT-1.	12 weeks after PDT-1

Only) Assessed
12 Weeks After
PDT-1.

Main Target
Lesion
Histological
Response
(According to
Histological
Assessment
Only) Assessed
12 Weeks After
PDT-1.

Lesion
Complete
Clinical
Response Rate
Per Treatment
Arm (Complete
Clearance of
Individual
Lesions (Main
and Additional
Target
Lesions))
According to
Clinical
Assessment
Only, Assessed
12 Weeks After
PDT-1.

Subject
Complete
Clinical

Further secondary endpoint: Percentage of
Main Target Lesions that are histologically
cleared 12 weeks after PDT-1.

Further secondary endpoint: Percentage of
Individual Target Lesions that are completely
clinically cleared per treatment arm 12 weeks
after PDT-1

Further secondary endpoint: Percentage of
subjects with complete clinical clearance 12
weeks after PDT-1.

12
weeks
after
PDT-1

12
weeks
after
PDT-1

12
weeks

Response (Complete Clearance of All Target Lesions According to Clinical Assessment Only) Assessed 12 Weeks After PDT-1.		after PDT-1
Subject Complete Response (Clinically and Histologically Cleared Main Target Lesion (See Above) and Complete Clinical Remission of All Additional Target Lesions) Assessed 12 Weeks After PDT-1..	Further secondary endpoint: Percentage of subjects with complete clinical and histological clearance of the Main Target Lesion and complete clinical clearance of Additional Target Lesions 12 weeks after PDT-1.	12 weeks after PDT-1
For All Target Lesions, Assessment of Esthetic Appearance by the Investigator 12 Weeks After the Start of the Last PDT Cycle, But Prior to	Further secondary endpoint: Investigators assessment of the esthetic appearance of all Target lesions but prior to surgical excision of the Main Target Lesion or alternative Treatment of Additional Target Lesions	12 weeks after the start of the last PDT cycle

Surgical Excision of the Main Target Lesion and Any Alternative Treatment of Additional Target Lesions.		
Subjects' Satisfaction Regarding Esthetic Outcome and Treatment 12 Weeks After the Start of the Last PDT Cycle, But Prior to Surgical Excision of the Main Target Lesion or Alternative Treatment of Additional Target Lesions	Further secondary endpoint: Subject's assessment regarding the esthetic outcome and the Treatment 12 weeeeks after the start of the last PDT cycle but prior to surgical excision of the Main Target Lesion or alternative Treatment of Additional Target Lesions	12 weeks after the start of the last PDT cycle

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Biofrontera Inc.

Investigators ⓘ

- Principal Investigator: David M. Pariser, MD, Virginia Clinical Research, Inc.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2018-06-19

First Submitted that Met QC Criteria ⓘ

2018-06-28

First Posted ⓘ

2018-06-29

Results Reporting Dates

Results First Submitted ⓘ

2025-03-13

Results First Posted with QC Comments ⓘ

2025-04-04

Results First Submitted that Met QC Criteria ⓘ

2025-04-24

Results First Posted ⓘ

2025-04-29

Study Record Updates

Last Update Submitted that Met QC Criteria ⓘ

2025-12-19

Last Update Posted ⓘ

2026-01-14

Last Verified ⓘ

2025-12

More Information

Terms related to this study

Keywords Provided by Biofrontera Inc.

ALA-PDT

Additional Relevant MeSH Terms

- Combined Modality Therapy
- Therapeutics
- Drug Therapy
- Phototherapy
- Photochemotherapy
- 1-phenyl-3,3-dimethyltriazene

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

Yes

Study Documents ⓘ Provided by Biofrontera Inc.

- [Study Protocol](https://cdn.clinicaltrials.gov/large-docs/01/NCT03573401/Prot_000.pdf) (https://cdn.clinicaltrials.gov/large-docs/01/NCT03573401/Prot_000.pdf) [PDF, 2.02MB, 2018-07-17]
- [Statistical Analysis Plan](https://cdn.clinicaltrials.gov/large-docs/01/NCT03573401/SAP_001.pdf) (https://cdn.clinicaltrials.gov/large-docs/01/NCT03573401/SAP_001.pdf) [PDF, 4.11MB, 2024-07-29]