Red Light Photodynamic Therapy with 10% Aminolevulinic Acid Gel Showed Robust Efficacy for the Treatment of Superficial BCC in a Randomized, Vehicle-Controlled, Double-Blind, Multicenter Phase III Study

Todd Schlesinger, MD, FAAD [1]; M. Shane Chapman, MD, MBA [2]; John H. Tu, MD, MS [3]; Joel L. Cohen, MD [4]; John Strasswimmer, MD, PhD, FAAD, FACMS [5]; Nathalie C. Zeitouni, MD [6]; Abel Torres, MD, JD, MBA [7]; S. Sasha Jazayeri, MD [8]; Mitchel P. Goldman, MD [9]; Sherrif F. Ibrahim, MD, PhD [10]; Edward L. Lain, MD, MBA [11]; Megan P. Couvillion, MD, MS [12]; Suzanne Bruce, MD [12]; Vivian T. Laquer, MD [13]; C. William Hanke, MD, MPH, FACP [14]; David M. Ozog, MD [15]; Jane Schneider, MD [16]; Orit Markowitz, MD, FAAD [16]; Brian Berman, MD, PhD [17]; Mark S. Nestor, MD, PhD [17]; Michael H. Gold, MD [18]; Girish S. Munavalli, MD, MHS, FAAD, FACMS [19]; Douglass W. Forsha, MD [20]; Daniel M. Siegel, MD [21]; David Mrohs, PhD [22]; Beate Schmitz, PhD [22]; Ruth Schäning, MSc [22]; Nicole Pospiech, PhD [23]; Jon Lyons, PhD, MBA [24]; Montserrat Foguet, PhD [23]; Matthias Lübbert, PhD [22]; Hermann Lübbert, PhD [22,24]; David M. Pariser, MD, FAAD, FACP [25]

[1] Clinical Research Center of the Carolinas, 1364 Ashley River Road, Charleston, SC 29407. [2] Dartmouth-Hitchcock Medical Center - Dept. Of Dermatology, One Medical Center Drive, Lebanon, NH 03756. [3] Skin Search of Rochester, 100 White Spruce Blvd, Rochester, NY 14623 [4] AboutSkin Dermatology & Derm Surgery, 5340 S. Quebec St. Suite 300, Greenwood Village, CO 8011. [5] Dermatology Associates PA of the Palm Beaches - Delray Location, 2600 W. Atlantic Ave, Suite D204, Delray Beach, FL 33445. [6] Medical Dermatology Specialists, 1331 N. 7th St. #250, Phoenix, AZ 85006. [7] University of Florida, UF Department of Dermatology. 4037 NW 86th Terrace, Room 4115, Gainesville, FL 32606. [8] Alliance Dermatology & Mohs Center, 4045 E. Bell Road, Suite #125, Phoenix, AZ 85032. [9] Cosmetic Laser and Dermatology: A Platinum Dermatology Company, 9339 Genesee Ave, Suite 300, San Diego, CA 92121. [10] Rochester Dermatologic Surgery, 7400 Pittsford Victor Rd, Victor, NY 14564. [11] Austin Institute for Clinical Research, Inc, 1601 E. Pflugerville Parkway Suite 1101, Pflugerville, TX 78660. [12] Austin Institute for Clinical Research, Inc, 1900 St. James Place, Suite 650, Houston, TX 77056. [13] First OC Dermatology Research, 17271 Brookhurst Street, Fountain Valley, CA 92708. [14] Laser & Skin Surgery Center of Indiana (The Lasa), 8925 N. Meridian St. #200, Indianapolis, IN 46260. [15] Henry Ford Health, Department of Dermatology, 3031 W Grand Blvd Suite 800 Detroit, MI 48202 and Michigan State University, Department of Medicine, East Lansing, MI 48823. [16] The Narrows Institute for Biomedical Research and Education, Inc., 800 Poly Place, Room 2-204, Brooklyn, NY 11209. [17] Center for Clinical and Cosmetic Research, 2925 Aventura Boulevard #205, Aventura, FL 33180. [18] Tennessee Clinical Research Center, 2000 Richard Jones Rd, #223, Nashville, TN 37215. [19] Dermatology , Laser & Vein Specialists of the Carolinas, 1918 Randolph Road, #550, Charlotte, NC 28207. [20] Jordan Valley Dermatology Center, 3570 W. 9000 S. Suite 200, West Jordan, UT 84088. [21] Veterans Affairs New York Harbor Healthcare System-Brooklyn, 800 Poly Place, Brooklyn, NY 11209. [22] Biofrontera Discovery GmbH, Hemmelrather Weg 201, 51377 Leverkusen, Germany. [23] Biofrontera Bioscience GmbH, Hemmelrather Weg 201, 51377 Leverkusen, Germany. [24] Biofrontera Inc., 120 Presidential Way, Suite 330, Woburn, MA 01801. [25] Eastern Virginia Medical School and Virginia Clinical Research, Inc., 6160 Kempsville Circle #200A, Norfolk, VA 23502

OBJECTIVE

We compared and evaluated the efficacy and safety of red light PDT with 10% 5-aminolevulinic acid (ALA) gel vs. vehicle in participants with sBCC.

CONCLUSION

PDT with 10% ALA gel demonstrated significantly higher clearance rates versus vehicle, with favorable safety and aesthetic outcomes.

These results support red light PDT with 10% ALA gel as a highly suitable non-surgical option for sBCC, particularly for multiple or large lesions, in low-risk areas, when patients either decline surgery or are not a good candidate for surgery.

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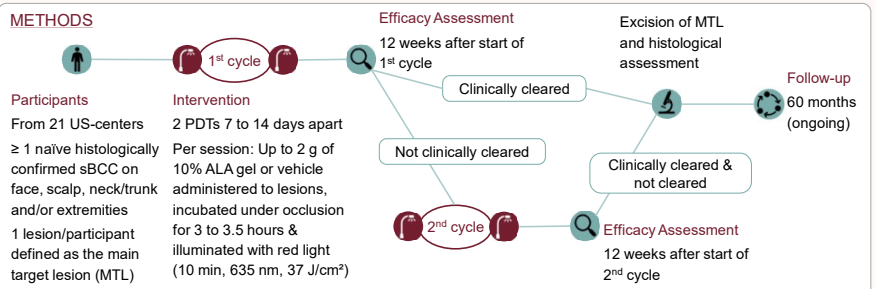
This study was sponsored by Biofrontera Bioscience GmbH.

BACKGROUND

Basal cell carcinoma (BCC) is often treated surgically; however, depending on lesion size, location, or patient preference, surgery may not be the best option. Photodynamic therapy (PDT) has emerged as one alternative treatment for low-risk tumors like superficial BCC (sBCC).

METHODS



Participants

From 21 US-centers

≥ 1 naïve histologically confirmed sBCC on face, scalp, neck/trunk and/or extremities

1 lesion/participant defined as the main target lesion (MTL)

Intervention

2 PDTs 7 to 14 days apart

Per session: Up to 2 g of 10% ALA gel or vehicle administered to lesions, incubated under occlusion for 3 to 3.5 hours & illuminated with red light (10 min, 635 nm, 37 J/cm²)

RESULTS

- 187 randomized participants, 145 received 10% ALA gel and 42 vehicle
- Mean age 63.2 years
- 58.3% of participants were male
- 95.2% of participants had skin type I-III
- Most participants had their MTL on neck/trunk (52.4%) or extremities (45.5%)
- Only 2.1% of MTLs were located on face/scalp
- 83.4% of participants had one lesion, 13.9% of participants had two lesions, 2.7% of participants had three lesions
- Total: 223 BCC lesions

High clinical, histological and composite clearance of MTLs

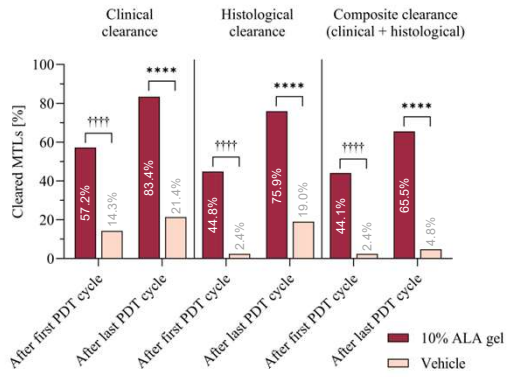


Figure 1. Clearance of MTLs after first and after last PDT cycle

After the first PDT cycle, clinically cleared MTLs were excised and histologically assessed. Clinically non-responding or partially responding MTLs were treated with a second PDT cycle. The bars for the assessment after last PDT cycle show the cumulated clearance of MTLs as assessed after first or second PDT cycle.

†††† Cochran-Mantel-Haenszel test, α = 0.05, two-sided, p<0.0001.
**** Cochran-Mantel-Haenszel test, α = 0.001, one-sided, p<0.0001.

Clearances in the vehicle arm:

- Likely attributable to a combination of lesion preparation, and accumulation and activation of endogenous protoporphyrin IX (PpIX)
- Might have caused a temporary superficial lesion clearance

High participant clearance rates

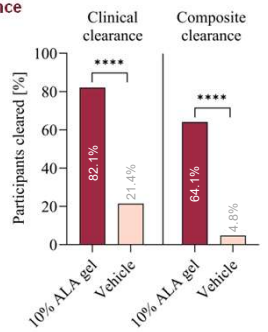


Figure 2. Participant clearance after last PDT cycle

Composite participant clearance: clinical and histological clearance of MTLs and clinical clearance of additional BCCs.
**** Cochran-Mantel-Haenszel test, α = 0.001, one-sided, p<0.0001.

Very good or good aesthetic outcome of most BCC lesions

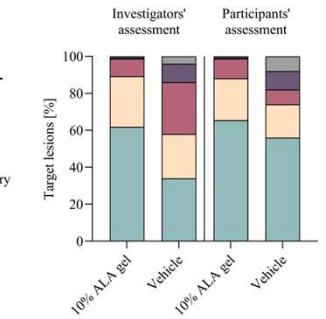


Figure 3. Aesthetic outcome after last PDT cycle prior to excisions

High lesion clearance rates

Clinical lesion clearance rate:

82.6% with 10% ALA gel

21.6% with vehicle

Clearance >80% aligns with previous findings for 10% ALA gel [1]

Note:

The size of non-cleared lesions was reduced after PDT in 23 of 30 lesions in the 10% ALA gel group (median change -41.9%)

→ Potential as adjunctive therapy [2,3]

Unproblematic safety profile

No previously unknown adverse reactions occurred. The most frequent at least possibly related treatment emergent adverse events were application site pain, application site erythema, application site pruritus, application site edema, application site paresthesia and application site scab. All of which were transient.

RERERENCES

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TS is a consultant and investigator for AbbVie, Almirall, Biofrontera Bioscience GmbH, Feldan Therapeutics, Galderma and a consultant for Apogee, Regeneron, SUN Pharma and Verrica Pharmaceuticals. MSC is an investigator for Biofrontera Bioscience GmbH. JHT is an investigator for Biofrontera Bioscience GmbH. JLC has served as a clinical research principal investigator as well as a consultant for Biofrontera Bioscience GmbH. JoS is an investigator for Biofrontera Bioscience GmbH, and serves as an investigator and also as a consultant for Regeneron Pharmaceuticals, Inc. Sun Pharmaceuticals, Inc, and Phio Pharmaceuticals, Inc. NCZ is a consultant and investigator for Biofrontera Bioscience GmbH, an investigator speaker bureau and advisory board member of Regeneron Pharmaceuticals, Inc, an investigator and speaker bureau member of Castle Biosciences, an Investigator and Advisory board member of Sun Pharmaceuticals, Inc, an investigator for Remplimune and Alpha Tau and a consultant for Dermasensor. AT is an investigator for Biofrontera Bioscience GmbH. SSJ declares speakership for Abbvie and Novartis, received grants for clinical research from Abbvie, Alumis, Amgen, Biofrontera Bioscience GmbH, Ventyx Biosciences, Concert Pharmaceuticals, Dermavant, Mindera Health, Bellus, Pfizer, DermTech, BMS, Anaptys, UCB Biopharma, Kiniksa, Eli Lilly, Bausch Health Americas, Novartis, Athenex, Dermira, Boehringer Ingelheim, Regeneron, Sandoz, Leo Pharmaceutical, Genentech, Janssen, Xenoport. MPG is an investigator and consultant to Biofrontera, Allergan, Galderma, Lumenis, Solta, SkinMedica and SkinCeuticals. 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MPC is an investigator for AbbVie, Alumis, AnaptysBio, Arcutis Biotherapeutics, Biofrontera Bioscience GmbH, Cara Therapeutics, Castle Biosciences, Concert Pharmaceuticals, Dr. Reddy's Laboratories, Eirion Therapeutics, Incyte, Janssen Biotech, Nielsen Bioscience Inc., Ortho Dermatologics, Timber Pharmaceuticals, TrialSpark, Inc., VeraDermics Inc., and Verrica Pharmaceuticals, is an investigator and speaker for Eli Lilly and Pfizer Inc., is a speaker for Revance therapeutics Inc., and consultant for Allergan Aesthetics and Dermavant Sciences Inc. SB was an investigator for Biofrontera Bioscience GmbH. VTL is an investigator for Biofrontera Bioscience GmbH. CWH is an investigator for AbbVie, Biofrontera Bioscience GmbH and Castle Biosciences, Inc., and received honoraria as a speaker for Sanofi/Regeneron and Sun Pharmaceutical Industries Ltd. DMO is an investigator for Biofrontera Bioscience GmbH. JaS is an investigator for Biofrontera Bioscience GmbH. OM is an investigator for Regeneron, DAMAE Medical, Candela Medical, Galderma, Bristol Myers Squibb, Janssen, Dermtech, Amgen, Eli Lilly, Celldex, Acelyrin, Alumis, Incyte, Pfizer, RAPT, Sanofi, Evommune, Incyte, Inmagene, Argenx, and Celldex. BB is a consultant and investigator for Sun Pharmaceuticals, Biofrontera, Sensus, Sinsacmics, Aviva, Mincklabs, Medwound, and consultant/advisor for Thirona, Pfizer, BMS and Novartis. MSN is an investigator for Biofrontera Bioscience GmbH and Sun Pharmaceutical Industries LTD and advisory board Sun Pharmaceutical Industries LTD. MHG is an investigator for Biofrontera Bioscience GmbH. GSM is an investigator for Biofrontera Bioscience GmbH. DWF is a speaker for UCB and Pfizer. DMS declares financial relationships with Avita, Bifrontera AG, Caliber Imaging and Diagnostics Inc., Cara Therapeutics, DermaSensor Inc., Elsevier Inc., Feldan Therapeutics, Greenway Therapeutix, Lazarus Enterprises Inc., Logical Images, Medforce Technologies Inc., Modernizing Medicine, MycoMedica Life Sciences, Novascan, Omnilux, Or-Genix Therapeutics, Plasmend, Puse Biosciences, RaMedical, RBC Consultants, Regeneron, Seaspire Skincare, SkinVision, SPC Dermatology, Strata Skin Sciences, Takeda Pharmaceuticals USA Inc., Tetros Group, Verrica Pharmaceuticals Inc. DM, BS, RS, NP, MF, ML and HL were or are employees of Biofrontera Bioscience GmbH and may hold stock options. JL is an employee of Biofrontera, Inc., and may hold stock options. DMP is an investigator for Biofrontera, Novartis and Regeneron and was the chair of a Data Safety Monitoring Board for Bristol-Myers-Squibb.