A-101 40% Topical Solution

Phase 3 Studies

Top-Line Results

ACLARIS THERAPEUTICS

A-101 40% Topical Solution Phase 3 Pivotal SEBK-301 and SEBK-302

Trial Design

- Two identical multi-center, randomized double-blind, placebo-controlled trials conducted in the U.S. which enrolled a total of 937 patients.
- Assessed safety, efficacy, and tolerability of A-101 40% topical solution versus placebo.
- Patients were 18 years and older; and received up to 2 treatments 21 days apart

Primary Endpoint

- Primary efficacy endpoint was the percentage of patients with clearance (PLA=0) of all 4 target lesions at 106 days after first treatment

Secondary and Other Endpoints

- Secondary efficacy endpoint was the percentage of patients with clearance (PLA=0) in at least 3 of the 4 target lesions
- Mean Per-Patient Percentage of Target Lesions Judged to be Clear/Near-Clear (PLA≤1)
- Percentage of All Target Lesions of the Face Judged to be Clear/Near-Clear (PLA≤1)

Safety

- Safety – assessed adverse events, local skin reactions, vitals, and clinically-relevant abnormal lab results

ACLARIS THERAPEUTICS

Patient Baseline Characteristics

Study A-101-SEBK-301

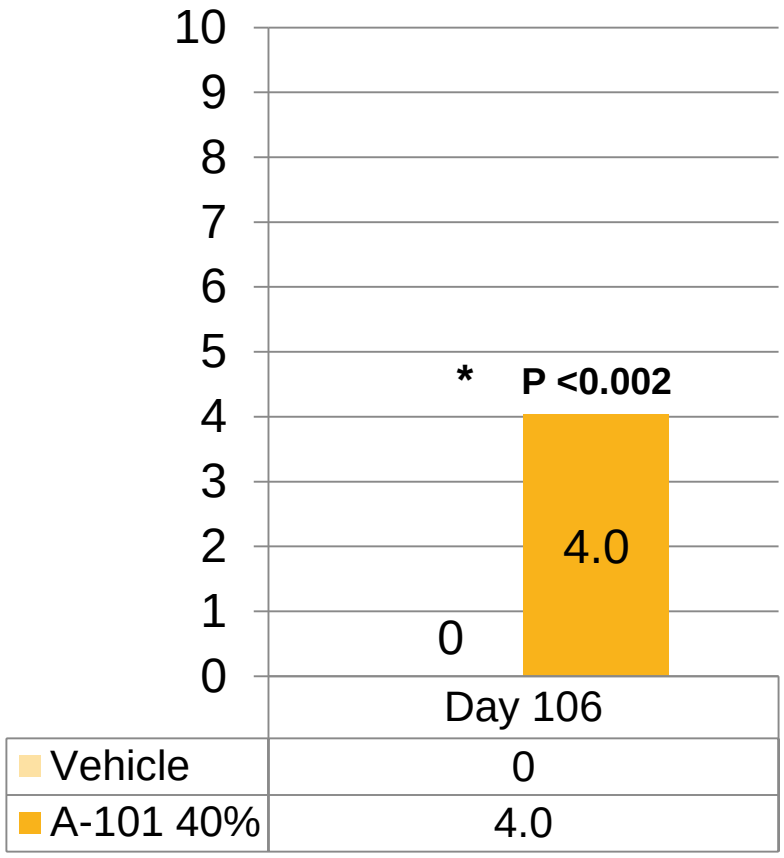
- 450 subjects were randomized to Study 301 with 439 subjects completing the study per protocol.
- The 450 subjects were randomized as:
  - 223 subjects – A-101 40% Topical Solution
  - 227 Subjects – A-101 Vehicle Solution
- The mean age was 68.7 years (range: 42 – 90)
- 58.7% were female and 41.3% male
- 97.8% of the subjects were Caucasian
- Skin types varied within the study population as indicated by the proportion of baseline Fitzpatrick scores:
  - Type 1 – 16.0%
  - Type 2 – 46.9%
  - Type 3 – 27.3%
  - Type 4 – 8.9%
  - Type 5 – 0.9%

Study A-101-SEBK-302

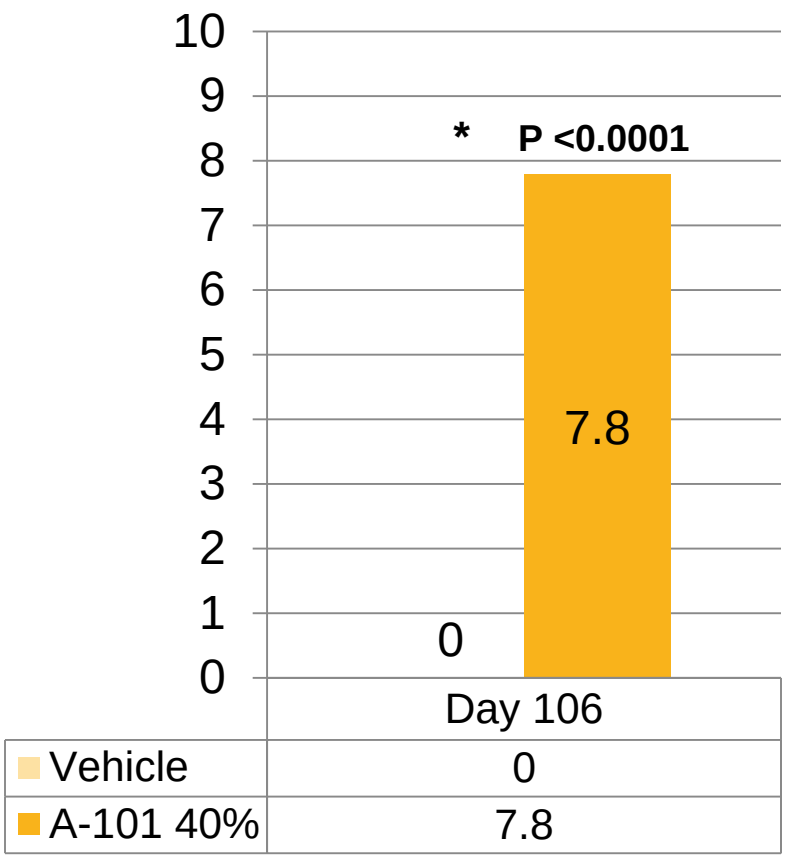
- 487 subjects were randomized to Study 302 with 469 subjects completing the study per protocol.
- The 487 subjects were randomized as:
  - 244 subjects – A-101 40% Topical Solution
  - 243 Subjects – A-101 Vehicle Solution
- The mean age was 68.8 years (range: 45 – 91)
- 58.3% were female and 41.7% male
- 97.9% of the subjects were Caucasian
- Skin types varied within the study population as indicated by the proportion of baseline Fitzpatrick scores:
  - Type 1 – 9.4%
  - Type 2 – 46.6%
  - Type 3 – 33.1%
  - Type 4 – 9.4%
  - Type 5 – 1.2%
  - Type 6 – 0.2%

Primary Endpoint: Responder Analysis - Percentage of Patients Achieving Clearance of All 4 Target SK lesions (PLA=0)

Study A-101-SEBK-301



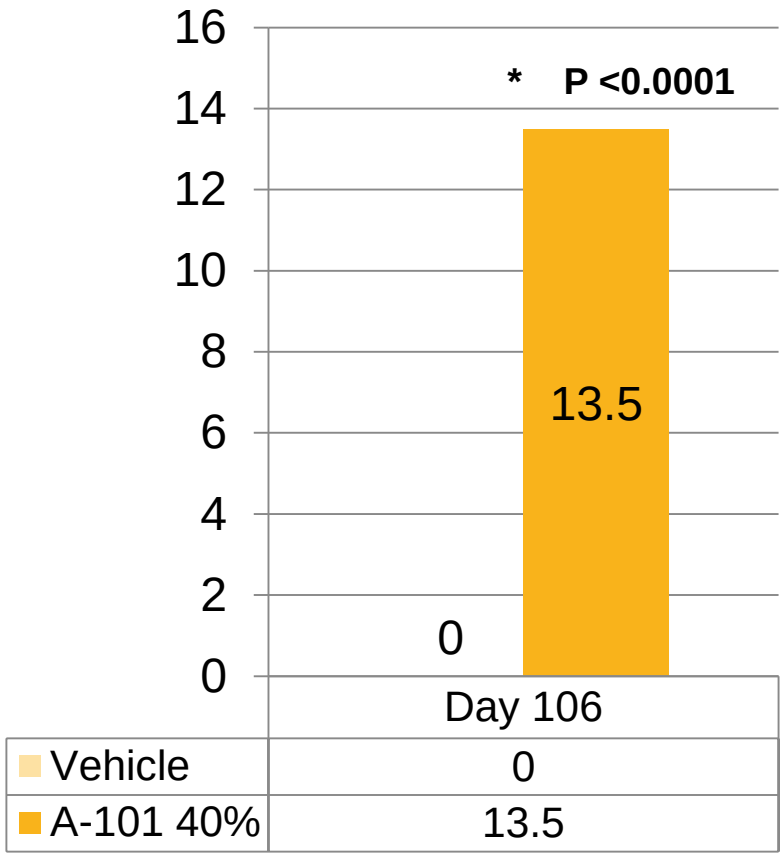
Study A-101-SEBK-302



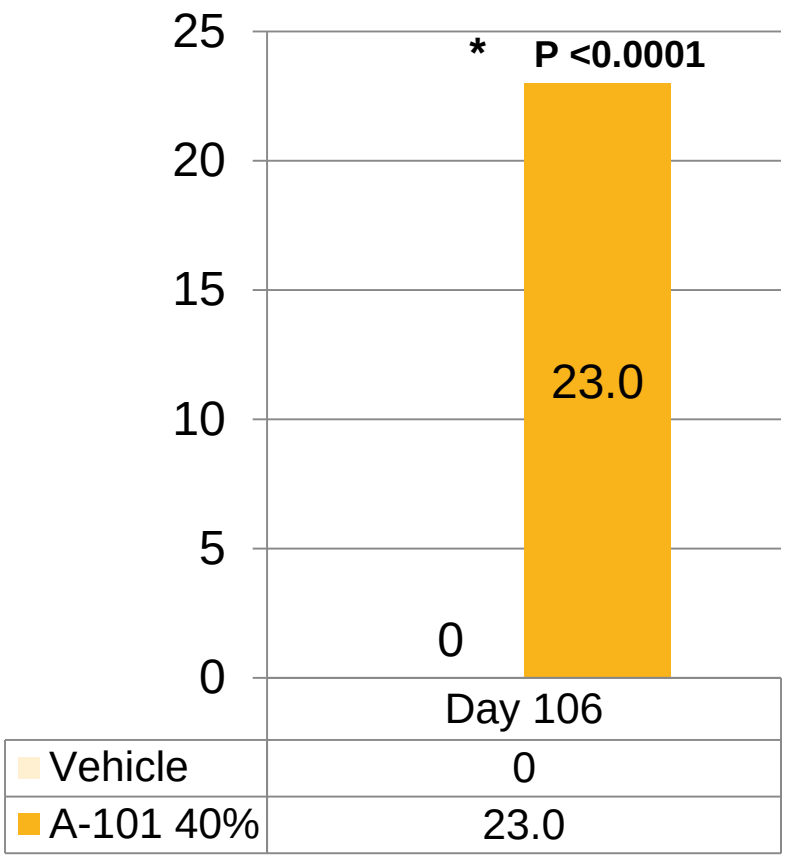
Secondary Endpoint: Responder Analysis - Percentage of Patients Achieving Clearance of at Least 3 of 4 Target SK lesions (PLA=0)

(EUROPEAN PRIMARY REGULATORY ENDPOINT)

Study A-101-SEBK-301

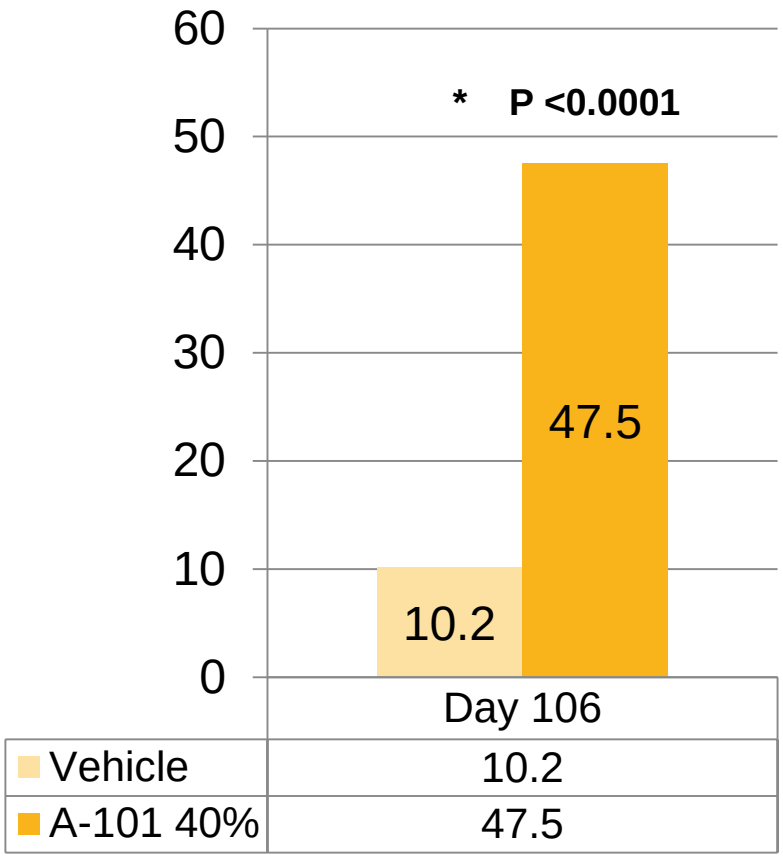


Study A-101-SEBK-302

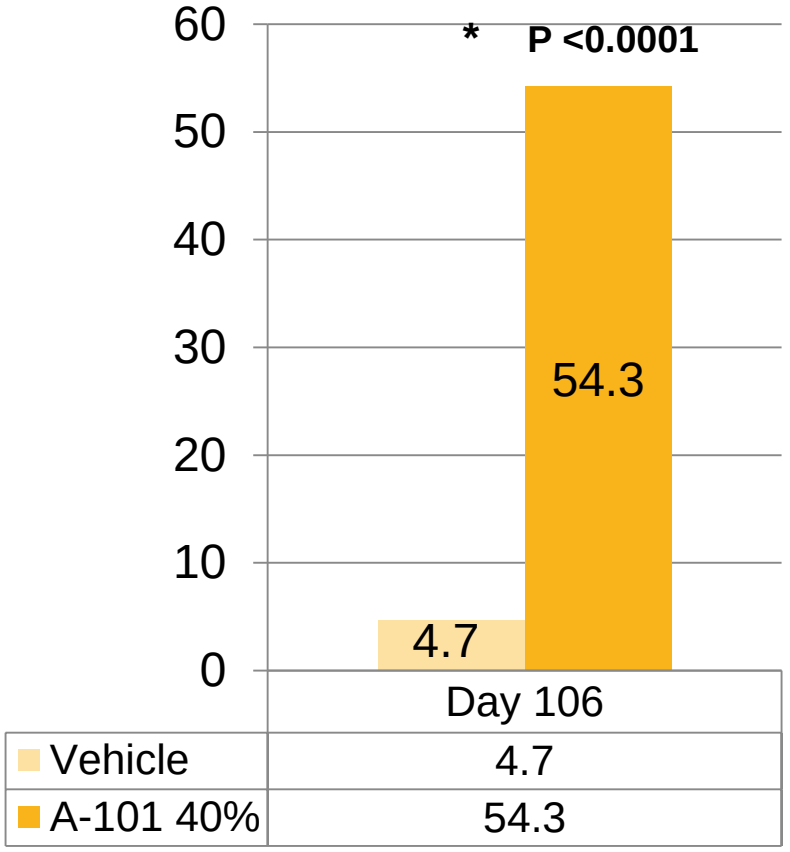


Mean Per-Patient Percentage of Target Lesions Judged to be Clear/Near-Clear (PLA≤1)

Study A-101-SEBK-301

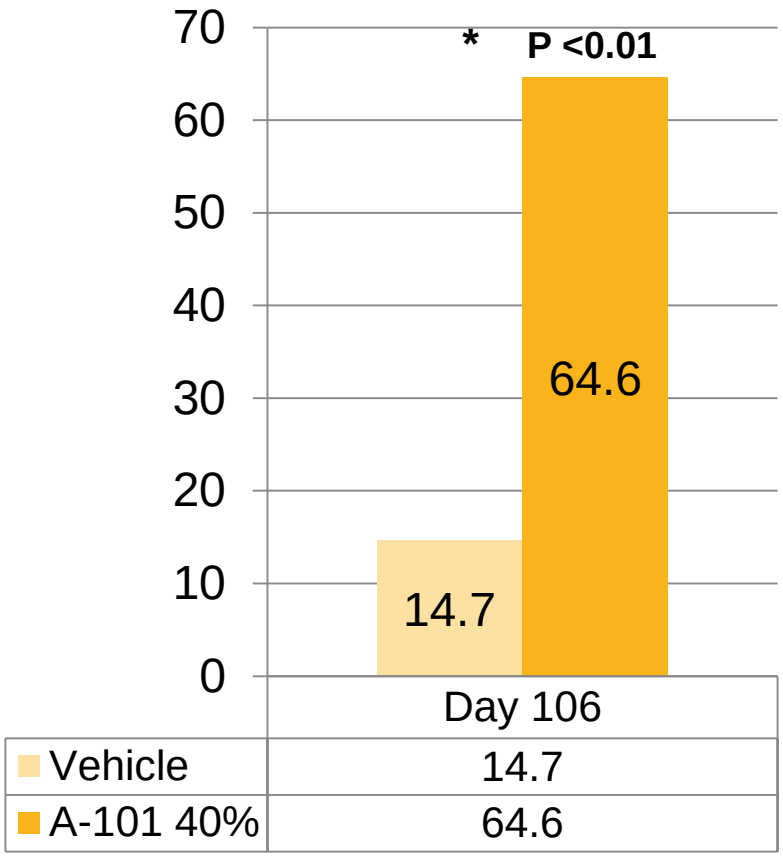


Study A-101-SEBK-302

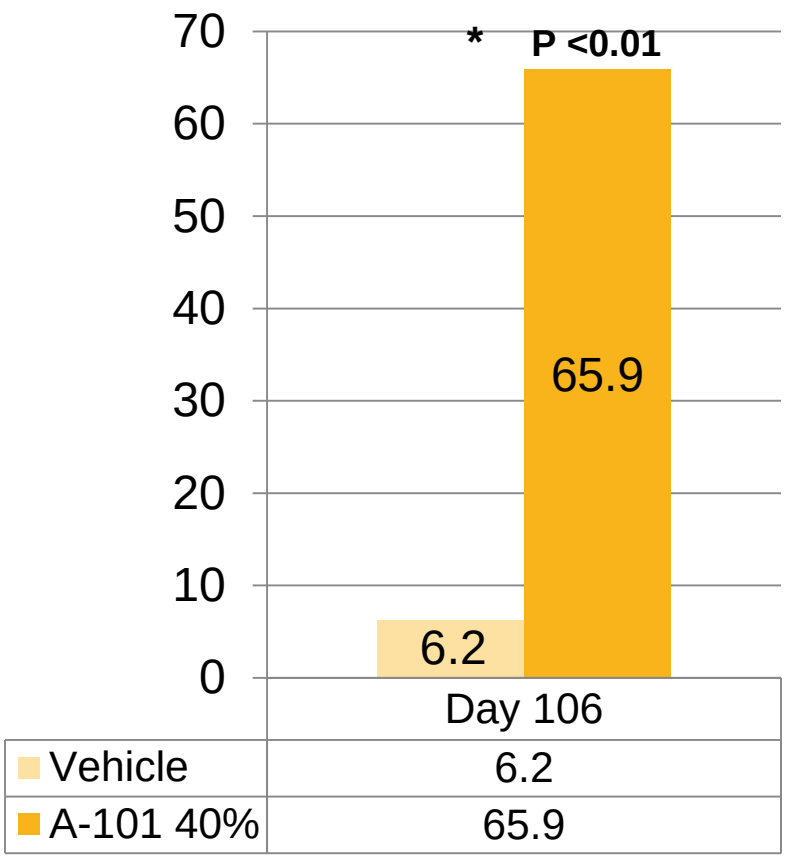


Percentage of All Target Lesions of the Face Judged to be Clear/Near-Clear (PLA≤1)

Study A-101-SEBK-301



Study A-101-SEBK-302

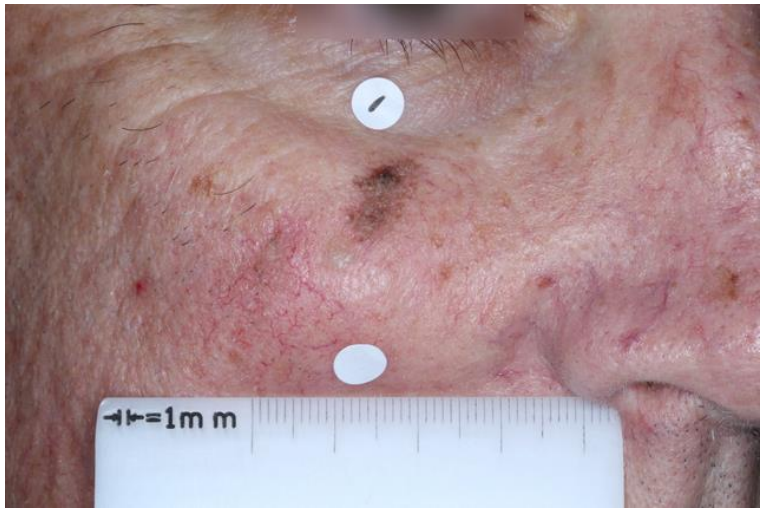


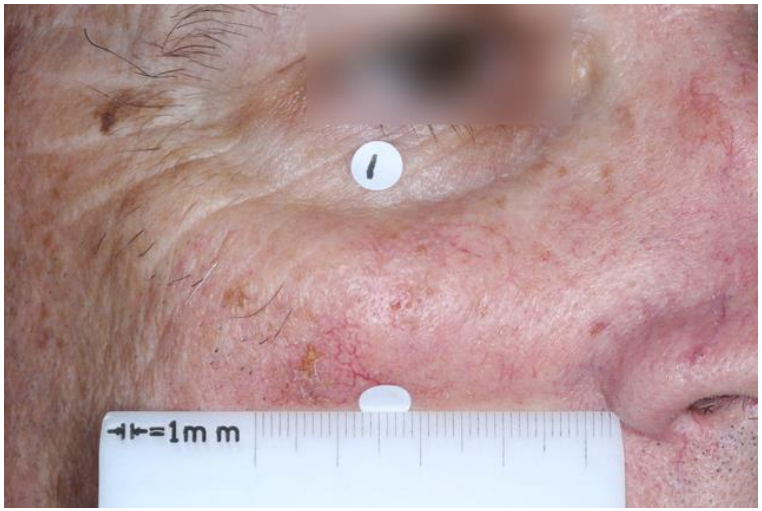
Patient Photos: PLA 3 to PLA 0 (Clear)

Male

Skin Type
3

Location:
Face

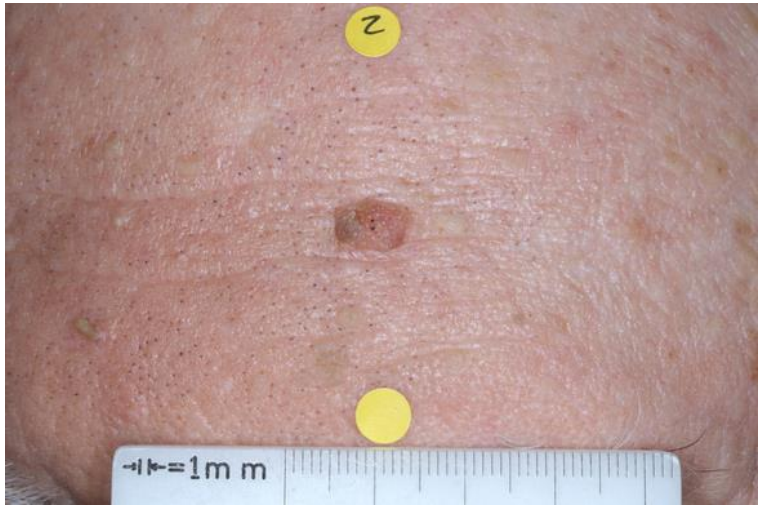


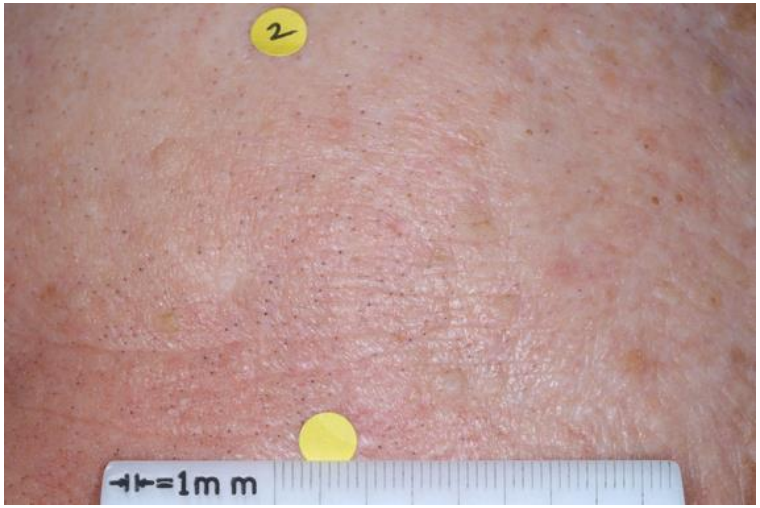


Male

Skin Type
3

Location:
Face





Pre-Treatment with A-101

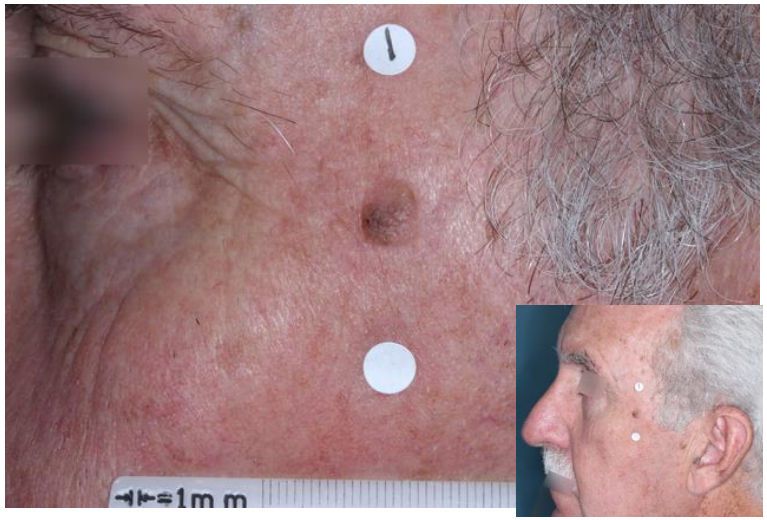
Final Visit f/u

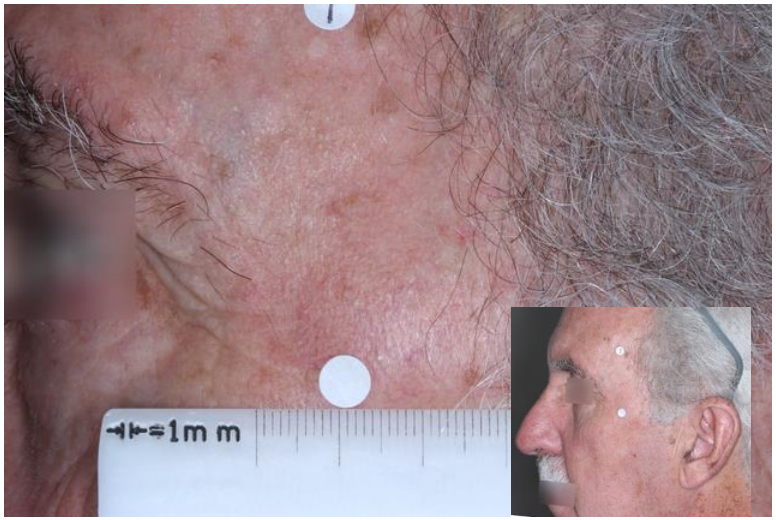
Patient Photos: PLA 3 to PLA 0 (Clear)

Male

Skin Type
2

Location:
Face

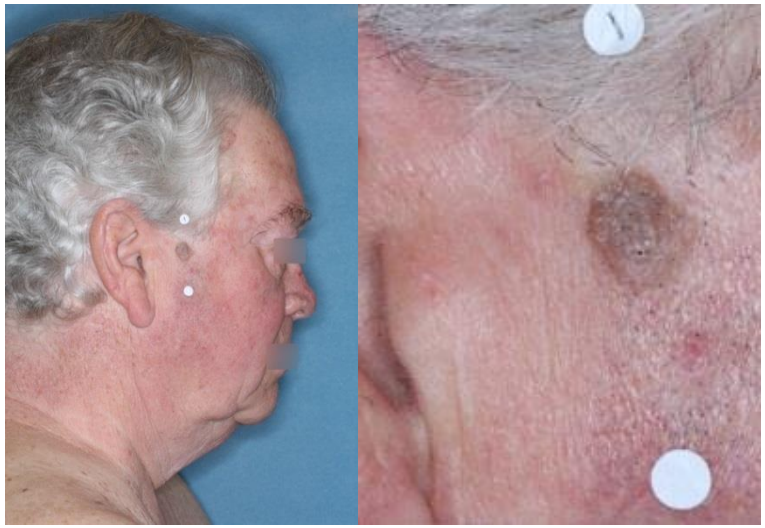


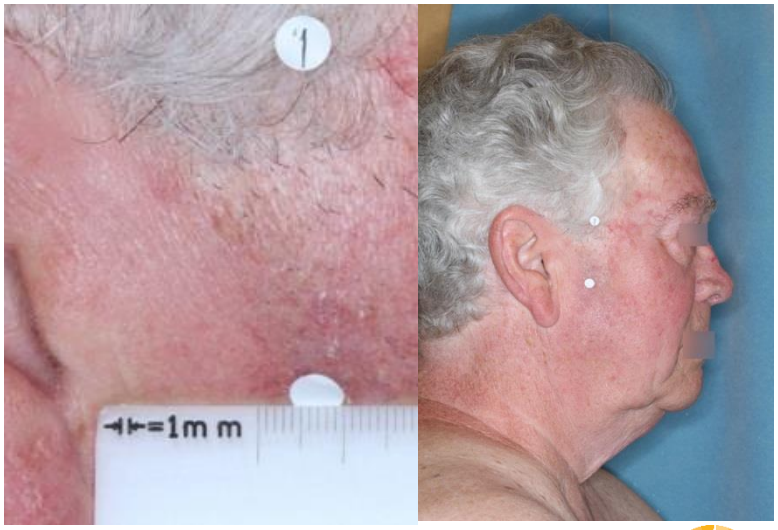


Male

Skin Type
3

Location:
Face





Pre-Treatment with A-101

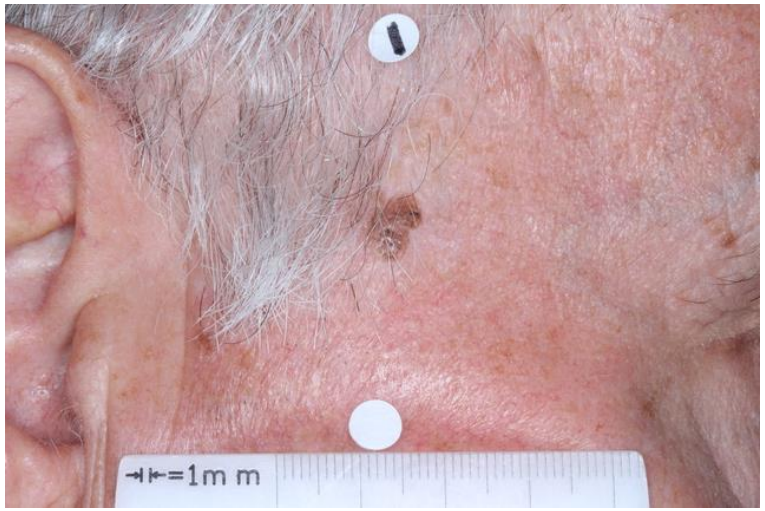
Final Visit f/u

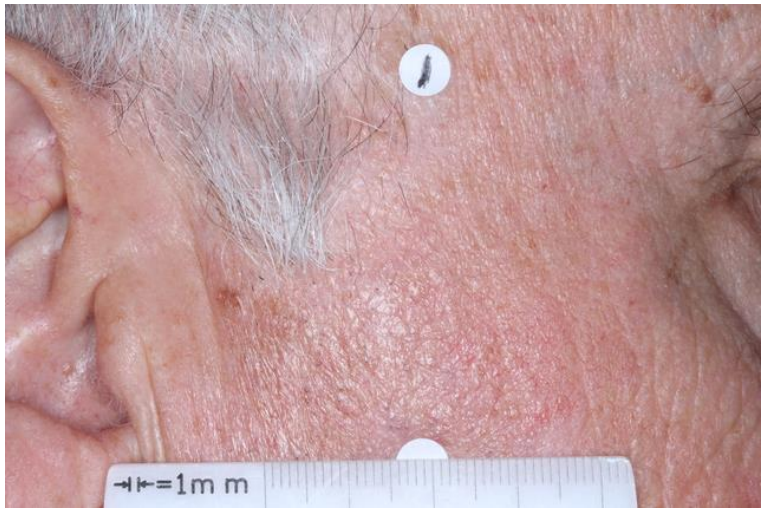
Patient Photos: PLA 2 to PLA 0 (Clear)

Male

Skin Type
3

Location:
Face

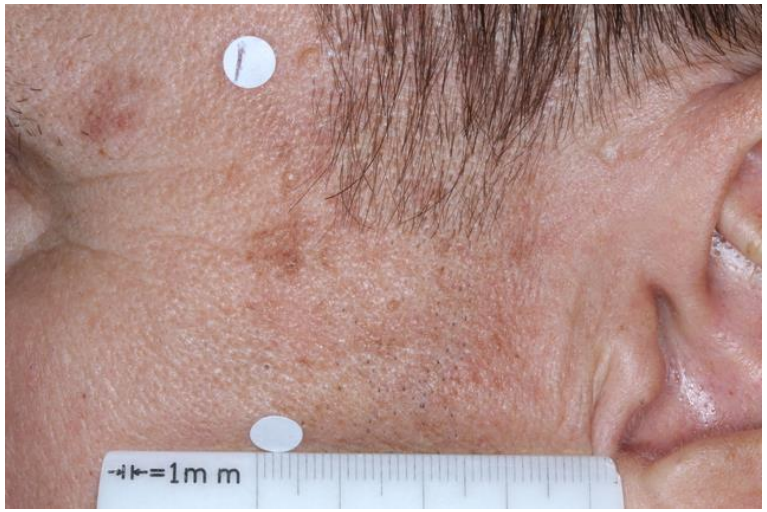


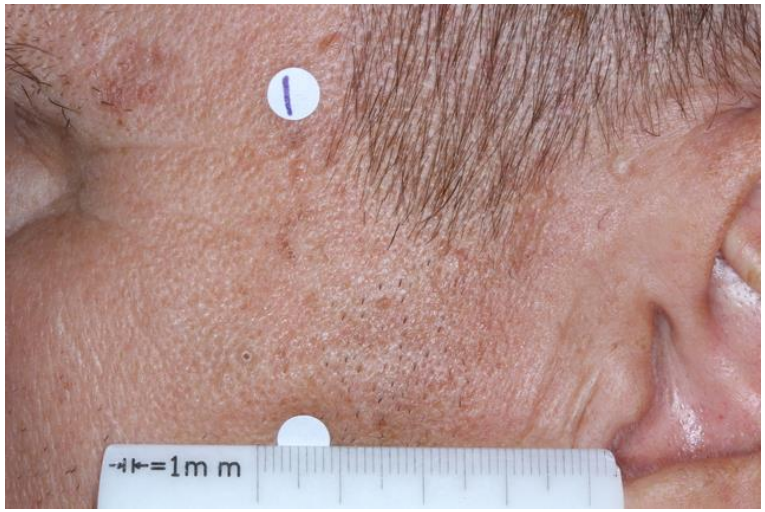


Male

Skin Type
4

Location:
Face





Pre-Treatment with A-101

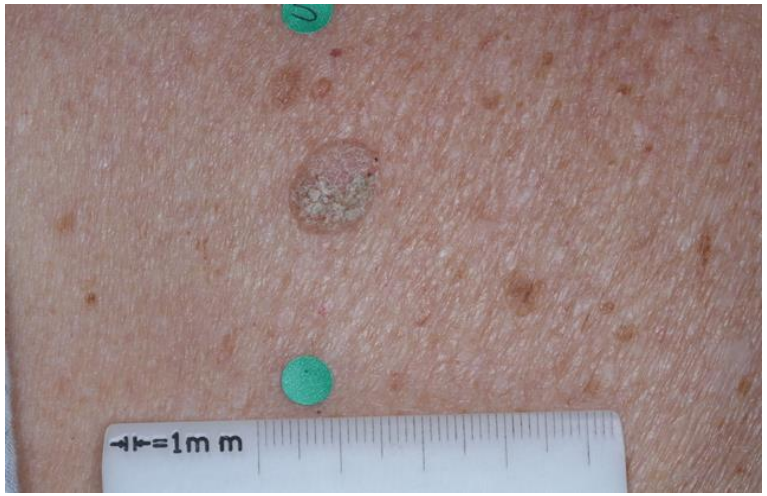
Final Visit f/u

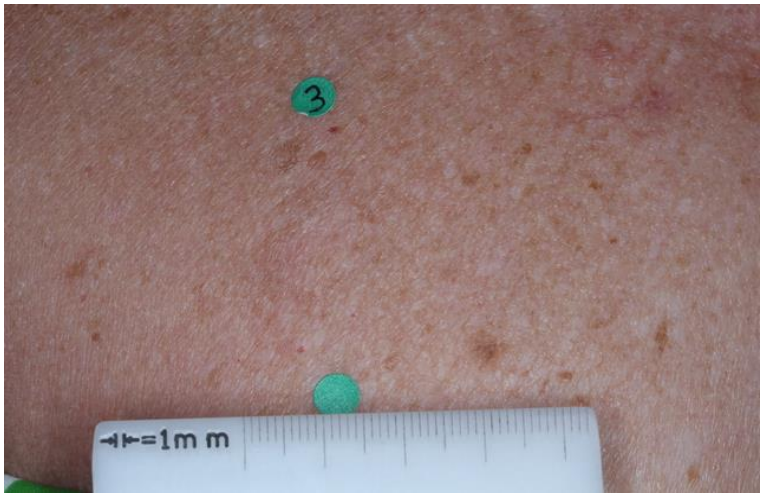
Patient Photos: PLA 1 (Near Clear)

Female

Skin Type
2

Location:
Back



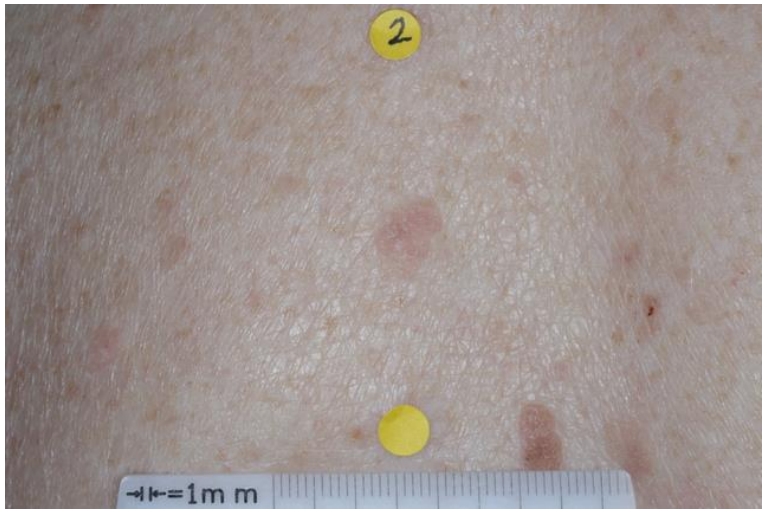


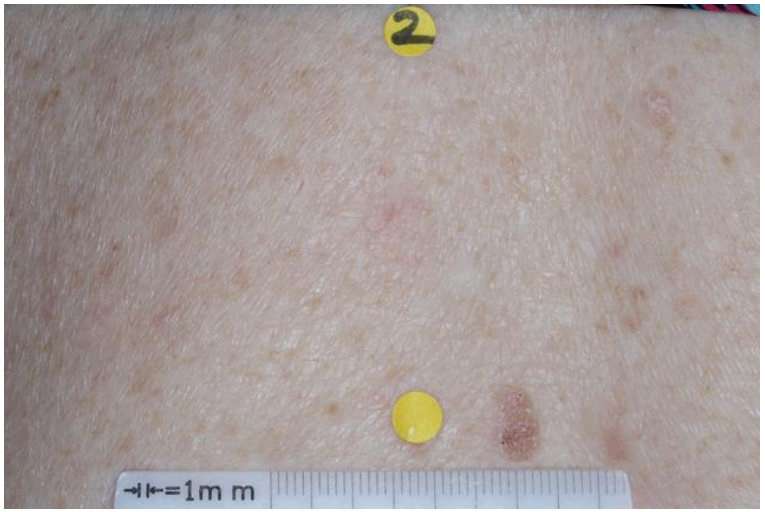
Pre-Treatment with A-101

Female

Skin Type
2

Location:
Back





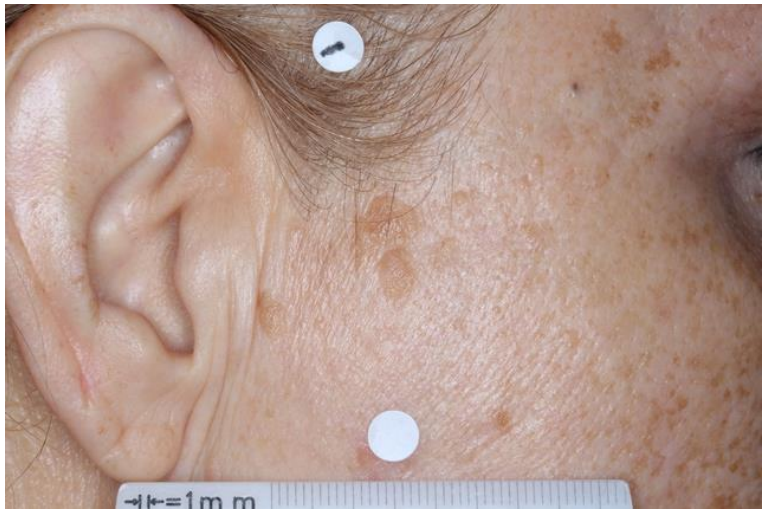
Final Visit f/u

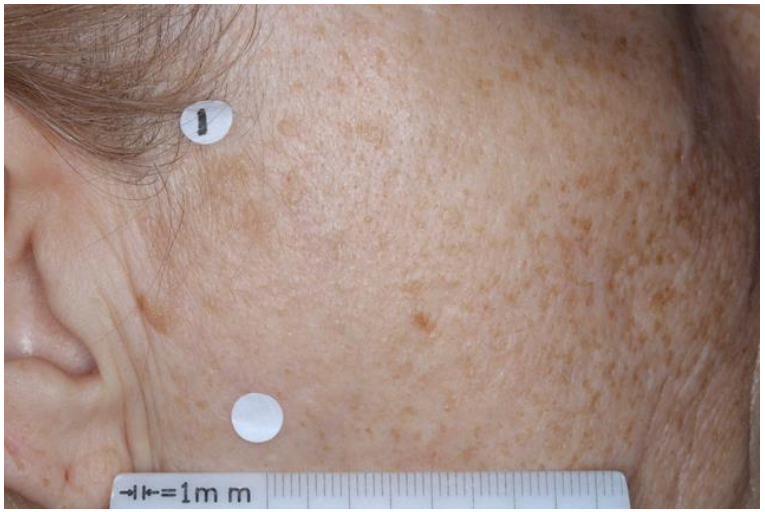
Patient Photos: PLA 1 (Near Clear)

Female

Skin Type
2

Location:
Face

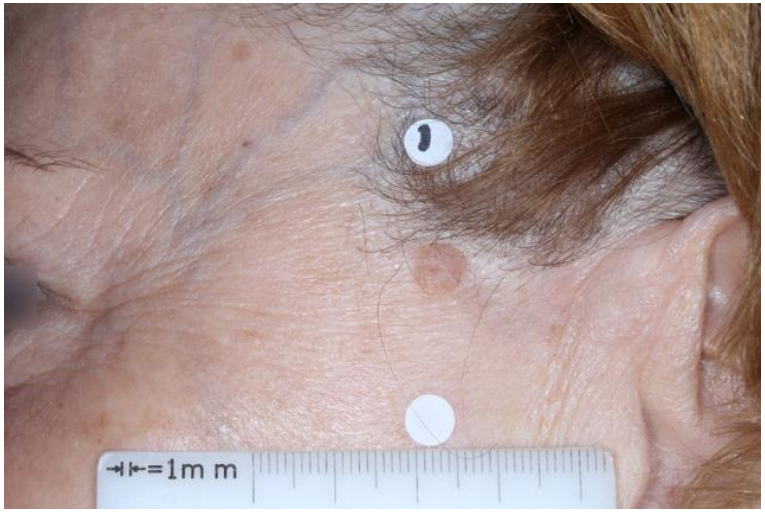


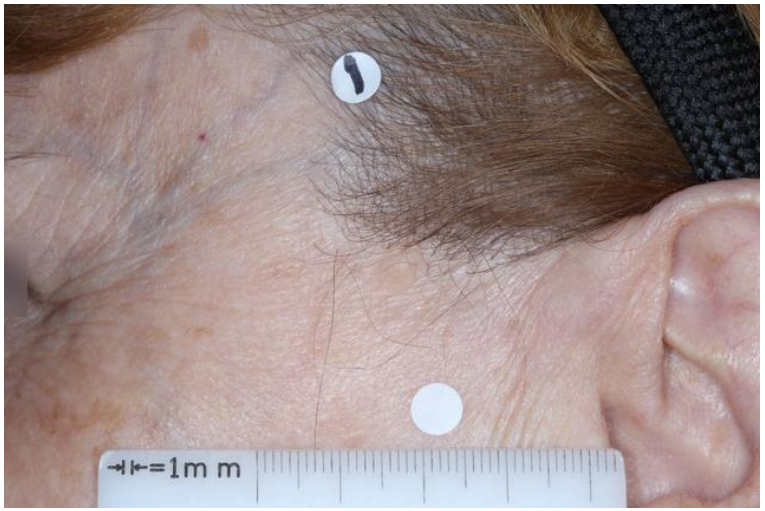


Female

Skin Type
2

Location:
Face

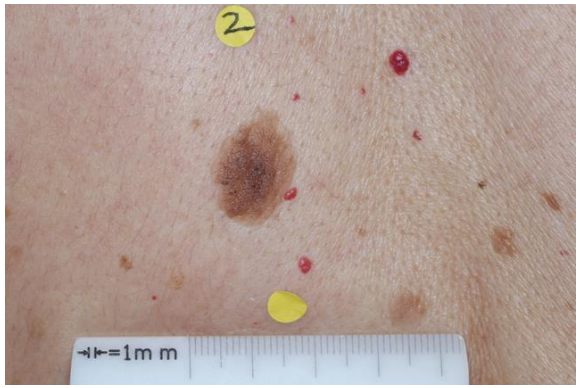
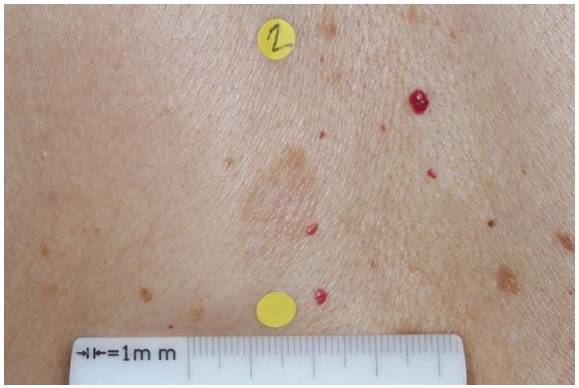
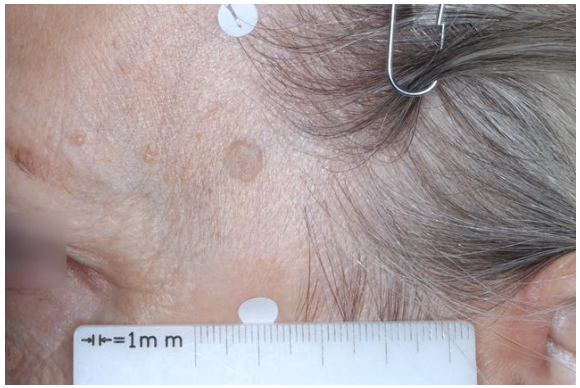
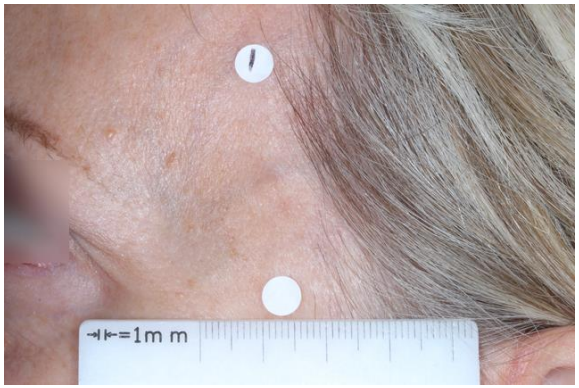
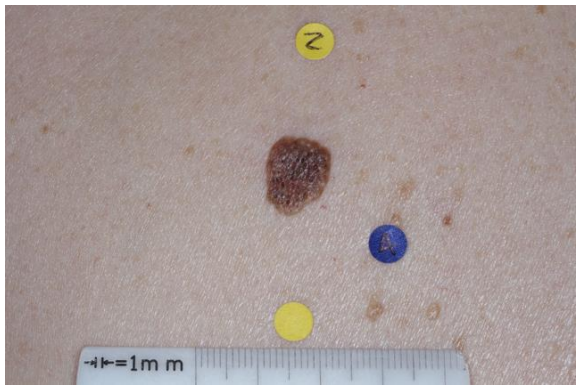
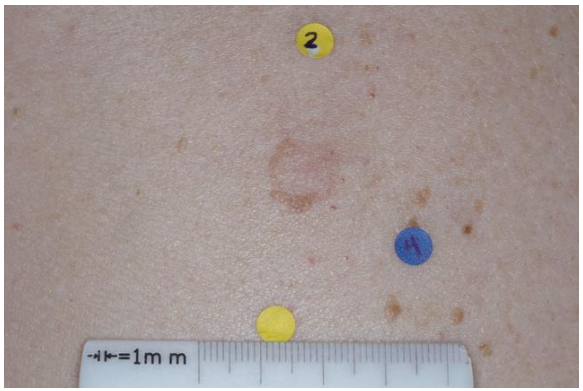




Pre-Treatment with A-101

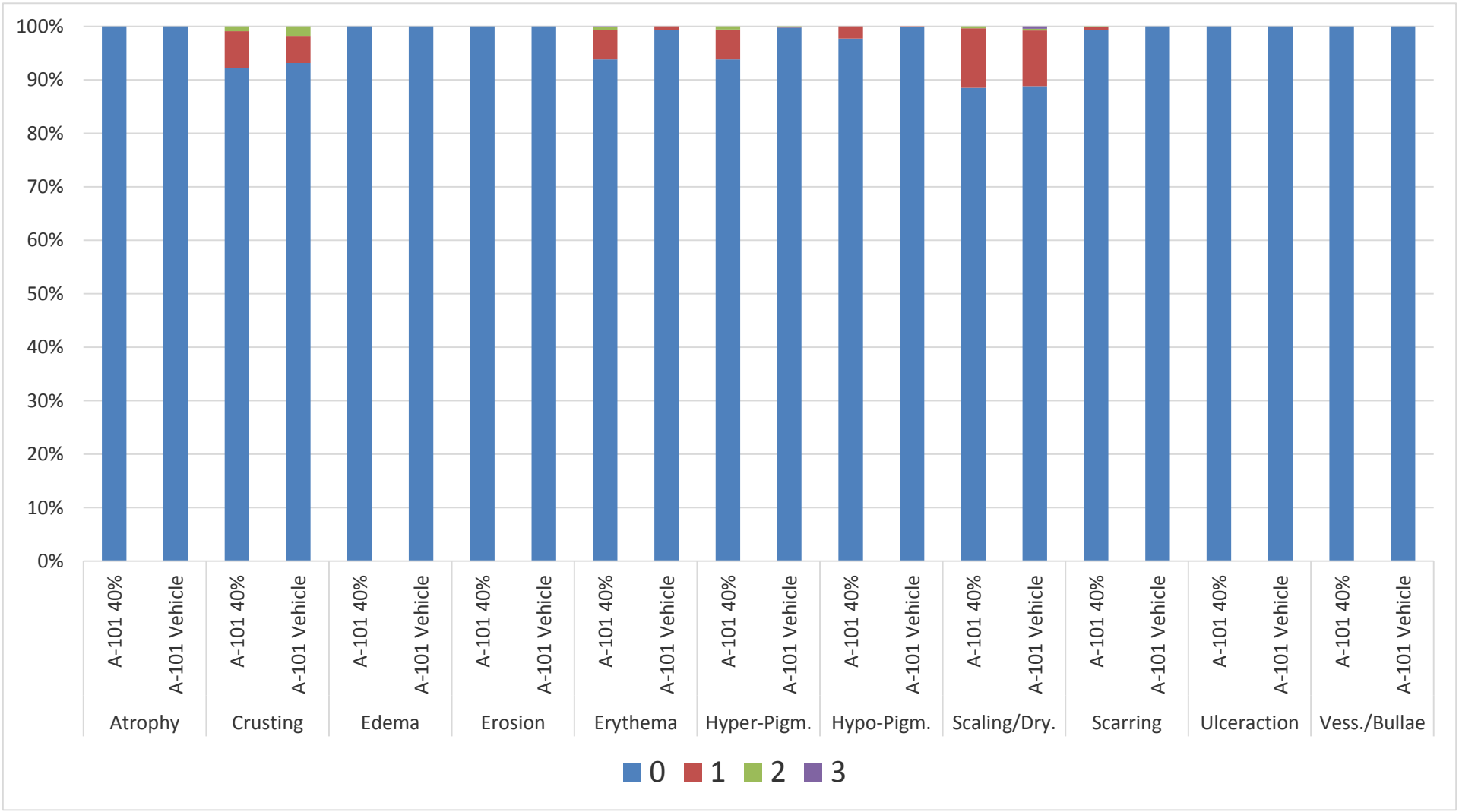
Final Visit f/u

Patient Photos: PLA 1 (Near Clear)

	Pre-Treatment with A-101	Final Visit f/u
Female **Skin Type:1** **Location:** Back		
Female **Skin Type 2** **Location:** Face		
Female **Skin Type** 3 **Location:** Back		

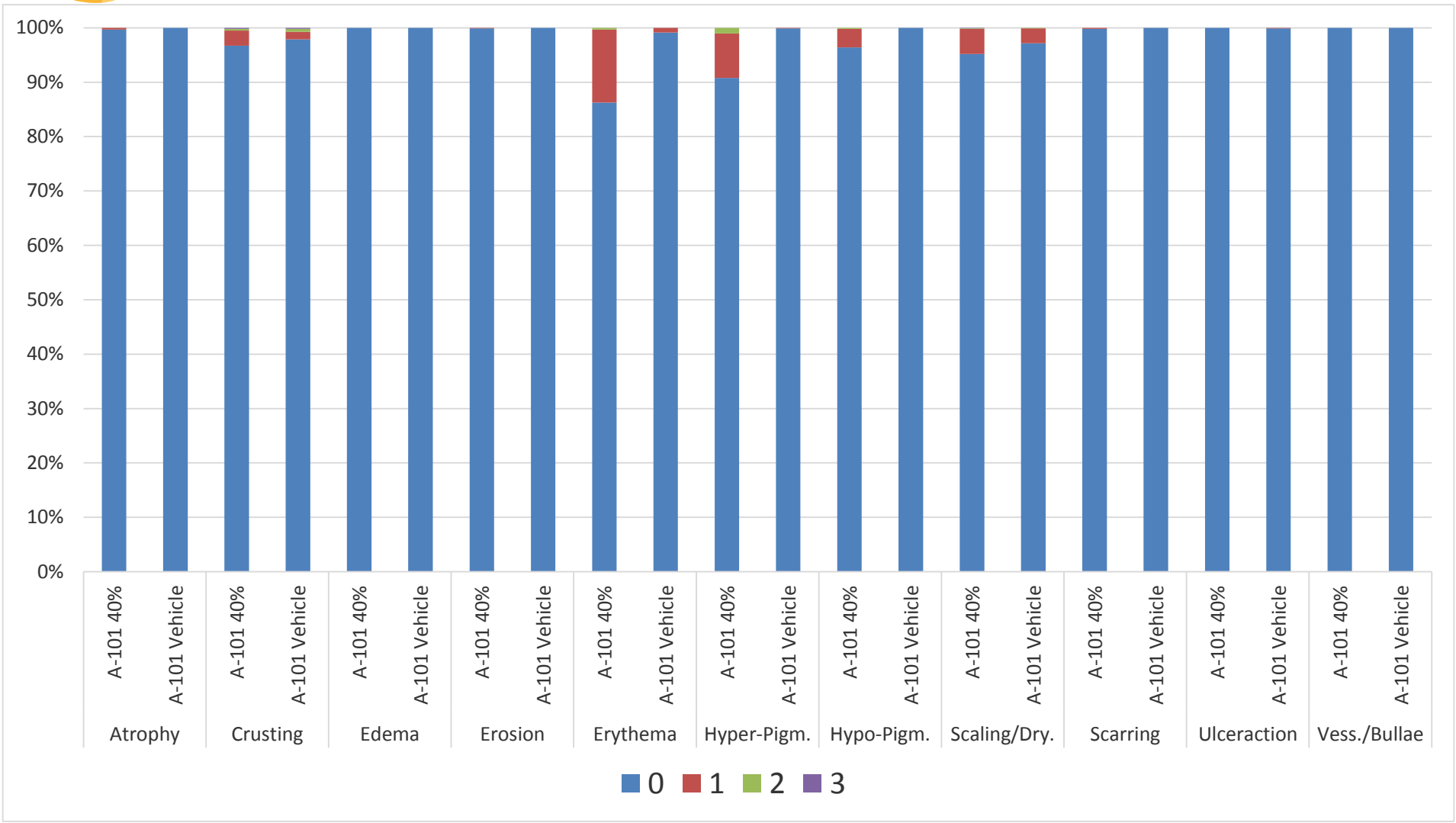
Study A-101-SEBK-301: Local Skin Reactions at Last Visit

0 = No Reaction 1 = Mild 2 = Moderate 3 = Severe



Study A-101-SEBK-302: Local Skin Reactions at Last Visit

0 = No Reaction 1 = Mild 2 = Moderate 3 = Severe



Opportunity for A-101 to Become the Standard of Care in SK

FAVORABLE MARKET DYNAMICS

- Seborrheic Keratosis (SK) is a very common disease ~**83 million** sufferers in the US
- **~8.3 million SK treatments** performed annually by dermatologists
- Highly concentrated core physician targets
- Large and growing market for minimally invasive, self-pay aesthetic treatments

UNMET NEED IN SK

- No FDA-approved topical treatments
- Current SK treatments are invasive, often painful, and can result in scarring or dyspigmentation
- Majority of patients have SKs in cosmetically sensitive areas

HIGH LEVEL OF INTEREST

- Dermatologists very interested in a topical, non-invasive treatment for SK
- Patients interested in an effective, non-invasive treatment and willing to pay a reasonable fee
- Dermatologists grow their aesthetic practices by incorporating new self-pay treatments

ACLARIS THERAPEUTICS

Favorable Market Dynamics for a New Seborrheic Keratosis (SK) Topical Treatment

About SKs:

- Most common benign skin lesion
- Prevalent in all skin types
- ~5K dermatologists most active in treating SK
- No FDA-approved topical treatment for SK

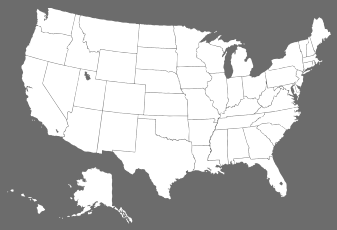
Self-Pay Aesthetic Treatments:

- Number of minimally invasive aesthetic procedures up six-fold from 1997 - 2015[3]

SEBORRHEIC KERATOSIS (SK)

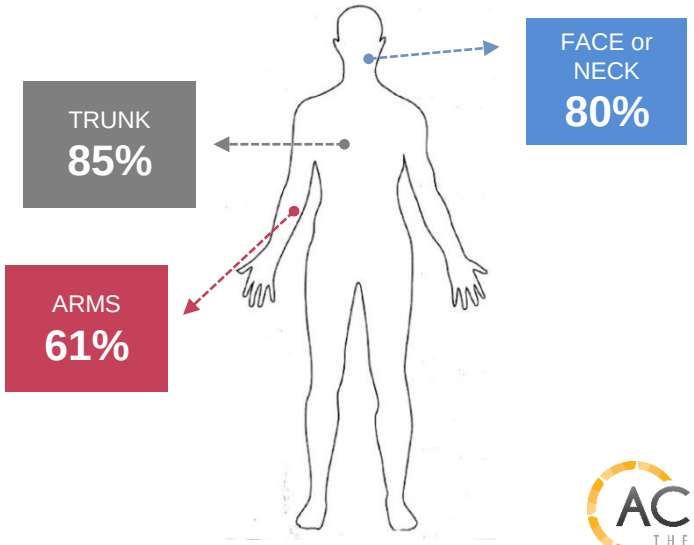
83.8MM people

in U.S.[1]; 8.3 million SK treatments by dermatologists annually[2]



SK Distribution[3]

% of Patients who Have SKs on the:



[1] Bickers et al, The Burden of Skin Disease, J Am Acad Dermatol, 2006;55:490-500.
[2] Data on File: Aclaris Therapeutics Burke Screener of 594 dermatologists – 2014
[3] Data on File: Aclaris Therapeutics Burke Survey of 406 Patients – 2016.

Value Proposition for New SK Treatment Has Potential to Address Unmet Need

New treatment likely to be adopted by many dermatologists if it offers[1]:

Good cosmetic outcomes, especially for:
- SKs in cosmetically sensitive areas (i.e., face and neck)
- Darker skin tones

Non-invasive approach
- Minimal pain and discomfort
- Topical

Minimal risk; especially for scarring, hypopigmentation

Ease of application

Potential to be **administered by ancillary staff** which can save dermatologists' time

Affordability for patients

[1] Data on File: Aclaris Therapeutics Inc. Burke Survey of 251 dermatologists – 2014 . Note: Surveyed dermatologists met this screening criteria: In practice 1-30 years, work in a full time, active practice and spend at least 75% of professional time in direct patient care, see at least 50 patients with SK in an average month and treat at least 20% of these patients to remove SKs and have some interest in a new SK topical drug treatment . Survey respondents represent a population estimate of 5,069 dermatologists.

High Level of Interest in New Self-Pay Treatment

Patients said that even when aware the treatment would not be covered by insurance, they probably or definitely would ask their dermatologist about it[2]

Large patient segment willing to pay more for a non-invasive treatment that provides good aesthetic outcomes[3]

HOW DERMATOLOGISTS GROW THEIR AESTHETIC PRACTICE:

1. Provide **existing treatments** to existing patients (76%)[1]
2. Attract **new aesthetic patients** they haven't seen before (55%)[1]
3. Offer **new treatments** to existing patients (49%)[1]

[1] Data on File: Aclaris Therapeutics Inc. Burke Survey of 251 dermatologists – 2014 . Note: Surveyed dermatologists met this screening criteria: In practice 1-30 years, work in a full time, active practice and spend at least 75% of professional time in direct patient care, see at least 50 patients with SK in an average month and treat at least 20% of these patients to remove SKs and have some interest in a new SK topical drug treatment . Survey respondents represent a population estimate of 5,069 dermatologists.

[2] Data on File Aclaris Therapeutics Burke Survey of 957 Patients – 2015

[3] Data on File: Aclaris Therapeutics Burke Survey of 406 Patients – 2016.

ACLARIS THERAPEUTICS

A-101 Phase 3 Studies Conclusions and Next Steps

- A-101 met all primary and secondary endpoints in both trials, achieving clinically and statistically significant clearance of SK lesions.
- Administration of A-101 was well tolerated and safe with no treatment-related serious adverse events reported.
- Local skin reactions, if present, were predominantly classified as mild.
- Aclaris plans to submit an NDA for A-101 to the FDA 1Q17.