Assessing Patient Satisfaction With Hydrogen Peroxide Topical Solution, 40% (w/w) Treatment of Seborrheic Keratoses on the Face, Neck, and Décolletage: Objectives and Design of the Phase 4, Open-Label SK-FAN Study

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CONCLUSIONS

1. The Phase 4 SK-FAN study is designed to assess patient satisfaction with HP40 treatment for SKs
2. The study will also assess how patient satisfaction correlates with efficacy
3. The study is currently ongoing with results expected early in 2019

SYNOPSIS

- Seborrheic keratoses (SKs) are benign cutaneous lesions affecting nearly 84 million individuals in the United States[1]
- Although SKs are benign growths, these lesions are often cosmetically bothersome to patients, and over 60% of individuals with SKs have reported taking measures to hide or disguise their SKs[2]
- Current treatments for SKs involve surgical or ablative modalities such as liquid nitrogen cryotherapy, shave removal, curettage, chemical peels, and laser treatments[2,3]
- Recently, a proprietary hydrogen peroxide topical solution, 40% (w/w) (HP40) was approved by the US Food and Drug Administration for the treatment of adults with raised SKs[4]
- The Phase 4, open-label Seborrheic Keratoses of the Face, Neck and Décolletage (SK-FAN) study was designed to assess participants' satisfaction following HP40 treatment of SKs located on these body regions

OBJECTIVE

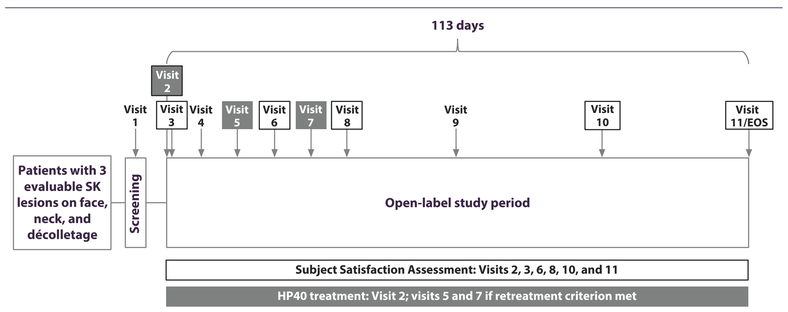
- The objective of this presentation is to describe the methodology of the ongoing SK-FAN study

METHODS

Study Design

- The SK-FAN study is a Phase 4, open-label, single-group trial (NCT03487588) that is currently ongoing at 3 sites in the United States
- A schematic of the study design is presented in **Figure 1** and the detailed timing of key study procedures is summarized in **Table 1**
- During the study, HP40 is applied to all target lesions at visit 2, then again at visits 5 (day 15) and 7 (day 29) if target lesions meet the retreatment criterion (see "**Investigational Product and Treatments**" section)
- Assessments of participant satisfaction with HP40 treatment take place during visits 2, 3, 6, 8, 10, and 11 (see "**Subject Satisfaction Assessment**" [SSA] section)

Figure 1. Study Design



EOS, end of study; HP40, hydrogen peroxide topical solution, 40% (w/w); SK, seborrheic keratosis.

Table 1. Timing of Key Study Procedures

Study Visit:	1	2	3	4	5	6	7	8	9	10	11
Treatment Day:	**−13 to 0**	**1**	**2**	**8**	**15**	**22**	**29**	**36**	**57**	**85**	**113**
Allowable Window:	**N/A**	**N/A**	**N/A**	**±1 day**	**±1 day**	**±1 day**	**±1 day**	**±1 day**	**±7 days**	**±7 days**	**±7 days**
Treatment with HP40		X			X[a]		X[a]				
Physician Lesion Assessment	X	X	X	X	X		X			X	X
Subject Satisfaction Assessment		X	X			X		X		X	X
Adverse events		X	X	X	X	X	X	X	X	X	X

HP40, hydrogen peroxide topical solution, 40% (w/w); N/A, not applicable.
[a]If retreatment criterion met.

Study Participants

- The targeted enrollment of the SK-FAN study is 30 participants
- Key inclusion and exclusion criteria are described in **Table 2**

Table 2. Key Inclusion and Exclusion Criteria of the SK-FAN Study

Key Inclusion Criteria
• Male or female, 30–75 years of age
• Have a diagnosis of stable, clinically typical SKs, with 3 target SKs
— 2 target SKs must be located on the face
— 1 target SK must be located on the neck or décolletage
— Target SKs are required to:
• Have a Physician Lesion Assessment™ (PLA) grade of ≥2 on a 4-point scale (0 = clear; 1 = near clear; 2 = thin [≤1 mm]; 3 = thick [>1 mm])
• Have a diameter of 5–15 mm
• Have a clinically typical appearance
• Be a discrete lesion
• Not be covered with hair that would interfere with study medication treatment or study evaluations
• Not be in an intertriginous fold, on the eyelids, within 5 mm of the orbital rim, or pedunculated
• Patients may also have up to 4 nontarget SKs on the face, neck, or décolletage

Table 2. Key Inclusion and Exclusion Criteria of the SK-FAN Study (cont'd)

Key Exclusion Criteria
• Clinically atypical and/or rapidly growing SK
• Presence of multiple eruptive SKs (sign of Lesser-Trélat)
• Current systemic malignancy
• Previous treatment with HP40
• Used previous/current therapies that could interfere with the study treatment or the assessments:
— Laser, light, or other energy-based therapy (eg, intense pulsed light, photodynamic therapy) within 30 days of first study treatment
— Imiquimod, 5-fluorouracil, or ingenol mebutate within 60 days of first study treatment
— Retinoids within 28 days of first study treatment
— Microdermabrasion or superficial chemical peels within 14 days of first study treatment
• Currently or recently had on, or in proximity to, any target or nontarget SK:
— Cutaneous malignancy within 180 days of first study treatment
— Current sunburn
— Current pre-malignancy (eg, actinic keratosis)
— Body art
— Excessive tan (use of self-tanning lotions/sprays is prohibited)
• Any current skin disease (eg, psoriasis, atopic dermatitis, eczema, sun damage) or condition (eg, sunburn, excessive hair, open wounds) that might put the subject at undue risk by study participation or interfere with the study conduct or evaluations

SK, seborrheic keratosis; SK-FAN, Seborrheic Keratoses of the Face, Neck and Décolletage.

Investigational Product and Treatments

- HP40 is supplied as a single-use applicator to be applied topically to an SK lesion by a medical professional
- HP40 is applied to 3 target SKs and up to 4 nontarget SKs during visit 2 (study day 1)
- During visit 5 (day 15) and visit 7 (day 29), SKs that meet the retreatment criterion (PLA score of ≥1, indicating lesion not cleared) are retreated
- During treatments, HP40 is applied to each target and nontarget SK for approximately 20 seconds, and each target and nontarget SK may be treated up to 4 times with approximately 60 seconds between each application

Subject Satisfaction Assessment

- Participants are asked to assess their level of satisfaction regarding the study medication treatment experience using the SSA
- There are 3 versions of the SSA to be administered at specified visits as follows:

At visit 2 prior to application of HP40:

1. What prior treatments have you used/had performed for SK removal? (Select all that apply)
- Cryotherapy (freezing with liquid nitrogen)
- Curettage (scraping off tissue)
- Electrodessication (burning off with electricity)
- Laser therapy (burning off)
- Other (provide name)

2. How bothered are you by the appearance of your face/hairline neck SKs?
- 1 – Not bothered at all
- 2 – A little bit bothered
- 3 – Neutral
- 4 – Somewhat bothered
- 5 – Extremely bothered

3. How do you feel about getting your SKs treated? (Select all that apply)
- Anxious/Nervous
- Concerned/Worried
- Unsure/Neutral
- Hopeful
- Excited

4. What prior facial cosmetic treatment(s), excluding cryotherapy for SK removal, have you had for your face in a dermatology clinic or medical spa? (Select all that apply)
- Botulinum toxin injections
- Hyaluronic acid fillers
- Hair removal with laser or pulsed light
- Chemical peel
- Microdermabrasion
- Plastic surgery
- Other (provide name)
- None, HP40 will be my first cosmetic treatment for my face

At visit 3 approximately 24 hours after the treatment on visit 2, and at visit 6 (if treated at visit 5), approximately 1 week after visit 5 treatment, and at visit 8 (if treated at visit 7), approximately 1 week after visit 7 treatment:

1. During treatment, what was your level of discomfort?
- 1 – No discomfort
- 2 – Mild discomfort
- 3 – Moderate discomfort
- 4 – Severe discomfort
- 5 – Unbearable discomfort

2. One hour after treatment, what was your level of discomfort?
- 1 – No discomfort
- 2 – Mild discomfort
- 3 – Moderate discomfort
- 4 – Severe discomfort
- 5 – Unbearable discomfort

3. One day after treatment, what was your level of discomfort?
- 1 – No discomfort
- 2 – Mild discomfort
- 3 – Moderate discomfort
- 4 – Severe discomfort
- 5 – Unbearable discomfort

4. Within 24 hours after treatment, were you comfortable enough with the appearance of your treated SKs to go out in public (with or without makeup)?
- Yes
- No

4.a. How soon after your treatment were you comfortable enough with your appearance of your treated SKs to go out in public (with or without makeup)?
- Immediately after treatment
- 1–2 hours after treatment
- 2–4 hours after treatment
- 4–6 hours after treatment
- More than 6 hours after treatment

At visits 10 and 11 during the visit:

1. Please check prior treatments <u>you</u> have personally had for SKs (check mark all that apply).
- Cryotherapy (freezing with −196°C liquid nitrogen)
- Curettage (scraping off tissue with a sharp instrument)
- Electrodessication (burning off with high-voltage electricity)
- Other (please describe)

2. After your experience with HP40, how likely will you pursue future treatment for other SKs on your face or body?
- 1 – Very unlikely
- 2 – Unlikely
- 3 – Neither unlikely or likely
- 4 – Likely
- 5 – Very likely

3. On a scale of 1–5, rate your level of satisfaction of your <u>treatment experience</u> with 1 being not satisfied at all and 5 being completely satisfied?
- 1 – Not satisfied at all
- 2 – Slightly satisfied
- 3 – Moderately satisfied
- 4 – Satisfied
- 5 – Very satisfied

4. On a scale of 1–5, rate your level of satisfaction with the appearance of your skin treated with HP40 with 1 being not satisfied at all and 5 being completely satisfied?
- 1 – Not satisfied at all
- 2 – Slightly satisfied
- 3 – Moderately satisfied
- 4 – Satisfied
- 5 – Very satisfied

5. What is the likelihood you will get other SKs treated in the future with HP40?
- 1 – Not likely at all
- 2 – Slightly likely
- 3 – Moderately likely
- 4 – Very likely
- 5 – Extremely likely

6. What is the likelihood you will recommend HP40 to a friend/relative?
- 1 – Not likely at all
- 2 – Slightly likely
- 3 – Moderately likely
- 4 – Very likely
- 5 – Extremely likely

7. For an SK you would like to treat in the future, please rank your preferred treatment method (1 – most preferred; 5 – least preferred).
- HP40 (topical application)
- Cryotherapy (freezing with −196°C liquid nitrogen)
- Curettage (scraping off tissue with a sharp instrument)
- Electrodessication (burning off with high-voltage electricity)
- Other (please describe)

8. After treatment with HP40, how bothered are you by the appearance of your treated SKs today?
- 1 – Not bothered at all
- 2 – A little bit bothered
- 3 – Neutral
- 4 – Somewhat bothered
- 5 – Extremely bothered

9. Since your treatment with HP40, how do you feel about getting your untreated SKs treated in the future?
- Anxious/Nervous
- Concerned/Worried
- Unsure/Neutral
- Hopeful
- Excited

10. Please indicate the level of agreement you have to the following statements:

A) Since my treatment with HP40, I feel more confident:
- Strongly agree
- Disagree
- Neither disagree or agree
- Agree
- Strongly agree

B) Since my treatment with HP40, I feel more attractive:
- Strongly agree
- Disagree
- Neither disagree or agree
- Agree
- Strongly agree

C) Since my treatment with HP40, I feel less embarrassed:
- Strongly agree
- Disagree
- Neither disagree or agree
- Agree
- Strongly agree

D) Since my treatment with HP40, I feel more comfortable being photographed in pictures:
- Strongly agree
- Disagree
- Neither disagree or agree
- Agree
- Strongly agree

Physician Lesion Assessment

- At visits 1, 2, 3, 4, 5, 7, 10, and 11, the investigator will assess the target and nontarget SK using the PLA, a validated tool, and report the integer that best describes the severity of the target or nontarget SK (**Table 3**)
- At visit 2, and if applicable, at visits 5 and 7, the investigator completes the PLA prior to the study medication treatment

Table 3. Physician Lesion Assessment Scoring

Grade	Description
0	Clear: no visible SK lesion
1	Near clear: a visible SK lesion with a surface appearance different from the surrounding skin (not elevated)
2	Thin: a visible SK lesion (thickness ≤1 mm)
3	Thick: a visible SK lesion (thickness >1 mm)

SK, seborrheic keratosis.

Outcome Measures

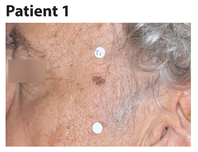
- Primary outcome measure
  - Question #4 of the end-of-study SSA: "On a scale of 1–5, rate your level of satisfaction with the **appearance** of your skin treated with [HP40]."
- Secondary outcome measure
  - Question #3 of the end-of-study SSA: "On a scale of 1–5, rate your level of satisfaction of your **treatment experience**."
- Tertiary outcome measures
  - Question #10 and its 4 constructs of confidence, attractiveness, embarrassment, and comfort with being photographed
- Exploratory outcome measures
  - Predose and postdose SSA ratings
- Additional analyses
  - Correlations between PLA and SSA scores
  - Predictors of treatment satisfaction (ie, participant characteristics)

RESULTS

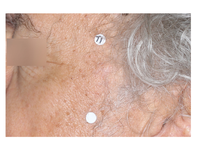
Status

- 41 participants have been enrolled at 3 US centers
- Data analyses are currently ongoing with results expected in early 2019; images of 3 patients treated thus far are shown below

Patient 1

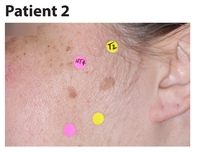


Day 1, Pretreatment

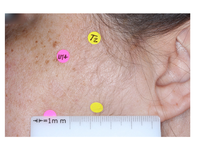


Day 113, End of study

Patient 2

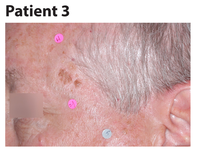


Day 1, Pretreatment

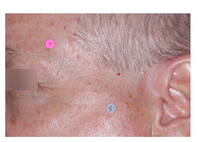


Day 113, End of study

Patient 3



Day 1, Pretreatment



Day 113, End of study

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Disclosures

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