Efficacy of Novel Multimodality Pigment-Correcting Serum for Moderate to Severe Facial Hyperpigmentation, Including Melasma, in a 12-Week, Split-Face, Double-blind, Randomized Controlled Trial

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OBJECTIVE

To assess the efficacy and tolerability of a novel hydroquinone (HQ)-free, multimodal, pigment-correcting serum (LYT3) compared with 4% HQ in women with moderate to severe overall hyperpigmentation on both sides of the face

CONCLUSIONS

- LYT3 significantly improved facial hyperpigmentation, including melasma, as early as week 2, with continued improvement through week 12 and a high rate of participant satisfaction with treatment
- LYT3 had similar effectiveness across a broad range of races and ethnicities based on a subgroup analysis, and the study population reflected all Fitzpatrick skin types
- The efficacy and tolerability of LYT3 were comparable to 4% HQ
- A majority of participants, both overall and in the melasma subgroup, preferred LYT3 over 4% HQ

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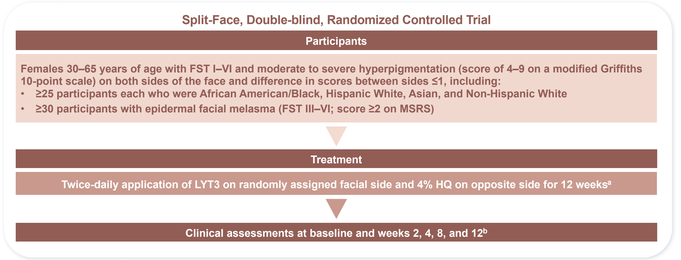
SYNOPSIS

- Hyperpigmentation of the skin occurs when excess melanin is produced, resulting in uneven skin tone and a photoaged appearance[1,2]
- Melasma, an acquired hyperpigmentation disorder occurring primarily on sun-exposed areas of the face, is particularly challenging to treat[3]
- Melasma and other hyperpigmentation disorders may disproportionately affect people with darker skin types, posing unique treatment challenges; a treatment that is effective in a broad range of ethnicities and skin types is needed[4-6]
- We conducted a split-face, single-center trial to assess the efficacy and tolerability of LYT3 (Allergan Aesthetics, an AbbVie Company) compared with 4% hydroquinone (HQ) for correcting hyperpigmentation, including melasma, in women with moderate to severe overall hyperpigmentation on both sides of the face

METHODS

Participants and Study Design



FST, Fitzpatrick skin phototypes; MSRS, Melasma Severity Rating Scale.
[a]All participants were additionally instructed to wash their face twice daily using the SkinMedica Facial Cleanser and apply the SkinMedica Ultra Sheer Moisturizer (*AM/PM*) and SkinMedica Essential Defense Mineral Shield SPF 35 (*AM* only) to the entire face.
[b]Self-assessment questionnaires also completed at weeks 2, 4, 8, and 12.

Study Assessments

Left and Right Sides of Face Evaluated Separately for Each Measure

- Clinical grading of efficacy (on a modified Griffiths scale: 0 [none], 1–3 [mild], 4–6 [moderate], 7–9 [severe]): overall hyperpigmentation and skin tone evenness
- VISIA-CR imaging
- Self-assessment questionnaires
- Tolerability assessments (0 [none], 1 [mild], 2 [moderate], 3 [severe]) on the left and right facial sides: erythema, edema, dryness, burning, stinging, and itching
- Melasma subgroup: modified Melasma Area and Severity Index (mMASI)
- Melasma subgroup: Melasma Quality of Life Questionnaire

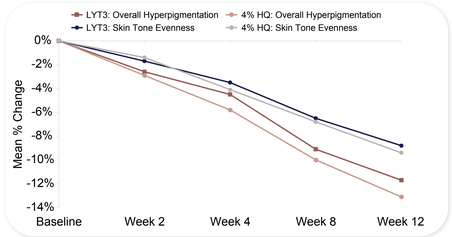
RESULTS

- The week 12 visit was completed by 110 participants (97.3%) overall and 42 (95.5%) in the melasma subgroup

Participant Demographics

	All Participants (N=113)	Melasma Subgroup (n=44)
Race and ethnicity subgroups, %		
African American	27	21
Non-Hispanic White	28	27
Hispanic White	22	27
Asian	22	25
Multi-Racial	1	0
Fitzpatrick skin type, %		
I	0.8	0
II	10.7	0
III	41.0	59.0
IV	21.3	25.0
V	22.1	14.0
VI	4.1	2.0

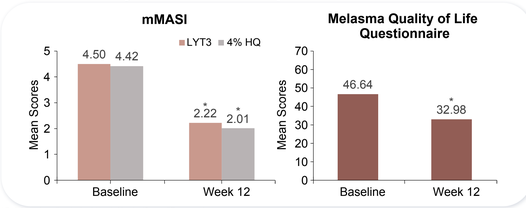
Significant Improvements Versus Baseline in Investigator Assessments Were Observed Starting at Week 2 and Continuing Throughout the Study



All timepoints statistically significant vs baseline for both treatment groups ($P \leq 0.005$; paired *t* test). No significant differences between LYT3 and 4% HQ treatment groups.

- Race and ethnicity subgroup analysis
  - Results were similar across all race and ethnicity subgroups, with significant improvements versus baseline starting at week 2 or 4 and continuing through week 12
  - Across all race and ethnicity subgroups, LYT3 achieved comparable results to 4% HQ, with no significant differences, and with a ≤3.1% mean change difference between the 2 treatment groups for each parameter

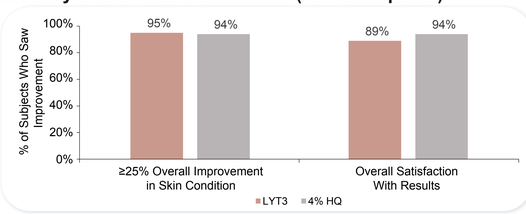
LYT3 Significantly Improved Melasma Severity and Melasma-Related Quality of Life in Participants With Melasma



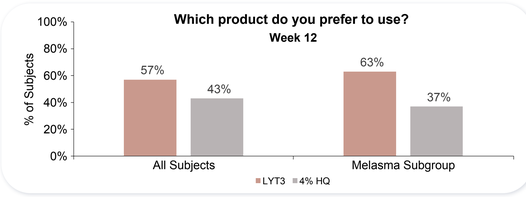
*$P<0.05$ vs baseline (paired *t* test). No significant differences between treatment groups.

- Race and ethnicity subgroup analysis: among participants with melasma across all ethnicities, LYT3 produced similar improvements in melasma severity and high rates of overall satisfaction with results (82% to 100% at week 12)

At Week 12, LYT3 Was Highly Rated by Participants for Efficacy and Overall Satisfaction (All Participants)



All Participants and Those in the Melasma Subgroup Preferred LYT3 Over 4% HQ



- Participants (overall and in the melasma subgroup) consistently preferred LYT3 over 4% HQ at every visit (weeks 2, 4, 8, and 12)

Standardized Images Showed That LYT3 and 4% HQ Were Effective in Improving the Appearance of (A) Overall Hyperpigmentation and (B) Melasma

A

Hispanic or Latino, female, 51 years of age, FST III

B

Black or African American, female, 60 years of age, FST IV

- Treatment was well tolerated, with mean scores remaining less than 0.25 (mild) for all tolerability parameters at each study visit and no significant differences observed between LYT3 and 4% HQ