

## Clinical Efficacy of a New Pigment Correcting Serum in Asian Populations



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Skin structure and function are generally similar among all humans; however, minor biological differences in melanogenesis determine the variation in skin color that is observed between ethnicities. Ethnic skin refers to non-Caucasian skin encompassing all races and ethnicities other than non-Hispanic white. Asia is currently home to 60% of the world's total population, and large Asian communities can be found on the other continents as well.

### SKIN AGING IN ASIAN POPULATIONS

Pigmentary changes and skin tone unevenness are generally the first visible signs of skin aging in Asian populations rather than wrinkling. In Asians wrinkles usually appear after the age of 50 years, and they are less pronounced compared to Caucasians.<sup>1,2</sup> Comparison studies have shown that hyperpigmentation spots are more prevalent in Chinese and Japanese women as compared to age-matched French women with similar lifetime sun exposure. The French women showed earlier onset of wrinkles (up to 10 years earlier) and increased severity of wrinkles.<sup>3,4</sup> Therefore, skin tone evenness is generally regarded as a sign of youth and well-being in many Asian cultures, and it plays a vital part in the perception of a person's attractiveness.<sup>5,6</sup> In fact, skin disorders and conditions (including hyperpigmentation) can negatively impact the quality of life in patients. Although pigmentary conditions rarely pose a threat to a patient's physical health, they can have severe psycho-social effects with regards to emotional well-being (self-

perception, embarrassment, self-esteem), relationships and social activities, and productivity at work/school.<sup>7-9</sup> However, treatment of these skin conditions can improve the quality of life in patients.<sup>10</sup>

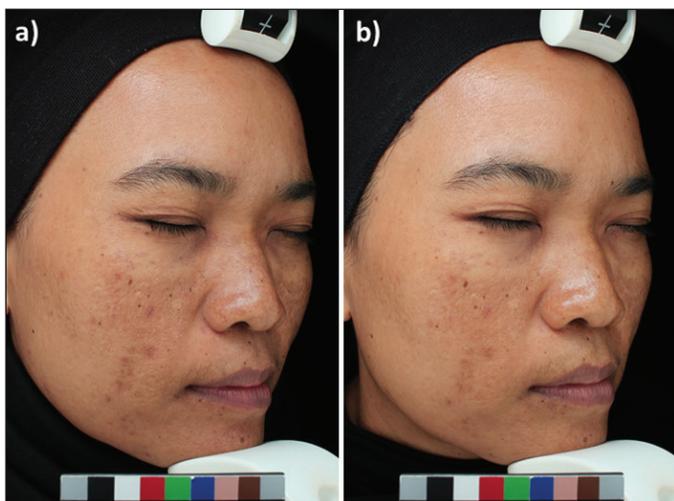
### CLINICAL TESTING IN ETHNIC SKIN

It is important to clinically test a product that addresses the appearance of hyperpigmentation in various ethnic backgrounds, because of innate differences in pigment biology between ethnicities. Most clinical studies on hyperpigmentation are conducted in Caucasian skin. SkinMedica® developed LYT2, a novel hydroquinone-free and retinol-free pigment correcting serum that was previously assessed in a clinical study involving subjects of different ethnic origins with facial hyperpigmentation. LYT2 showed clinical efficacy and tolerability in African American, Hispanic and Caucasian subjects. Two additional clinical studies in Thailand and Japan are presented here that specifically address the efficacy of LYT2 in Asian populations.

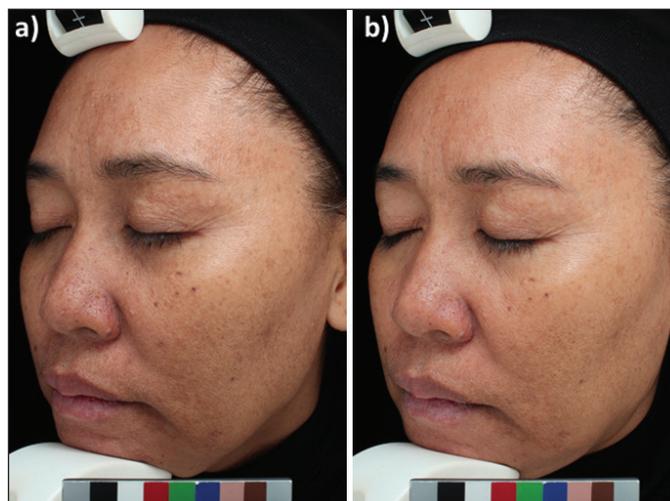
### EFFICACY OF A PIGMENT CORRECTING SERUM IN THAI AND JAPANESE SUBJECTS

Two independent randomized, double-blind, placebo-controlled clinical studies were conducted in Thailand and Japan to assess the efficacy and tolerability of LYT2 in dark- and light-skinned Asian subjects presenting with moderate to severe facial hyperpigmentation. In both studies, subjects were randomized to use either LYT2 plus sunscreen placebo regimen (facial cleanser, mild moisturizer and SPF 30 sunscreen) or sunscreen placebo regimen only for eight (Thailand) or twelve weeks (Japan). LYT2 was applied twice-daily after cleansing, and subjects were assessed for efficacy and tolerability parameters at all visits (Thailand: baseline and weeks 2, 4 and 8; Japan: baseline and weeks 4, 8 and 12). Standardized digital photographs of the subjects' facial skin were also taken at all visits.

In both studies, the LYT2-treated groups demonstrated statistically significant improvements in efficacy parameters at the end of treatment compared to baseline (Thailand: overall hyperpigmentation, color, size, occurrence, num-



**Figure 1: Improvements in the appearance of post-inflammatory hyperpigmentation and dark patches at baseline (a) and after two weeks of twice-daily use of LYT2 (b) in a 40-year-old Thai female.**



**Figure 2: Improvements in the appearance of dark patches at baseline (a) and after eight weeks of twice-daily use of LYT2 (b) in a 46-year-old Thai female.**

ber and homogeneity of blotches at week 8 (all  $p \leq 0.01$ ; Wilcoxon signed-rank test); Japan: overall hyperpigmentation, skin tone evenness at week 12 (all  $p \leq 0.02$ ; Wilcoxon signed-rank test)). Early significant improvements were also observed in both studies at week 4 and 8 for overall hyperpigmentation compared to baseline (Thailand: all  $p \leq 0.01$ ; Wilcoxon signed-rank test; Japan: all  $p \leq 0.02$ ; Wilcoxon signed-rank test). LYT2 also provided significantly greater improvements over sunscreen placebo regimen in both studies. LYT2 was well-tolerated in both Japanese and Thai subjects, with mean tolerability scores remaining similar to baseline scores (Thailand) or mild or below (Japan) throughout the study durations. Representative standardized digital photography of subjects from the Thailand study are shown in Figures 1 and 2, and a subject from the Japan study is shown in Figure 3.

## CONCLUSIONS

The two independent clinical studies conducted in Thailand and Japan support the efficacy and tolerability of LYT2 in dark- and light-skinned Asian populations. The results can be extended to several other Asian ethnicities; for example, Chinese and Korean have similar skin characteristics as Japanese. Furthermore, these results build upon the clinical efficacy previously observed in a LYT2 clinical study in a multi-ethnic population with African American, Hispanic, Asian and Caucasian subjects. Additional studies are in progress to assess efficacy of LYT2 in specific hyperpigmentation conditions such as melasma and post-inflammatory hyperpigmentation. ■



**Figure 3: Improvements in the appearance of dark spots at baseline (a) and after twelve weeks of twice-daily use of LYT2 (b) in a 52-year-old Japanese female.**

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