

# Safety and Effectiveness of Two Reconstitution Volumes of Poly-L-Lactic Acid for Correction of Décolletage Wrinkles

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## ABSTRACT

**Background:** Aesthetic patients are increasingly aware of the contrast between rejuvenated facial skin and untreated aging skin of the décolletage, and frequently request cosmetic enhancement of this area. Poly-L-lactic acid (Sculptra<sup>®</sup>, Galderma; PLLA-SCA) is a regenerative biostimulator that stimulates collagen and elastin production to help regenerate the skin's inner structure.

**Objective:** This 9-month, open-label study investigated the effectiveness and safety of correcting décolletage wrinkles with PLLA-SCA using 2 reconstitution volumes.

**Method:** Women with moderate/severe wrinkles on the Galderma Décolletage Scale (GDS) were randomized 1:1 to receive PLLA-SCA reconstituted with 8 mL or 17 mL sterile water for injection, plus 1 mL 2% lidocaine (up to 4 treatments, 1 month apart). Assessments included GDS, Global Aesthetic Improvement Scale (GAIS), subject satisfaction, skin quality, and adverse events (AEs).

**Results:** Of 30 randomized subjects, the majority (8 mL: 93.8%; 17 mL: 78.6%) showed a  $\geq 1$ -point improvement on investigator-assessed GDS at month 9 (primary endpoint), with  $\geq 93\%$  improved also at month 6. GAIS improvement was also great ( $>90\%$  of subjects) across both groups at months 6 and 9. In both groups,  $>90\%$  of subjects reported satisfaction with the appearance of their wrinkles by month 3, and this satisfaction was sustained throughout the study. The majority ( $>80\%$ ) of subjects were satisfied with the texture, smoothness, and radiance of their skin at months 6 and 9. One AE was judged as treatment-related; no AEs were serious or led to discontinuation.

**Conclusion:** Treatment of the décolletage area with PLLA-SCA was effective and well tolerated with both reconstitution volumes, with high subject satisfaction.

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## INTRODUCTION

Sculptra<sup>®</sup> poly-L-lactic acid (PLLA-SCA, Galderma) is a regenerative biostimulator containing microparticles of PLLA, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family.<sup>1</sup> PLLA-SCA works as a regenerative biostimulator to gradually build collagen and elastin fibers over time, remodel the extracellular matrix, and potentially have effects on adipose tissue in the injected area to help regenerate and restore the skin's inner structure and give the appearance of fuller and more youthful-looking skin.<sup>2-9</sup> In the United States (US), PLLA-SCA is approved for correction of nasolabial fold contour deficiencies and fine lines and wrinkles in the cheek region using reconstitution volumes of 5 mL or 8 mL sterile water for injection (SWFI) with the optional addition of 1 mL 2% lidocaine.<sup>10</sup>

As aesthetic patients achieve a younger appearance through facial rejuvenation, they are often left with an abrupt contrast

between their facial and non-facial (body) skin, such as the chest décolletage, and therefore frequently request cosmetic enhancement of this area.<sup>11</sup> Initial clinical trials and other clinical reports suggest that treatment of wrinkles with PLLA-SCA in the décolletage area is effective and well tolerated, with satisfactory aesthetic outcomes.<sup>12-15</sup>

Since the initial approval of PLLA-SCA in 1999 and 2004 in the European Union and the US, respectively, the amount of SWFI used to reconstitute PLLA-SCA has gradually increased. Based on medical literature and physician experience, practitioners have reported improved clinical outcomes with increased reconstitution volumes up to 2 times larger than the volume recommended by the manufacturer, usually in combination with anesthetic solutions such as lidocaine 2%.<sup>6,16</sup> There are also data that show that an increased reconstitution volume helps to reduce the frequency of nodules and papules.<sup>11,17</sup>

Consensus recommendations and investigator-initiated studies on the use of PLLA-SCA advocate larger reconstitution volumes (up to 18 mL) for treatment of body areas including the décolletage area, than those used for facial indications.<sup>8,9,11,12,15,18,19</sup> This is because it involves treating larger surface areas compared to facial indications, and uniform product dispersion is critical for achieving an optimal treatment effect.<sup>20-22</sup> In addition, leading experts recommend multiple treatment sessions at least 4 weeks apart.<sup>1,8,19</sup>

In this study, the safety and effectiveness of correction of wrinkles in the décolletage with PLLA-SCA were explored using 2 different reconstitution volumes for PLLA-SCA, 8 mL and 17 mL (+1 mL 2% lidocaine).

## MATERIALS AND METHODS

### Study Design

This was a 9-month, prospective, open-label study (NCT05538728). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (1964 and subsequent amendments), as well as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice. Subjects provided written informed consent, and ethical approval was obtained from each relevant institutional review board.

### Study Population

The study was performed at 2 centers in the US between September 2022 and August 2023, and planned to include approximately 30 women, aged  $\geq 22$  years, with moderate/severe décolletage wrinkles on the Galderma Décolletage Scale (GDS).

Eligible participants were non-pregnant, non-breastfeeding females, seeking treatment for the correction of moderate or severe wrinkles in the décolletage area (Grade 2 or 3 on the GDS). Subjects must not have received treatment with collagen and hyaluronic acid in the décolletage within 12 months prior to the study, or any previous treatment with calcium hydroxyapatite, PLLA, autologous fat (permanent), plastic surgery, or permanent surgical implant in the décolletage area.

### Study Treatment

Subjects were randomized 1:1 to treatment with PLLA-SCA reconstituted with either 8 mL or 17 mL SWFI, plus the addition of 1 mL 2% lidocaine.

Up to 4 treatment sessions were scheduled at 1-month (+2 weeks) intervals with the first treatment on day 1 (baseline), followed by 3 optional treatments at months 1, 2, and 3. A maximum of 2 vials could be injected per session. One month was defined as 4 weeks in the study.

Following reconstitution, PLLA-SCA was used immediately. Injections were made using a 25 G needle at subdermal depth. Injection techniques were chosen at the discretion of the Treating Investigator. The boundaries of the treatment area were the suprasternal notch of the manubrium sterni superiorly, 2/3 of the clavicle line laterally, and above the xiphoid process inferiorly. Treatment of the breast tissue was not permitted.

### Study Endpoints

*Primary effectiveness endpoint: GDS responder rate at month 9*

The primary effectiveness endpoint was the GDS responder rate at month 9 after the first treatment, assessed live by the treating investigator. A response was defined as  $\geq 1$  grade improvement from baseline. The GDS is a validated 5-point scale assessing décolletage wrinkle severity from none/minimal (0) to very severe (4).

### Secondary Effectiveness Endpoints

*GDS responder rate at month 6*

The percentage of responders, defined by  $\geq 1$  grade improvement from baseline, was assessed on the GDS by the treating investigator at month 6.

*Global Aesthetic Improvement Scale (GAIS) responder rate at months 6 and 9*

The 7-graded GAIS was used to live assess the aesthetic improvement of the décolletage region, by comparing it to a photograph taken at the baseline visit before treatment. The 7 ratings were: very much improved, much improved, improved, no change, worse, much worse, and very much worse. The percentage of responders, defined by having at least "improved" (improved, much improved, or very much improved), was assessed on the GAIS by the subject and the treating investigator separately, at months 6 and 9.

### Subject Satisfaction Questionnaire (SSQ) at months 6 and 9

Subjects responded to the SSQ at months 6 and 9, and results were reported as a percentage of subjects in each response category.

### Time to Return to Social Engagement

The time that subjects felt comfortable returning to social engagement after treatment was recorded in subject diaries.

### Skin Quality

Biophysical assessments of skin quality included measurements of skin surface roughness by 2D and 3D cameras, skin elasticity by DermaLab with an Elasticity Probe, and skin hydration by MoistureMeterD Compact (Delfin Technologies, Kuopio, Finland). The measurements were carried out under standardized climate conditions.

### Safety Endpoints

Adverse events (AEs) were collected throughout the study period. Subjects also reported pre-defined, expected, post treatment events ie, any symptoms of pain (including burning), tenderness, redness, bruising, swelling, or itching, using subject diaries for 28 days from each treatment.

### Statistical Analyses

A sample size of approximately 30 subjects was considered adequate for a preliminary evaluation of the safety and effectiveness in this study. Before the start of the study, a randomization list was prepared under the supervision of a statistician. Subjects were stratified by baseline GDS severity score and study site. Randomization numbers were allocated sequentially to each subject.

All data analyses were generated using SAS® software version 9.4. Effectiveness analyses were performed using the intent-to-treat (ITT) population, which included all randomized subjects, analyzed according to their randomized treatment. For the primary effectiveness endpoint, the primary imputation method for missing data was baseline observation carried forward, ie, missing values were assumed to be missing due to lack of effect. The impact of missing data on the primary endpoint was evaluated by performing sensitivity analysis based on the observed cases, as well as worst-case and best-case imputation.

All other endpoints were evaluated based on the observed cases.

Time (hours) to feel comfortable returning to social engagement after treatment was analyzed descriptively using Kaplan-Meier methods.

Safety endpoints were summarized using descriptive statistics using the safety population, including all subjects who were administered PLLA-SCA, and analyzed according to the treatment actually received.

## RESULTS

### Subjects and Treatment

A total of 31 subjects were screened. There was 1 screening failure, and 30 subjects were randomized: 16 to PLLA-SCA reconstituted with 8 mL SWFI, and 14 to PLLA-SCA reconstituted with 17 mL SWFI. All 30 randomized subjects were treated in at least 1 session, and 28 subjects completed the study. Two (6.7%) subjects withdrew consent (not due to COVID-19) before study end: 1 subject in the 8 mL group after treatment session 2, and 1 subject in the 17 mL group after treatment session 1. Of those who completed the study, 1 subject in the 8 mL group missed 1 treatment session, and the other 27 subjects received all 4 treatments.

**TABLE 1.****Demographics and Baseline Characteristics, ITT Population**

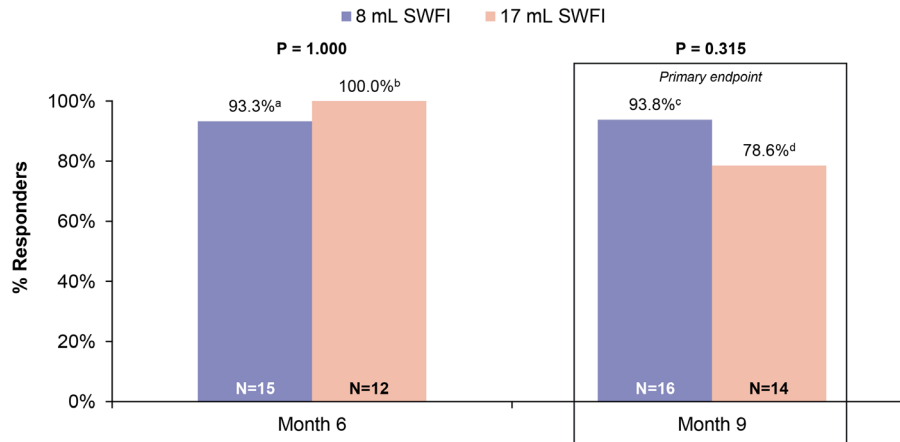
	8 mL SWFI (N=16)	17 mL SWFI (N=14)	Total (N=30)
<b>Age (years)</b>			
Mean (standard deviation)	53.2 (9.77)	55.0 (8.88)	54.0 (9.25)
Minimum, Maximum	38, 71	41, 67	38, 71
<b>Race, n (%)</b>			
White	14 (87.5)	13 (92.9)	27 (90.0)
Asian - Chinese	1 (6.3)	0	1 (3.3)
Asian - Thai	1 (6.3)	0	1 (3.3)
Other - Mexican	0	1 (7.1)	1 (3.3)
Multiple	2 (12.5)	0	2 (6.7)
<b>Ethnicity, n (%)</b>			
Not Hispanic or Latino	13 (81.3)	12 (85.7)	25 (83.3)
<b>Fitzpatrick Skin Type, n (%)</b>			
III	6 (37.5)	8 (57.1)	14 (46.7)
IV	3 (18.8)	3 (21.4)	6 (20.0)
V	1 (6.3)	1 (7.1)	2 (6.7)
<b>Baseline Galderma Décolletage Scale, n (%)</b>			
Moderate	7 (43.8)	7 (50.0)	14 (46.7)
Severe	9 (56.3)	7 (50.0)	16 (53.3)

\*Multiple\* race category includes subjects with more than one race selected.

N = Number of subjects in Intent-to-Treat Population, n = Number of subjects in specific category.

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**FIGURE 1.** Galderma Decolletage Scale (GDS) Responder Rates ( $\geq 1$ -grade improvement) assessed by treating investigators, ITT Population. Two-sided P-value calculated using Fisher’s Exact Test. Confidence intervals calculated using Clopper-Pearson method (based on binomial distribution). Results from the sensitivity analyses, using alternative methods of handling missing data, were consistent with the primary endpoint analysis at month 9.



<sup>a</sup>95% CI, 68.1-99.8; <sup>b</sup>95% CI, 73.5-100  
<sup>c</sup>95% CI, 69.8-99.8; <sup>d</sup>95% CI, 49.2-95.3  
SWFI, sterile water for injection

All subjects were injected with 2 vials of PLLA-SCA at each session, resulting in a mean total volume across all sessions of 68.0 mL in the 8 mL group (range 16.0–18.0 mL at each treatment session) and 135.6 mL in the 17 mL group (range 34.0–36.0 mL at each treatment session). All injections were administered via a 25 G needle, most commonly using a fanning technique (used in 100% of subjects in both groups) or retrograde linear threading (used in 41.0% in the 8 mL group and 52.8% in the 17 mL group).

**Demographics and Baseline Characteristics**

Demographic and baseline characteristics were generally similar between the 2 treatment groups (Table 1). Overall, the mean age of the female subjects enrolled in the study was 54.0 years (range 38 to 71 years). The majority were White (90.0%) and not Hispanic or Latino (83.3%). Approximately half of the subjects had moderate (46.7%), and half had severe (53.3%) décolletage wrinkles on the GDS scale at baseline, with a similar distribution of severity in both groups.

**GDS Responder Rate at Months 6 and 9**

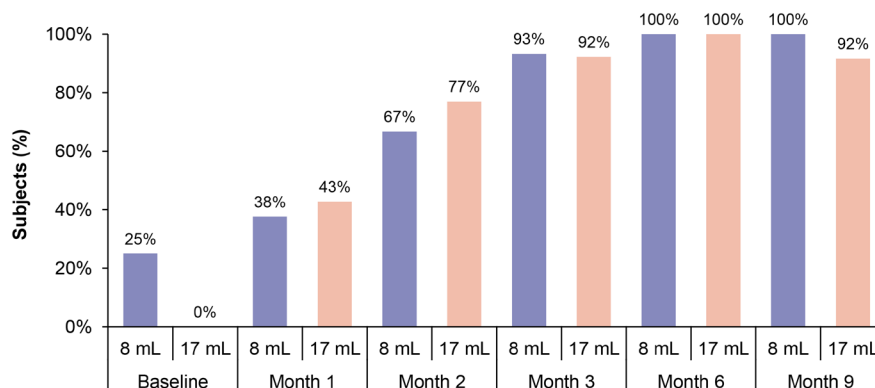
In the treating investigator assessments of GDS at month 9 (primary endpoint), the majority of subjects in both groups (8 mL group: 93.8%; 17 mL group: 78.6%) were responders, ie, showed a  $\geq 1$ -grade improvement in décolletage wrinkle severity from baseline. Both treatment groups also had high GDS responder rates at month 6: 93.3% and 100% (Figure 1).

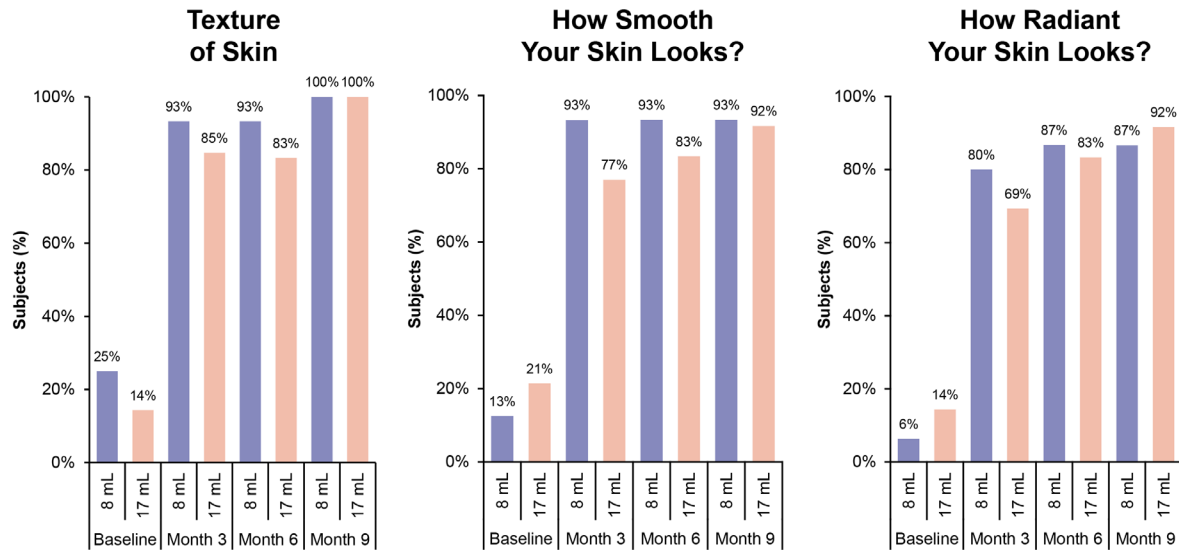
**GAIS Responder Rate at Months 6 and 9**

GAIS responder rates for aesthetic improvement of the décolletage area, defined as subjects reported as ‘improved’, ‘much improved’, or ‘very much improved’ on the GAIS, were 100% in both groups at month 6 (8 mL, 15/15; 17 mL, 12/12) and month 9 (8 mL, 15/15; 17 mL, 13/13) as assessed by investigators.

Subject-reported GAIS responder rates were also high at month 6 (8 mL, 15/15 [100%]; 17 mL, 12/12 [100%]) and at month 9 (8 mL, 15/15 [100%]; 17 mL, 11/12 [92%]). The comparison between

**FIGURE 2.** Subjects satisfied or very satisfied with overall appearance of wrinkles.



**FIGURE 3.** Subjects satisfied or very satisfied with skin texture, smoothness, and radiance

groups (17 mL group – 8 mL group) was -8.3% (95% CI: -24.0 to 7.3,  $P=0.444$ , Fisher's Exact test) at month 9.

#### SSQ at Months 6 and 9

Subject satisfaction was generally high in both treatment groups. From months 3 through 9,  $\geq 92\%$  of subjects in both groups were satisfied or very satisfied with the overall appearance of their wrinkles in the décolletage area (Figure 2).

With regard to skin quality attributes, the majority ( $\geq 83\%$ ) of subjects in both groups were satisfied with the texture, smoothness, and radiance of their skin in the décolletage area at months 6 and 9, compared to  $\leq 25\%$  at baseline (Figure 3).

At month 9,  $\geq 87\%$  of subjects in both groups were satisfied or very satisfied with the following aspects of their décolletage: the number and depth of wrinkles; skin crepiness; how firm and refreshed their skin looked; how young they looked and felt; how they looked showing off their upper chest in clothing; and how confident they felt about their upper chest (Table 2).

The majority of subjects in both groups ( $\geq 92\%$ ) also responded at month 9 that they would recommend the treatment to a friend and would receive the treatment again, and all subjects agreed that treatment results fulfilled or exceeded their expectations (Table 2).

#### Time to Return to Social Engagements

Based on subject diaries, the median time to feeling comfortable returning to social engagements was less than 1 day, ranging from 1.2–7.8 hours (8 mL group) and from 1.3–2.8 hours (17 mL group) across the 4 treatment sessions.

#### Skin Quality

A reduction in skin roughness occurred following treatment and was more prominent at month 6 than at month 9. The arithmetic mean roughness (SRa - average of the absolute values of the profile heights over the evaluation length) changed by a mean of -0.3 (standard deviation [SD]: 5.12) in the 8 mL group and by -3.6 (SD: 8.06) in the 17 mL group from baseline to month 6.

In terms of increased skin extensibility ( $U_e$  - immediate extensibility, 1 sec after force is applied), an increase from baseline was observed in both groups at month 6, suggesting improved elasticity and firming of the skin. Mean (SD) change from baseline at month 6 was 0.019 (0.2971), left; 0.081 (0.2254), right, in the 8 mL group; and 0.225 (0.2266), left; 0.159 (0.2633), right, in the 17 mL group.

Skin hydration (MoistureMeterD Compact), reported separately for the left and right sides of the décolletage, showed similar improvement in both treatment groups post-treatment. From baseline values of  $\sim 45$ – $46\%$ , medians increased by around  $\sim 5$ – $8$  percentage units to  $\sim 51$ – $52\%$  at month 6, and then remained at  $\sim 51$ – $53\%$  at month 9 (across both sides and both groups).

#### Safety Endpoints

After the first treatment session, 87.5% (8 mL group) and 100% (17 mL group) of subjects reported at least 1 pre-defined injection-related event, ie, pain (including burning), tenderness, redness, bruising, swelling, itching or other, in the 28-day diary, with bruising (87.5% 8 mL group; 100% 17 mL group) and tenderness (81.3%; 78.6%) as the most common in both groups. The pattern of symptoms was generally the same in both groups and across all treatment sessions.

TABLE 2.

Subject Satisfaction Questionnaire, Month 9		
n (%) subjects responding 'satisfied' or 'very satisfied'	8 mL SWFI (N=15)	17 mL SWFI (N=12)
1. The appearance of wrinkles overall?	15 (100.0)	11 (91.7)
2. The number of wrinkles?	15 (100.0)	11 (91.7)
3. The depth of wrinkles?	14 (93.3)	11 (91.7)
4. The texture of your skin?	15 (100.0)	12 (100.0)
5. How smooth your skin looks?	14 (93.3)	11 (91.7)
6. How firm your skin looks?	14 (93.3)	11 (91.7)
7. The crepiness of your skin?	14 (93.3)	12 (100.0)
8. How young your skin looks?	13 (86.7)	11 (91.7)
9. How radiant your skin looks?	13 (86.7)	11 (91.7)
10. How refreshed your skin looks?	13 (86.7)	11 (91.7)
11. How you look in clothing that shows your upper chest?	14 (93.3)	12 (100.0)
12. How young you feel when you think about your upper chest?	13 (86.7)	12 (100.0)
13. How self-confident you feel when you think about your upper chest?	14 (93.3)	12 (100.0)
14. How you feel about yourself when you think about your upper chest?	14 (93.3)	12 (100.0)
15. The appearance of your upper chest overall?	15 (100.0)	12 (100.0)
16. Are the results of the treatment . . .		
Worse than you expected?	0	0
About what you expected?	4 (26.7)	7 (58.3)
Better than you expected?	11 (73.3)	5 (41.7)
17. Would you recommend the treatment to a friend? 'Yes'	15 (100.0)	11 (91.7)
18. Would you do this treatment again? 'Yes'	14 (93.3)	11 (91.7)

N=number of subjects with available data at month 9

For the majority of subjects, the symptoms were tolerable and resolved within 2 weeks. Two subjects (14.3%) following treatment session 1 (tenderness and bruising), and 2 subjects (13.3%) following treatment session 2 (pain and bruising) in the 8 mL SWFI group had symptoms affecting daily activities. No subjects reported disabling symptoms.

AEs occurred in 31.3% (5/16) of subjects in the 8 mL group and 28.6% (4/14) in the 17 mL group. One subject (7.1%, in the 17 mL group) had an AE judged as treatment-related: injection site nodules (mild intensity), appearing on the day of the third treatment in the superior medial décolletage area. The nodules were injected with triamcinolone acetonide and fluorouracil and had resolved after 10 months. No AEs were serious or led to treatment discontinuation. There were no late onset AEs (occurring more than 21 days after treatment), and no AEs of special interest (respiratory abnormalities or visual disturbances).

## DISCUSSION

Treatment of the décolletage area with PLLA-SCA with both reconstitution options (8 mL or 17 mL SWFI) in this study resulted in high rates of wrinkle severity improvement on the GDS at month 9. Moreover, high rates of aesthetic improvement on the GAIS and subject satisfaction were consistently observed in both groups, in support of the effectiveness of either treatment option.

Overall, the safety results in this study were aligned with PLLA-SCA treatment of other indications<sup>7</sup> and treatment in the décolletage area was well tolerated with both reconstitution volumes (8 mL or 17 mL). Apart from the one AE considered as treatment-related, all AEs were assessed as unrelated to the study product or injection procedure. Pre-defined, expected, post treatment events reported in the subject diary were mostly tolerable and the vast majority of them resolved within 2 weeks. Prior breast augmentation was not an exclusion criterion per se

in the study unless it affected the planned treatment area of the décolletage. Injectors should therefore exercise care to make sure that any prior procedures will not interfere with the area to be injected.

Although the study was limited by an open-label design and a small population size, the results align well with other treatment indications in terms of effect onset and duration after PLLA-SCA treatment and add to the evidence already published on aesthetic treatment of the décolletage area with this product.<sup>12-15</sup>

Overall, PLLA-SCA at both reconstitution volumes appears to be a safe and effective treatment for the correction of wrinkles in the décolletage area and merits further investigation. The improvements were sustained over time and accompanied by a high level of subject satisfaction.

## CONCLUSION

The effectiveness of PLLA-SCA treatment of the décolletage area was high throughout the study with both reconstitution volumes (8 mL and 17 mL, +1 mL lidocaine) as shown by both GDS and GAIS. The majority of subjects were satisfied with the texture, smoothness, and radiance of their skin post-treatment. Treatment was well tolerated in both treatment groups.

## DISCLOSURES

John Joseph is a clinical trial investigator and paid speaker for Galderma. Melanie Palm is a clinical investigator, speaker, advisory board member, consultant for Galderma, and Abbvie/Allergan, a clinical investigator, speaker, consultant for Merz, and a clinical investigator for Ipsen. Daniel Bråsäter, Charlotta Wolgast, Felipe Weinberg, and Inna Prygova are employees of Galderma.

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