

# Results of Subject's Assessment of Behavior and Attitudes (SABA) survey toward psoriasis and treatments in the PSO-INSIGHTFUL study

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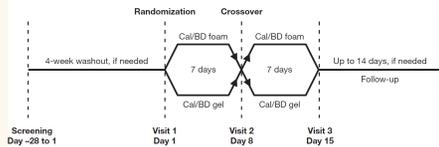
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## BACKGROUND

- Topical therapies are the first-line treatment for mild-to-moderate psoriasis or in combination with other therapies for severe disease.<sup>1</sup>
- Compliance to topical therapies is a significant problem, with adherence rates of just 40-70%.<sup>2</sup>
- Among other factors, it has been shown that patients' attitudes toward both psoriasis and its treatment influence compliance.<sup>3</sup>
- The PSO-INSIGHTFUL study was designed to assess patient-reported factors that influence preference following once-daily topical treatment with Cal/BD foam and gel. The SABA questionnaire was developed with the aim to gain insight into how patients' lives were impacted by psoriasis, and their attitudes to psoriasis and psoriasis treatments.<sup>4</sup>

## METHODS

Figure 1. PSO-INSIGHTFUL Study Design



- PSO-INSIGHTFUL was a prospective, multicenter, Phase IIIb, open-label, randomized, two-arm crossover study including patients  $\geq 18$  years with mild-to-severe psoriasis of  $\geq 6$  months' duration involving 2-30% BSA and mPASI of  $\geq 2$ . [NCT02310646]
- After 4-week washout, 213 patients were randomized 1:1 to once-daily Cal/BD foam for 1 week, followed by Cal/BD gel for 1 week, or vice-versa.
- Patients completed 6 questionnaires at different time periods evaluating patient preferences, one of which was a LEO-created survey titled the Subject's Assessment of Behavior and Attitudes (SABA) questionnaire, following randomization.

### The SABA questionnaire (13 questions)

- 6 yes/no questions on "impact of psoriasis"
- 7 questions on "attitudes to psoriasis and treatments" using a 5-point scale (-2 to +2)
- NOTE: more detail on questionnaires available at clinicaltrials.gov.

### Statistical analyses

- Full analysis set (FAS) comprised all randomized patients who completed an on-study questionnaire (212 patients).

## RESULTS

Table 1. Patient Demographics at Baseline

	All patients (n=212)
<b>Age category, n (%)</b>	
18-39 years	48 (22.6)
40-59 years	92 (43.4)
$\geq 60$ years	72 (34.0)
<b>Male:female, n (%)</b>	133:79 (63:37)
<b>BMI, n (%)</b>	
<25 kg/m <sup>2</sup>	37 (17.5)
25-30 kg/m <sup>2</sup>	73 (34.4)
>30 kg/m <sup>2</sup>	102 (48.1)
<b>PGA, n (%)</b>	
Mild	61 (28.8)
Moderate	122 (57.5)
Severe	29 (13.7)
<b>Duration of psoriasis, n (%)</b>	
<2 years	4 (1.9)
2-5 years	30 (14.2)
>5 years	178 (84.0)
<b>BSA, n (%)</b>	
<4%	93 (43.9)
4-6%	56 (26.4)
6-11%	38 (17.9)
11-15%	11 (5.2)
$\geq 15\%$	14 (6.6)
<b>mPASI, n (%)</b>	
2-5	86 (40.6)
5.1-10	91 (42.9)
>10	35 (16.5)
<b>Mean DLQI</b>	7.8
<b>Localized:widespread distribution of psoriasis, %</b>	62:38

BMI, body mass index; BSA, body surface area; mPASI, modified psoriasis and severity index; PGA, Physician's Global Assessment of disease severity

Table 2. Patient SABA Responses

Impact of Psoriasis	Yes, n (%)	No, n (%)	N/A, n (%)
Psoriasis impacts on my work	56 (26.4)	115 (54.2)	41 (19.3)
Psoriasis impacts on my social life	105 (49.5)	107 (50.5)	0
Psoriasis impacts on my relationships/sex life	73 (34.8)	137 (65.2)	0
Psoriasis has a physical impact on my life	85 (40.1)	127 (59.9)	0
Psoriasis impacts on my self confidence	125 (59.0)	87 (41.0)	0
Psoriasis impacts on my emotional well being	112 (53.1)	99 (46.9)	0

Attitudes to Psoriasis and Treatments	Strongly/slightly agree, n (%)	Neither agree nor disagree, n (%)	Strongly/slightly disagree, n (%)
I prefer my doctor to recommend the best treatment rather than offering me different options and letting me decide	159 (75.4)	18 (8.5)	34 (16.1)
I regularly seek out information about psoriasis	145 (68.7)	27 (12.8)	39 (18.5)
I am keen to try the newest treatments available	189 (90.0)	12 (5.7)	9 (4.3)
Being able to apply treatment quickly is very important to me	190 (90.1)	15 (7.1)	6 (2.8)
I have a busy lifestyle that limits time for treatment	111 (52.6)	41 (19.4)	59 (28.0)
I worry about the side effects of treatment	123 (58.2)	34 (16.1)	54 (25.6)
I feel very self-conscious about psoriasis	134 (63.8)	33 (15.7)	43 (20.4)

### Impact of Psoriasis

- About half of patients reported that psoriasis has an impact on self confidence (59.0%), emotional well being (53.1%), and social life (49.5%).
- Responses indicate that psoriasis also impacts work (26.4%), relationships/sex life (34.8%), and physical aspects (40.1%) of the lives of surveyed individuals.

### Attitudes to Psoriasis and Treatments

- More patients preferred that their doctors recommend the best treatment rather than being offered different options (75.4%) and/or regularly seek out information about psoriasis (68.7%).
- Majority of patients agreed with the statements "being able to apply treatment very quickly is very important to me" (90.1%) and "I am keen to try the newest treatments available" (90.0%).
- Approximately half of patients agreed with the statements "I have a busy lifestyle that limits time for treatment" (52.6%) and "I worry about the side effects of treatment" (58.2%).
- More patients reported that they feel self-conscious about psoriasis (63.8%) than not (20.4%).

## DISCUSSION

- Fewer patients agreed with the statements "I have a busy lifestyle that limits time for treatment" (52.6%) and "I worry about the side effects of treatment" (58.2%) as compared to the majority of patients whom agreed with statements "being able to apply treatment very quickly is very important to me" (90.1%) and "I am keen to try the newest treatments available" (90.0%).
- Psychosocial impairment is highly heterogeneous across populations of psoriasis patients; the results of this survey only speak to the population in this study since the SABA questionnaire is not a validated survey.
- While these supplementary data provide insight into patient attitude and behavior toward psoriasis and treatments, more research is necessary to obtain a complete understanding of the data presented.

## LIMITATIONS

- PSO-INSIGHTFUL was conducted in EU and Canada; no US subjects participated in the study.
- SABA responses should be interpreted in the context of the PSO-INSIGHTFUL study due to utilization of a LEO-designed survey.
- Statistical analysis was not performed for responses to SABA questionnaire; adjustments with baseline patient characteristics or treatment arm were not made.
- No specific analyses of different responses based on patient characteristics (age, gender, severity of disease) was conducted.

## CONCLUSION

- Results from the SABA questionnaire in the PSO-INSIGHTFUL study show that fewer patients reported psoriasis impacts interpersonal relationships (work and sex life), while more than half of patients reported psoriasis has a personal impact on their lives (self confidence and emotional wellbeing).
- Overall, SABA responses indicate patients' attitudes toward specific aspects of psoriasis treatment (i.e., quick treatment application, willingness to try newest treatments) are stronger than their worry of side effects or self-perception of lifestyles that limit time for treatment.
- While these supplementary data provide insight into patient attitude and behavior toward psoriasis and treatments, more research is necessary to obtain a complete understanding of the data presented.

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