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Sphaeranthus indicus (East Indian globe thistle)—a promising natural remedy for psoriasis

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Background: Cytokine(s), especially tumor necrosis factor—alfa (TNF- α), has been shown to play an important role in psoriasis. Extract of *Sphaeranthus indicus* (a well known Indian herb) has been found to inhibit the release of TNF- α and IL-12/23.

Objectives: To evaluate safety and efficacy of an orally administrable pharmaceutical dosage form containing the standardized extract of *S indicus* as an active ingredient in subjects with moderate to severe chronic plaque psoriasis.

Methods: The clinical activity of *S indicus* extract (1.4 g/day and 2.8 g/day) was examined in a double-blind, parallel group, placebo-controlled, prospective, multicenter study in subjects with moderate to severe psoriasis (74 subjects with PASI score 10) along with evaluation of adverse events, physical examination, clinically significant changes in laboratory parameters and ECG.

Results: Of the 74 subjects recruited, 47 completed the study per protocol. Forty percent and 23% of the subjects treated with 2.8 g/day and 1.4 g/day of *S indicus* extract achieved PASI75 response, whereas 14% of the placebo-treated subjects achieved PASI75. Fifteen percent of subjects treated with 2.8 g/day achieved PASI90 response. Histopathology and gene expression analysis also supported improvement in PASI score. Histopathology (hemotoxin—eosin staining) revealed complete absence of parakeratosis and neutrophils; restoration of granular layer; reduction in rete ridge elongation in epidermis and reduction in dilation of papillary capillaries and absence of neutrophils in dermal infiltrate in 35% and 38% of subjects receiving 2.8 g/day and 1.4 g/day of *S indicus* extract, respectively. Gene expression profiling (KRT-16, FABP-5, S100A9, TNF- α , serpin-B4, and interferon- γ) revealed response in 14 subjects in the 2.8 g/day group, five in the 1.4 g/day group, and the four subjects treated with placebo. Pyonephrosis (reported in 1 subject at 2.8 g/day) was the only serious adverse event (possibly) related to *S indicus* extract. One event of hyperchlorhydria and hyperglycemia was reported in 2.8 g/day and 1.4 g/day groups, respectively.

Conclusion: The results of this clinical study provide initial efficacy signal of *S indicus* extract administered over a 3-month period in moderate to severe psoriatic patients.