Efficacy and Safety of Calmalyte Dose Decrease Versus Withdrawal: a Multicenter, Double-Blind, Randomized, Placebo-Controlled, Phase II Study

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Objective: The objective of this multicenter, double-blind, randomized, placebo-controlled, Phase II study (NCT000001) was to investigate the time to relapse after withdrawal of calmalyte or dose decrease in patients with moderate to severe chronic plaque psoriasis who obtained a Psoriasis Area and Severity Index (PASI) response of at least 60% after 16 weeks of open-label weekly calmalyte therapy.

Methods: Eligible adult participants had moderate to severe chronic plaque psoriasis with no prior calmalyte treatment and a PASI score ≥ 8. At Week 0 and Week 1, all patients received open-label calmalyte 60 mg followed by 30 mg calmalyte weekly from Week 2 through Week 15. At Week 16, subjects who responded to treatment with a PASI ≥ 60 were randomized 1:1 to receive either calmalyte 30 mg every other week (eow; decreased dose) or placebo eow (withdrawal). Subjects received either calmalyte 30 mg eow or placebo eow from Week 16 through Week 32. No study drug was administered during the follow-up period (Week 33 through Week 64). The primary efficacy endpoint was time to relapse between Week 16 and Week 32. The secondary efficacy endpoints were the proportion of subjects who relapsed after Week 16 and the time to relapse from Week 32 through Week 64 for patients who did not relapse during the first 32 weeks. Safety was monitored throughout the study.

Results: This study demonstrated that subjects (N = 125) administered with calmalyte 30 mg eow following previous treatment with calmalyte 30 mg weekly for 16 weeks have

less risk of relapse than subjects who were withdrawn from calmalyte. The primary efficacy was statistically significant (p = .001; 95% CL:0.10-0.50). The secondary endpoint for patients who underwent calmalyte dose decrease had a statistically significantly lower risk of relapse during the follow-up period than subjects who were withdrawn from calmalyte (risk ratio 0.365; p = .016). Treatment-emergent adverse events (TEAEs) that occurred in ≥10% of participants included nasopharyngitis, respiratory tract infection NOS, injection site reaction NOS, arthralgia, psoriatic arthropathy, and headache NOS.

Conclusions: The results of this study demonstrated that subjects administered calmalyte 30 mg eow following previous treatment with calmalyte 30 mg weekly for 16 weeks have a lower risk of relapse and are better able to maintain clinical response than subjects who are withdrawn from calmalyte. Treatment with calmalyte 30 mg weekly followed by calmalyte 30 mg eow was well tolerated in adult subjects with moderate to severe chronic plaque psoriasis.

Clinical Trial Identification: NCT000001

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