Phase 3 FLASH Study Success!

HyBryte™ (hypericin) ointment 0.25%

FLASH (Fluorescent Light Activated Synthetic Hypericin) Study Findings:

- The largest multicenter, randomized, double-blind, placebo-controlled skin directed therapy study in MF/CTCL to date, enrolling a total of 169 patients with Stage IA, IB or IIA CTCL.
- Treatment is a combination of ointment application and, 18-24 hours later, visible light exposure.
    - HyBryte™ is activated by externally administered light at a wavelength of 500-650 nm, which provides ***deeper dermal penetration than ultraviolet (UV) light***.
- Treatments were administered twice weekly for the first 6 weeks and treatment response was determined at the end of the 8th week of each cycle. Treatment was administered as 3 cycles:
    - Cycle 1: ***placebo-controlled, double-blinded***
    - Cycle 2: Open-label, crossover, all patients receiving SGX301 on index lesions
    - Cycle 3: Open-label, optional, all patients receiving SGX301 on up to all index lesions
- Treatment responders were defined as those achieved a ≥50% improvement in cumulative CAILS score over 3 index lesions.
- In the first double-blind treatment cycle (Primary Endpoint) - there was a ***statistically significant improvement*** in the number of treatment responders (p-0.04) with 16% of the 116 patients receiving HyBryte™ versus 4% of the 50 receiving placebo treatment of their index lesions.
- Longer treatments improved response rates substantially.
    - Patients receiving 2 cycles of HyBryte™ had a ***40% response rate*** (p<0.0001, n=110)
    - Patients receiving 3 cycles of HyBryte™ had a ***49% response rate*** (p<0.0001, n=78)
- Patch and plaque lesions responded to HyBryte™ similarly
    - ***37% patch lesion response rate*** after 2 cycles of HyBryte™ (p=0.0009)
    - ***42% plaque lesion response rate*** after 2 cycles of HyBryte™ (p<0.0001)
- Compared to other, second-line, approved drugs for the treatment of CTCL, this response rate was shown to be as good or better than other treatments, with significantly less safety concerns.
    - ***Only 2.4% of AEs were SAEs***
    - ***Only 4% of AEs were severe***
    - Most frequent AEs were skin related events such as pruritus, erythema, hyperpigmentation, burning sensation, dermatitis, which were generally mild or moderate in severity and occurred in 16% of HyBryte™ treated patients vs 10% of the placebo patients
- Compared to other, second-line, approved drugs for the treatment of CTCL, HyBryte™ demonstrated significantly less safety concerns. HyBryte™ treated patients, lower than typically observed in other early stage CTCL trials, with a dropout rate on treatment ***of only 5%***.

Thanks to all site investigators, and especially our patients, for their contributions to developing this promising new therapy!

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