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Soligenix is a late-stage biopharmaceutical company committed to developing and commercializing products to treat rare diseases where there is an unmet medical need

HyBryte™ is a novel, first-in-class photodynamic therapy utilizing safe visible light for activation. The active ingredient in HyBryte™ is synthetic hypericin, a potent photosensitizer which is topically applied to skin lesions and then activated by visible light. Combined with photoactivation, hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from Cutaneous T-Cell Lymphoma (CTCL) patients.

A successful pivotal Phase 3 has been completed, demonstrating rapid onset of efficacy (within 6 weeks) and continued improvement with continued treatment, achieving outcomes other therapies may require months-years to attain in 18 weeks, and similar efficacy against patches and plaques, where other treatments typically work on patches but not plaques. HyBryte™ was well-tolerated throughout the study, with a significantly improved adverse event rate compared to other second-line treatment options.

Unmet Need

- Clinicians see a need for additional treatment options with fewer side effects
- Most patients cycle through several treatments over the course of their disease
- The chronic nature of early stage CTCL and dissatisfaction with current therapies provides an opportunity for HyBryte™

Positive Feedback

- Derms like the efficacy of HyBryte™, rapid response with equal effect on both patches and plaques
- Derms like the safety of HyBryte™, mainly the lack of UV exposure
- 4 of 5 Derms likely to prescribe HyBryte™

Efficient Commercialization

- Planned launch focused on high volume CTCL specialists
- Targeted sales force of ~20 reps; reaching >80% of high-volume prescribers
- Convenient end-to-end business solution for companion light device to customers

Sales Potential

- Anticipated U.S. launch 1Q 2024
- Estimated peak sales in the U.S. of approximately ~$90 M, with life cycle management upside. Competing 2nd line products with inferior profiles have achieved similar sales

HyBryte™
(hypericin) ointment 0.25%

$90 M
U.S. Annual Net Sales

HyBryte™ (hypericin) ointment 0.25%

"Topical hypericin ointment photodynamic therapy is effective and safe in CTCL (FLASH study)"

Ellen J. Kim, Brian Poligone, Aaron Mangold, Jennifer DeSimone, Lucia Seminario-Vidal, Henry Wong, Joan Guitart, James Appel, Larisa Geskin, Christopher Pullion, Richard Straube.

Society of Investigative Dermatology Meeting 2021

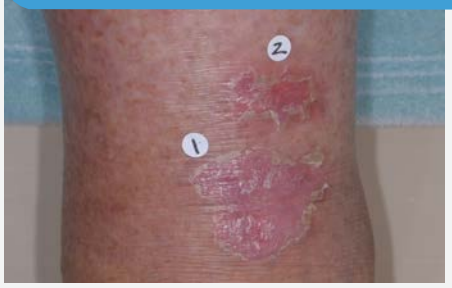
Key Study Findings

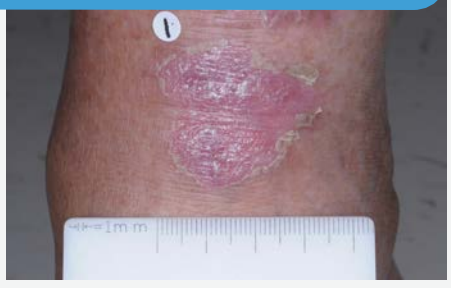
- Largest multicenter, randomized, double-blind, placebo-controlled skin directed therapy study in MF/CTCL to date enrolling a total of 169 patients with CTCL.
- Consisted of three treatment cycles. Treatments were administered twice weekly for the first 6 weeks and treatment response was determined at the end of the 8th week of each cycle.
- In the first double-blind treatment cycle, 116 patients received HyBryte™ treatment and 50 received placebo treatment of their index lesions. A total of 16% of the patients receiving HyBryte™ achieved at least a 50% reduction in their lesions to only 4% of patients in the placebo group at 8 weeks ($p=0.04$).
- In the second open-label treatment cycle, all patients received HyBryte™ treatment of their index lesions. Evaluation of 155 patients in this cycle demonstrated that the response rate among the 12-week treatment group was 40% ($p<0.0001$). Comparison of the 12-week and 6-week treatment groups also revealed a statistically significant improvement ($p<0.0001$) between the two groups, indicating that continued treatment results in better outcomes.
- The third (optional) treatment cycle (Cycle 3) was focused on safety and all patients could elect to receive HyBryte™ treatment of all their lesions. Of note, 66% of patients elected to continue with this optional compassionate use / safety cycle of the study. Of the subset of patients that received HyBryte™ throughout all 3 cycles of treatment, 49% of them demonstrated a treatment response ($p<0.0001$).
- Compared to studies in 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. In the FLASH study, the rate of serious adverse events was only 2.4%, with none related to the use of HyBryte™, and the rate of severe adverse events was only 4%.
- Skin related events such as pruritus, erythema, hyperpigmentation, burning sensation, dermatitis, occurred in only 16% of HyBryte™ treated patient's vs 10% of the placebo patients and were generally mild or moderate in severity.
- HyBryte™ is activated by externally administered visible light at a wavelength of 500-650 nm, which provides deeper dermal penetration than ultraviolet (UV) spectrum light. This resulted in statistically significant clinical responses observed in patches as well as deeper plaque lesions.
- Compared to studies in other, second-line, approved drugs for the treatment of CTCL, HyBryte™ demonstrated significantly less safety concerns. This was reflected in the low rate of study discontinuation attributed to adverse events which showed only a 5% overall drop-out rate during the treatment phase in HyBryte™ treated patients, lower than typically observed in other early stage CTCL trials.

HyBryte™ has not been evaluated by the US FDA and is not yet approved for sale in any jurisdiction.

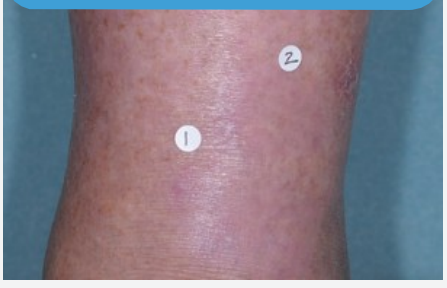
HyBryte™ (synthetic hypericin): index lesion complete

Baseline





C1/week 8



Except for the historical information contained herein, the matters discussed in this document are forward-looking statements, the accuracy of which is subject to risks and uncertainties. Please refer to the Soligenix most recent Form 10-K and Form 10-Q for additional information about the company and related risks.