Response in a patient with refractory folliculotropic mycosis fungoides to a topical hypericin cream activated with fluorescent light.

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I've got a mule and her name is Sal
Fifteen years on the Erie Canal
She's a good old worker and a good old pal
Fifteen years on the Erie Canal

We've hauled some barges in our day
Filled with lumber, coal, and hay
And every inch of the way I (we) know
From Albany to Buffalo

Erie Canal Completed 1825, 363 miles (584 km)

Disclosures

Honoraria

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Introduction

- Recommendations in the current National Comprehensive Cancer Network (NCCN) Guidelines for Mycosis Fungoides (Version 1.2020)for patients with early stage mycosis fungoides stage IA, IB, IIA are Skin Directed Therapies [1]

- Folliculotropism is a histologic feature than can occur irrespective of stage and is associated with a higher risk of disease progression.[1]

- Indeed, the recommendations for patients with early stage disease who have folliculotropism change in the the NCCN guidelines to skin-directed therapies reaching the subcutaneous tissue (e.g. PUVA or localized ionizing radiation) or systemic therapies[1]

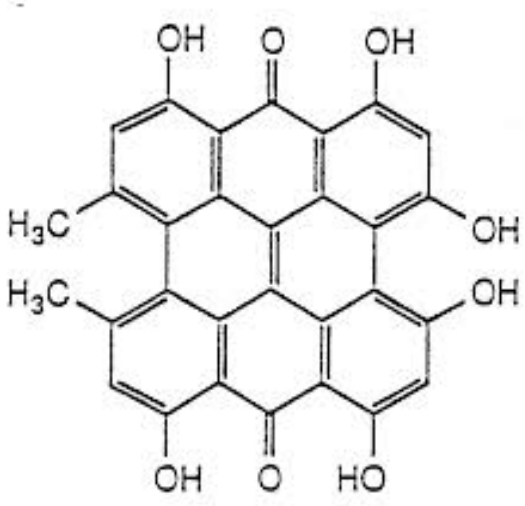
NCCN: National Comprehensive Cancer Network; PUVA: Psoralen with ultraviolet A phototherapy

1. NCCN clinical practice guidelines in oncology (NCCN guideline®) for primary cutaneous lymphomas. V.1.2020.

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study

Hypericin

- Hypericin is a natural photoactive compound found in stems and petals of plants of the genus *hypericum*
- Within this genus are eight families and 43 species, including the common St. John's wort
- SGX301 is hypericin that is chemically synthesized and is not extracted from plants



Hypericin Mechanism of Action

Reported modes of action[1]

- Generation of reactive oxygen species
- Generation of singlet oxygen species
- Anti-angiogenesis
- Induction of immune responses

Alteration of molecular pathways[2]

- Triggers intrinsic apoptotic pathway
- Triggers extrinsic apoptotic pathway
- Enhanced degradation of Heat Shock Protein 90
- ERK inhibition

1. Karioti, A, et al. Int J Mol Sci. 2010; 11(2); 562-594, 2. Yi, J, et al. Biosci Rep. 2015 April 20; 35(3).

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study

Randomized, double-blind, placebo controlled multicenter study (NCT02448381)

- Adults with early stage MF-CTCL
- 169 subjects
- 3 Cycles
- Primary Endpoint CAILS

Cycle	Lesions Treated	Ointment Used
1	3 index lesions	SGX301 or Placebo
2	3 index lesions	SGX301
3	All lesions	SGX301

CAILs: Composite Assessment of Index Lesions;

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study

Patient Description

- 46-year-old male with stage IB folliculotropic mycosis fungoides
- Failed on topical ultrapotent topical steroids, phototherapy (NBUVB), and oral bexarotene

NBUVB: Narrowband UVB Phototherapy;

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study

Baseline

End of Cycle 2

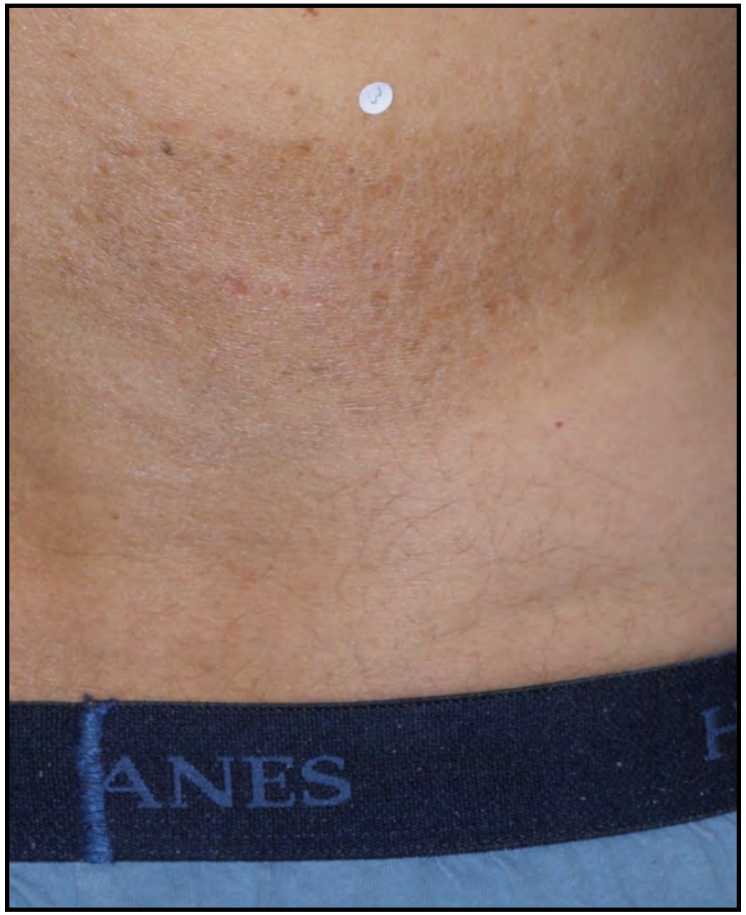
End of Cycle 3

CAIL measureable?

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study

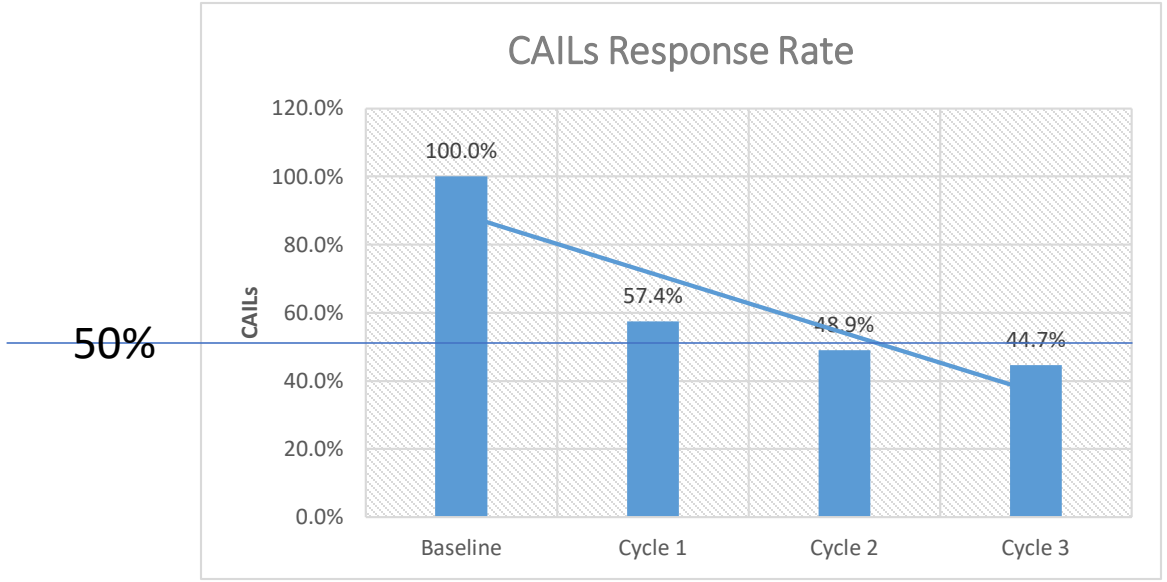
Baseline

End of Cycle 2



End of Cycle 3

Fluorescent Light Activated Synthetic Hypericin (SGX301) - FLASH Study



Currently the patient has complete clearance

Summary of Findings

- A patient with folliculotropic MF had a partial response after SGX301 hypericin therapy on the FLASH clinical trial.
- Several lesions showed completed resolution. Pustules and follicular papules cleared.
- Currently, the patient is clear with sunlight being his only additional therapy since hypericin (the patient had previously failed sunlight and office phototherapy with narrowband UVB).
- Hypericin with Fluorescent light may provide response in patient's with folliculotropic disease.

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