side effects of currently available treatments including prolonged topical corticosteroid or chemotherapy use or treatment with PUVA. This cautious approach to treating early-stage CTCL could place the patient at risk of an earlier and more accelerated progression to a more severe stage of disease with poorer prognosis (survival rates decrease as the level of cutaneous involvement increases).

In summary, patients diagnosed with early stages of disease are predominantly managed with skin directed therapies including topical corticosteroids, chemotherapy creams (chlormethine, mechlorethamine [Ledaga®]), phototherapy (UV treatments, such as PUVA) or radiotherapy (either local conventional radiotherapy or TSEBT). No specific photodynamic therapy or phototherapy, although used quite extensively, is approved for CTCL. Patients diagnosed with early-stage MF may also be monitored through watchful waiting where the disease is actively monitored without any lymphoma specific treatment. In that case, the patient will have regular check-ups with a specialist and treatment will be restricted to the use of a moisturizing cream and bath emollients to reduce symptoms. This approach largely reflects the limitations and potential toxicities of the available methods and treatments, and highlights the need for safe and efficacious therapies for early-stage CTCL.

There remains a need in the art to have a stable form of composition, combined with photodynamic therapy, in order to treat CTCL.

SUMMARY

In one aspect, the present disclosure refers to use of an effective amount of hypericin in the manufacture of a medicament for use in combinatorial therapy for treating CTCL, wherein said medicament is to be administered together with a form of visible light photodynamic therapy. The present disclosure also provides for a method of treating CTCL comprising applying a combination of an effective amount of hypericin together with a form of visible light photodynamic therapy. Preferably, the effective amount of hypericin is an ointment comprising less than 1% hypericin. More preferably, the form of photodynamic therapy comprises an administration of escalating doses of visible light. Optionally, the escalating doses of visible light starts at about 5 J/cm^2 and increases to a maximum dose of about 12 J/cm^2.

In one example, the escalating doses of visible light is increased by about 1 J/cm^2 from about 1 week to about 3 weeks. Optionally, the escalating doses of visible light will continue until about 12 J/cm^2 or until light erythema of the lesions is observed.

In one example, the administration of hypericin ointment is administered at least once weekly. In another example, the administration of hypericin ointment is administered at least twice weekly. Application of the ointment is followed by 12-24 hours of absorption into the skin, while covered, and then followed by a light exposure.

In another example, application of hypericin ointment and light treatment is continued twice weekly for at least 6 weeks.

In another example, the effective amount of hypericin is administered more frequently than the form of visible light photodynamic therapy. In an alternative example, the effective amount of hypericin is administered less frequently than the form of visible light photodynamic therapy.

BRIEF DESCRIPTION OF THE DRAWINGS

The following figures provide illustrative examples of the present invention and are incorporated by reference within this disclosure.

FIG. 1 shows an outline of the Phase III study supporting the preferred embodiment of the present invention.

FIG. 2 shows patient success rates over time (Cumulative Composite Assessment of Index Lesion Severity (CAILS) ≥50% Improvement from Baseline) Over Time (ITT).

DETAILED DESCRIPTION OF THE INVENTION