treatment, and therefore is only prescribed as a last resort. Furthermore, in patients with concurrent AD, this medication is not advisable due to its effects on the skin barrier and skin microbiome.

Thus, there are still large segments of the patient population for which there is no or insufficient treatment options for HE. This is especially true for people who use their hands in their jobs. Such people may not achieve a HECSI decrease of 75% (as will be described herein). For these and other reasons, there exists an unmet need for an improved treatment of HE. Such treatment should address the autoimmune cause of HE and, preferably, prevent or treat the autoimmune response that causes HE. Additionally, such treatment for HE should treat the people whose work or environment trigger HE and be able to treat chronic HE. Further, the treatment should address the itch (pruritus), and/or pain associated with HE. As with all therapeutic treatments, safety and toxicity remain a limitation, thus any improved treatments must not be attendant on unacceptable safety and toxicity profiles and provide a clinical benefit.

The present invention provides a therapeutic treatment for the treatment of HE that overcomes one or more of the challenges recognized above.

Summary

In a first aspect of the present disclosure, there is provided a use of baricitinib, or a pharmaceutical salt or formulation thereof, in the manufacture of a medicament for treating a patient in need of treatment for hand eczema.

In another aspect of the present disclosure, there is provided baricitinib, or a pharmaceutical salt or formulation comprising baricitinib, for use in treating hand eczema.

In a further aspect of the present disclosure there is provided baricitinib, or a pharmaceutical salt or formulation comprising baricitinib in pill form, for use in treating hand eczema.

Description

In some embodiments, a method of treating a patient in need of treatment HE is provided comprising administering to said patient an amount of baricitinib, or a pharmaceutically acceptable salt thereof, or a pharmaceutical formulation thereof. In some embodiments, the amount of baricitinib is administered orally. For example, the oral administration may comprise giving the patient a tablet that includes one or more excipients. In further embodiments, said pill comprises 4 mg of baricitinib, although other amounts of baricitinib may also be used.

Further embodiments comprise a method of treating a patient in need of treatment of one of HE by administering to said patient an amount of baricitinib, or a pharmaceutical formulation thereof, wherein the patient's HECSI score is assessed at Day 0 and then treatment with baricitinib is administered, and then the patient's HECSI score is re-assessed (such as, for example, after 16 weeks and 32 weeks, although other times may be used). In some embodiments, after the HECSI score is re-assessed, the patient's HECSI score has decreased. Patients may be assessed for their HECSI score, weekly, every two weeks, or monthly, etc. In further embodiments, the HECSI score is re-assessed before, during or after Week 16 of treatment with baricitinib. During some

What is Claimed Is:

1. Use of baricitinib, or a pharmaceutical salt or formulation thereof, in the manufacture of a medicament for treating a patient in need of treatment for hand eczema.

2. The use of claim 1, wherein the baricitinib is to be administered to the patient orally.

3. The use of any of claims 1-2, wherein the baricitinib is to be administered to the patient, and further comprising:

assessing the patient's HECSI score at Day 0 before administration of baricitinib; and

re-assessing the patient's HECSI score following the administration of baricitinib.

4. The use of claim 3, wherein the baricitinib is to be administered to the patient, and wherein the patient's HECSI score is re-assessed after 16 weeks of receiving a daily administration of baricitinib, wherein the HECSI score value assessed after week 16 is at least 75% lower than the HECSI score assessed on Day 0.

5. The use of any of claims 1-4, wherein the baricitinib is to be administered to the patient, and further comprising:

assessing the patient's EASI score at Day 0; and

re-assessing the patient's EASI score following the administration of baricitinib daily for 16 weeks.

6. The use of any of claims 1-5, wherein the baricitinib is to be administered to the patient, and further comprising:

assessing the patient's score at Day 0 in one or more of the following tests:

the patient's NRS itch score;

the vIGA-AD score;

the patient's HADS score;

the patient's HRQoL score;

the patient's IGA score;

the patient's mTLSS score;

the patient's WPAI score; and

re-assessing the patient's score in those tests following the administration of baricitinib daily for 16 weeks.

7. The use of any of claims 1-6, wherein the daily dose of baricitinib is 4 mg.

8. The use of any one of claims 1-7, wherein the baricitinib is in the form of a pill.

9. The use of any of claims 1-8, wherein the baricitinib is in the form of a 4 mg pill that includes one or more excipients.

10. Baricitinib, or a pharmaceutical salt or formulation comprising baricitinib, for use in treating hand eczema.

11. Baricitinib, or a pharmaceutical salt or formulation comprising baricitinib in pill form, for use in treating hand eczema.

12. Baricitinib, or a pharmaceutical salt or formulation comprising baricitinib, for use according to claim 10 or 11 wherein the baricitinib is in the form of a 4 mg pill that includes one or more excipients.

13. The use of claim 1, wherein the baricitinib is to be administered to the patient, and wherein the patient meets one or more of the following criteria prior to administration:

a HECSI score greater than to equal to 17,

an IGA score of greater than or equal 3;

greater than or equal to 1% BSA affected with HE; and

an EASI score greater than or equal to 7.

14. The use according to claim 1, wherein the baricitinib is to be administered to the patient, and wherein the patient meets the following criteria prior to administration:

a HECSI score greater than to equal to 17.

15. The use according to claim 1, wherein the baricitinib is to be administered to the patient, and wherein the patient meets the following criteria prior to administration:

an IGA score of greater than or equal 3.

16. The use according to claim 1, wherein the baricitinib is to be administered to the patient, and wherein the patient meets the following criteria prior to administration:

greater than or equal to 1% BSA affected with HE.

17 The use according to claim 1, wherein the baricitinib is to be administered to the patient, and wherein the patient meets the following criteria prior to administration:

an EASI score greater than or equal to 7.