

CLAIMS

What is claimed is:

1. Use of tasimelteon in the manufacture of a medicament for the treatment of autism spectrum disorder (ASD), wherein an effective dose of the medicament is to be administered to the patient to improve at least one symptom of ASD.

2. The use of claim 1, wherein the at least one symptom of ASD includes a symptom affecting social communication or interaction.

3. The use of claim 2, wherein the at least one symptom is selected from a group consisting of: avoidance of or inability to maintain eye contact; lack of facial expression; reduced use of gestures, including hand gestures; decreased sharing of interests with others; failure to point or look where others point; failure to notice when others are hurt or sad; failure to pretend in play; lack of interest in peers; difficulty understanding others' feelings or discussing the patient's own feelings; and failure to play games that involve turn-taking.

4. The use of claim 1, wherein the at least one symptom includes a symptom affecting restricted or repetitive behaviors or interests.

5. The use of claim 4, wherein the at least one symptom is selected from a group consisting of: lining up objects when upset or object order is changed; repetition of words or phrases (echolalia); playing with toys the same way every time; focusing on parts of objects; becoming upset by minor changes; obsessive interests; unusual adherence to routines; flapping of hands; body rocking; spinning in circles; and unusual reactions to sounds, smells, tastes, looks, or feels.

6. The use of claim 1, wherein the at least one symptom is selected from a group consisting of: delayed language skills; delayed movement skills; delayed cognitive or learning skills; hyperactive, impulsive, and/or inattentive behavior; epilepsy or seizure disorder; unusual eating or sleeping habits; sleep disturbances or impaired daytime functioning; gastrointestinal issues; unusual mood or emotional reactions; anxiety, stress, or excessive worry; and a lack of fear or more fear than expected.

7. The use of claim 1, wherein improvement of the at least one symptom includes an improvement in at least one measure selected from a group consisting of:

clinical global impression of change (CGI-C) scale, clinical global impression of severity (CGI-S) scale, patient global impression of change (PGI-C) scale, aberrant behavior checklist (ABC), patient global impression of severity behavior (PGI-S Behavior) scale, and patient global impression of change behavior (PGI-C Behavior) scale.

8. The use of claim 1, wherein the patient suffers from a sleep disturbance associated with autism spectrum disorder (ASD) and the dose of tasimelteon is effective to improve sleep, daytime functioning, or both,

wherein improved sleep includes an improvement in at least one measure selected from a group consisting of: clinical global impression of change (CGI-C) scale, clinical global impression of severity (CGI-S) scale, and patient global impression of change (PGI-C) scale; and

wherein improved daytime functioning includes an improvement in at least one measure selected from a group consisting of: aberrant behavior checklist (ABC), patient global impression of severity behavior (PGI-S Behavior) scale, and patient global impression of change behavior (PGI-C Behavior) scale.

9. The use of claim 8, wherein the sleep disturbance includes sleep latency of at least 45 minutes.

10. The use of claim 8, wherein the dose of tasimelteon is 20 mg.

11. The use of claim 10, wherein the tasimelteon is for administration once daily before bedtime.

12. The use of claim 11, wherein the tasimelteon is for oral administration without food.

13. The use of claim 8, wherein the dose of tasimelteon is 0.7 mg/kg.

14. The use of claim 13, wherein the tasimelteon is for administration once daily before bedtime.

15. The use of claim 14, wherein administering the tasimelteon is for oral administration without food.

16. Tasimelteon for use in the treatment of autism spectrum disorder (ASD).

17. The use of claim 1, wherein the patient is known to carry one or more variant in the retinoic acid induced 1 (RAI1) gene associated with reduced RAI1 function, wherein the one or more variant in the RAI1 gene is elected from a group consisting of the variants of Table 1.

18. The use of claim 17, wherein the one or more variant includes a frameshift variant selected from the group consisting of: a GA-to-AGC mutation at positions 444 and 445 of the RAI1 sequence and a C-to-CA mutation at position 5221 of the RAI1 sequence.