WHAT IS CLAIMED IS:

1. Use of (*R*)-N-(2,2-difluoroethyl)-7-methyl-l,2,3,4,6,7-hexahydro-[l,4]diazepino[6,7,l-hi]indole-8-carboxamide (Compound 1), or a pharmaceutically acceptable salt, hydrate, or solvate thereof, in the manufacture of a medicament for the treatment of developmental and epileptic encephalopathy (DEE) and other refractory epilepsies, in an individual in need thereof, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered *via* a titration scheme that comprises the up-titration of Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, until an optimized dose has been administered.

2. The use of claim 1, wherein the DEE is chosen from Lennox-Gastaut syndrome, Dravet syndrome, Doose syndrome (Epilepsy with Myoclonic Atonic Seizures (EM AS)), West syndrome (Infantile Spasms), Landau-Kleffner syndrome, and genetic disorders such as CDKL5 encephalopathy or CHD2 encephalopathy.

3. The use of claim 1, wherein the DEE is chosen from Ohtahara syndrome, Lennox-Gastaut syndrome, Dravet syndrome, Doose syndrome, West syndrome, Landau-Kleffner syndrome, tuberous sclerosis complex, CDKL5 encephalopathy, CHD2 encephalopathy, early myoclonic encephalopathy, epilepsy of infancy with migrating focal seizures, epilepsy with myoclonic-atonic seizures, and epileptic encephalopathy with continuous spike-and-wave during sleep.

4. Use of (*R*)-N-(2,2-difluoroethyl)-7-methyl-l,2,3,4,6,7-hexahydro-[l,4]diazepino[6,7,l-hi]indole-8-carboxamide (Compound 1), or a pharmaceutically acceptable salt, hydrate, or solvate thereof, in the manufacture of a medicament for the treatment of a seizure disorder in an individual in need thereof, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered to the individual in about 6-12 mg.

5. The use of claim 4, wherein the seizure disorder is selected from epilepsy, epilepsy with generalized tonic-clonic seizures, epilepsy with myoclonic absences, frontal lobe epilepsy, temporal lobe epilepsy, Landau-Kleffher Syndrome, Rasmussen's syndrome,

Dravet syndrome, Doose syndrome, CDKL5 disorder, infantile spasms (West syndrome), juvenile myoclonic epilepsy (JME), vaccine-related encephalopathy, intractable childhood epilepsy (ICE), Lennox-Gastaut syndrome (LGS), Rett syndrome, Ohtahara syndrome, CDKL5 disorder, childhood absence epilepsy, essential tremor, acute repetitive seizures, benign rolandic epilepsy, status epilepticus, refractory status epilepticus, super-refractory status epilepticus (SRSE), PCDH19 pediatric epilepsy, drug withdrawal induced seizures, alcohol withdrawal induced seizures, increased seizure activity and breakthrough seizures.

6. The use of any one of the preceding claims, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered to the individual and results in an improvement in the frequency of convulsive/motor seizures and other seizure types.

7. The use of claim 6, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered to the individual and results in an improvement in one or more of the following:

frequency of observed countable motor seizures;
number of total seizures;
frequency of non-convulsive seizure;
number of episodes of status epilepticus;
frequency of use of rescue medication; and/or
number of countable motor seizure-free days.

8. The use of any one of the preceding claims, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered to the individual and results in an improvement in the Subject/Caregiver and Investigator Clinical Global Impression of Improvement (CGI-I), the Investigator Clinical Global Impression of Severity (CGI-S), and/or the 55-item Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55).

9. The use of any one of the preceding claims, wherein the individual has a DEE but does not have Dravet syndrome or Lennox-Gastaut Syndrome.

10. The use of claim 9, wherein prior to administration, the individual had:
a history of onset of unprovoked seizures at 5 years of age or earlier;
a history of developmental delay;
a history of combined focal and generalized seizure types or multiple generalized seizure types;
a history of slow or disorganized electroencephalogram; and/or
no history of idiopathic generalized seizures.

11. The use of any one of claims 1 to 8 and 10, wherein the individual has Dravet syndrome.

12. The use of claim 11, wherein prior to administration, the individual had:
onset of seizures between 3 and 12 months of age in an otherwise healthy infant;
a history of seizures that were either generalized tonic-clonic or unilateral clonic or bilateral clonic;
normal initial development; and/or
a history of developmental delay.

13. The use of claim 11 or 12, wherein prior to administration, the individual had:
an emergence of another seizure type;
prolonged exposure to warm temperatures-induced seizures and/or seizures that were associated with fevers due to illness or vaccines, hot baths, high levels of activity, and sudden temperature changes, and/or
seizures were induced by strong natural and/or fluorescent lighting.

14. The use of any one of claims 11 to 13, wherein prior to administration, the individual had genetic test results consistent with a diagnosis of Dravet syndrome.

15. The use of any one of claims 1 to 8 and 10 to 14, wherein the individual has Lennox-Gastaut Syndrome.

16. The use of claim 15, wherein prior to administration, the individual had:
a history of tonic seizures or tonic/atonic seizures;

more than 1 type of generalized seizure, including but not limited to generalized tonic-clonic, tonic-atonic, atonic, tonic, myoclonic, or drop seizures;
a history of seizure before 8 years of age;
a history of developmental delay;
a previous electroencephalogram reporting diagnostic criteria for Lennox-Gastaut Syndrome (abnormal inter-ictal electroencephalogram background activity accompanied by inter-ictal slow spike-and-wave pattern ≤2.5 hertz or interictal generalized paroxysmal fast activity); and/or
an average of ≥4 observed drop seizures per 4-week while on stable ASM treatment.

17. The use of any one of the preceding claims, wherein the titration scheme comprises prescription and/or administration of Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, at an initial dose equivalent to 6 mg of Compound 1 three time daily for about five days and, provided that the individual tolerates the initial dose and that the individual has not had an adequate response, the dose is to be increased.

18. The use of claim 17, wherein the increased dose is equivalent to 9 mg of Compound 1 three time daily.

19. The use of claim 17 or 18, wherein the titration scheme further comprises Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, to be administered at the increased dose for about five days.

20. The use of any one of claims 17 to 19, wherein if the individual does not tolerate the increased dose, the optimized dose is the initial dose.

21. The use of any one of claims 17 to 19, wherein if the individual tolerates the increased dose and if the individual has had an adequate response, the optimized dose is the increased dose.

22. The use of claim 20 or 21, wherein the optimized dose of Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be further administered to the individual.

23. The use of claim 19, wherein if the individual tolerates the increased dose and if the individual has not had an adequate response, Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be administered with a further increased dose.

24. The use of claim 23, wherein the further increased dose is equivalent to about 12 mg of Compound 1 three times daily.

25. The use of claim 23 or 24, wherein if the individual does not tolerate the further increased dose, the optimized dose is the increased dose.

26. The use of claim 23 or 24, wherein if the individual tolerates the further increased dose and if the individual has had an adequate response, the optimized dose is the further increased dose.

27. The use of claim 25 or 26, wherein the optimized dose of Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is to be further administered to the individual.

28. The use of any one of the preceding claims, wherein Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof is to be administered to the individual and provides improvement in at least one symptom selected from ataxia, gait impairment, speech impairment, vocalization, impaired cognition, abnormal motor activity, clinical seizure, subclinical seizure, hypotonia, hypertonia, drooling, mouthing behavior, aura, convulsions, repetitive movements, unusual sensations, frequency of seizures and severity of seizures.

29. The use of any one of the preceding claims, further comprising down-titrating the Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

30. The use of any one of the preceding claims, wherein the Compound 1, or a pharmaceutically acceptable salt, hydrate, or solvate thereof, is an HCl salt of Compound 1.