ENROLLING AND ACTIVE CLINICAL TRIALS -NEREG

Please Reach Out to Hardik Rana, MBBS for More Information. hrana@epilepsygroup.com. 551-497-5000

Protocol	***Status***	***Ages***	***Inclusion / Exclusion***
Sponsor/Study Name SK Life/A phase 1, open label pharmacokinetic dose escalation study of Cenobamate (YKP3089) in Pediatric Subjects with POS.**YKP3089C039** PI – Dr. Segal- XCOPRI	Open for Enrollment.	Cohort 2b(4-6) : 4 open slots 3(2-3): 6 open slots	✓ DX POS ✓ Failed 2 previous AEDs ✓ May be on 1 to 3 AEDS ✓ If on Onfi must be off a least 30 days prior to Day 1.
Sponsor/Study Name SK Life/A phase 1, open label pharmacokinetic dose escalation study of Cenobamate (YKP3089) in Pediatric Subjects with POS.**YKP3089C039** PI – Dr Mahalingam XCOPRI	Open for Enrollment.	Cohort 2b(4-6) : 4 open slots 3(2-3): 6 open slots	✓ DX POS ✓ Failed 2 previous AEDs ✓ May be on 1 to 3 AEDS ✓ If on Onfi must be off a least 30 days prior to Day 1.
Sponsor/Study Name: SK Life/ "Open-Label Safety and Efficacy Study of Cenbamate (YKP3089) in Pediatric Subjects with Partial-onset (Focal) Seizures**"** **YKP3089C040** PI – Dr Segal XCOPRI	Open for Enrollment	Only Cohort 2 is open(4-12 years)	✓ DX with POS (Focal) ✓ May be on 1 to 3 AEDS Must have one POS within 8 weeks prior to baseline
Sponsor/Study Name: SK Life/ "Open-Label Safety and Efficacy Study of Cenbamate (YKP3089) in Pediatric Subjects with Partial-onset (Focal) Seizures**"** **YKP3089C040**	Open for Enrollment	Only Cohort 2 is open(4-12 years)	✓ DX with POS (Focal) ✓ May be on 1 to 3 AEDS ✓ Must have one POS within 8 weeks prior to baseline

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PI – Dr Mahalingam XCOPRI			
Sponsor/Study Name SK Life/ "A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Cenobamate Adjunctive Therapy in Subjects with Primary Generalized Tonic-Clonic Seizures" **YKP3089CO25** PI – Dr Segal- PEDS / Sub-I Dr Rafiuddin- Adults XCOPRI	OPEN for Enrollment	12-60 Years. Study is open for 12-18 years subjects only.	✓DX PGTC seizures ✓Must have 5 PGTC seizures 12 weeks prior to baseline ✓May be on 1 to 3 AEDS ✓VNS must be implanted a least 5 months prior to baseline ✓Excluded if they also have POS seizures or LGS DX
Sponsor/Study Name SK Life/ A Multicenter Open-label Extension Study to Evaluate the Long-term Safety of Cenobamate Adjunctive Therapy in Subjects with Primary Generalized Tonic Clonic Seizure (OLE for 025) **YKP3089CO33**	Open for Enrollment	12-60 years	
Sponsor/Study Name: SK Life/" A Randomized, Double-blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Carisbamate (YKP509) as Adjunctive Treatment for Seizures Associated with Lennox-Gastaut Syndrome in Children	Open for Enrollment	4-55 Years	✓ Documented HX of LGS ✓ Must have evidence of more than one type of seizure ✓ One of those seizure types must be either drop (atonic / tonic) or tonic-clonic seizures 6 months prior to baseline ✓ Drop seizures must have 2 with the potential to fall or tonic clonic seizures per week during the 4 wk baseline period ✓ Onset of LGS must be < 11 yrs. Old ✓May be on 1 to 4 AEDS

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and Adults, with Optional Open-Label Extension" YKP509 -- **YKP509COO3** PI – Dr Segal / Sub-I Dr Rafiuddin CARISBAMATE			
Sponsor/Study Name: Xenon Pharmaceuticals / A Randomized, Double-Blind Placebo-controlled multicenter Phase 3 Study to Evaluate the safety tolerability and efficacy of XEN1101 as adjunctive Therapy in focal -onset Epilepsy **XPF-008-301** PI – Dr Rafiuddin	Open for Enrollment	18-75 Years	✓ DX with POS (Focal) ✓ HX of only focal aware without motor seizures only will not be allowed ✓ May be on 1 to 3 AEDS ✓ During the 8-week baseline period must have more than 4 focal seizures within 28 days
Sponsor/Study Name A Multicenter, Open-label, Long-term, Safety, Tolerability, and Efficacy Study of XEN1101 in Adults Diagnosed With Epilepsy **XPF-008-304** **PI**- Asfi Rafiuddin	Open for Enrollment	18-75 Years	

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Sponsor/Study Name A Randomized, Double-blind, Placebo-Controlled, Multicenter, Phase 3 Study to Evaluate the Safety, Tolerability, and Efficacy of XEN1101 as Adjunctive Therapy in Primary Generalized Tonic-Clonic Seizures **XPF-008-303** **PI**- Asfi Rafiuddin	Open for Enrollment	>18 Years	✓ Dx with PGTCS ✓ On stable dose of 1 to 3 ASMs ✓ Must have at least 3 PGTCS during 8 week of screening ✓ Cannot have Hx of Status Epilepsticus Cannot have Hx of PNES
Sponsor/Study Name uniQure France SAS / "A Multi-center, Phase 1/2a, First-in-human (FIH) Study Investigating the Safety, Tolerability and Efficacy of AMT-260 in Adults with Unilateral Refractory Mesial Temporal Lobe Epilepsy (MTLE) Administered via Magnetic Resonance Imaging (MRI)-guided Convection-enhanced Delivery (CED)" CT-AMT-260-01 PI: Asfi Rafiuddin	Pending Site Activation	18-65 Years	✓ Dx of Unilateral Refractory MTLE ✓ Willingness to Undergo Surgical Procedure ✓ Average of 2 documented focal seizures per 30-day period for past 3 months. ✓ Cannot have any implant that is nor MRI compatible.
Sponsor/Study Name Biohaven Therapeutics, Ltd. / "A Phase 2/3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study to Evaluate the Efficacy, Safety and Tolerability of BHV-7000 in Subjects with Refractory Focal Epilepsy" **BHV7000-302** PI: Asfi Rafiuddin	Pending Site Activation	>18 Years	✓ DX with POS (Focal) ✓ HX of only focal aware without motor seizures only will not be allowed ✓ May be on 1 to 3 AEDS ✓ During the 8-week baseline period must have more than 4 focal seizures within 28 days