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BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner

v.

OVID THERAPEUTICS, INC.,
Patent Owner

Case PGR2023-00020
Patent 11,395,817

**SUPPLEMENTAL DECLARATION OF
MICHAEL SAPORITO**

I, Michael Saporito, declare as follows:

1. I worked as a consultant for Marinus from 2015-2020 and have been an employee of Marinus since 2020. My current title is Vice President of Research and Non-clinical Development.

2. I previously submitted a declaration, dated March 7, 2023, in this proceeding. I submit this declaration to provide additional information related to the matters discussed in my first declaration.

3. As I stated in my prior declaration, I stood by Saporito Poster 1 (Ex. 1013) when it was displayed at the meeting to interact with meeting attendees who chose to stop and view it. I was there by the poster during the time it was displayed, for about an hour and a half.

4. The poster shown at page 1 of Ex. 1013 is the same document that I remember displaying as a poster, standing by, and discussing with attendees at the meeting.

5. The full-page version of the poster at page 1 of Ex. 1013 is a small version of the large poster that was displayed at the meeting. The four partial pages that appear after that full-page version simply split the full-page version up and were added for this proceeding to make the data easier to read.

6. As I also stated in my prior declaration, I stood by Saporito Poster 2 when it was displayed at the meeting to interact with meeting attendees who chose to stop and view it. As with Saporito Poster 1, I was also there by Saporito Poster 2 during the time it was displayed, for about an hour and a half.

7. The poster shown at page 1 of Ex. 1014 is the same document that I remember displaying as a poster, standing by, and discussing at the meeting.

8. As with Ex. 1013, the full-page version of the poster at page 1 of Ex. 1014 is a small version of the large poster that was displayed at the meeting. The four partial pages that appear after that full-page version simply split the full-page version up and were added for this proceeding to make the data easier to read.

9. The Scientific Abstract Listing and Meeting Information Brochure for each AAN meeting is generally available for viewing online before the meeting occurs. That was no different for the AAN Meeting Brochure shown as Ex. 1012. In fact, the 2016 AAN Meeting Brochure shown as Ex. 1012 is still available online today at:

https://issuu.com/americanacademyofneurology/docs/16am_abstractlistingdigi_v14

24. I frequently view the brochures for these meetings online to look for posters and presentations of interest to me.

10. Furthermore, the full abstracts are generally available before the meeting occurs, as well. For the 2016 AAN Meeting, the Meeting Agenda and full

abstracts were published in the American Academy of Neurology's scientific journal, *Neurology*, in Issue 86 (16 Supplement) in advance of the meeting. The Table of Contents for that Issue (Exhibit 1034, attached) is still available on the publisher's website at https://n.neurology.org/content/86/16_Supplement. That issue includes the abstracts for my two posters (Exhibit 1029, attached and available at https://n.neurology.org/content/86/16_Supplement/P4.212 and Exhibit 1030, attached and available at https://n.neurology.org/content/86/16_Supplement/P2.020).

11. The slides included as Ex. 1016 are the slides that I used for my "Data Blitz" presentation, discussed in paragraphs 16 to 18 of my prior declaration, at the AAN meeting. I was personally involved in presenting and discussing these slides at the meeting. These slides themselves were not included in an abstract book or printed out for attendees, but were displayed on a screen while I was presenting and discussing the data. As I described in my previous declaration, a description of the Data Blitz is shown in the AAN Meeting Brochure at page 128.

Furthermore, the abstract for this "Data Blitz" presentation (Exhibit 1035, attached) was also included in *Neurology* Issue 86 (16 Supplement), and is still available today at https://n.neurology.org/content/86/16_Supplement/I11.003.

Supplemental Declaration of Michael Saporito
Proceeding No. PGR2023-00020

I declare under penalty of perjury that the foregoing is true and correct

Executed on SEPTEMBER 15, 2023



Michael Saporito

EXHIBIT 1034



Neurology®

April 5, 2016; 86 (16 Supplement)

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April 16, 2016

ePoster Session

Movement Disorders ePoster Session

INS Data Blitz

Redefining Parkinson's Disease: Novel Approaches to Understanding Its Mechanisms and Developing Treatments Data Blitz Presentations

Stroke in the Elderly and Young: Challenges for the Next Decade Data Blitz Presentations

Frontiers in Child Neurology: Cultivating Careers, Transitioning Care, and Highlighting Scientific Developments Data Blitz Presentations

INS Poster Session

Redefining Parkinson's Disease: Novel Approaches to Understanding Its Mechanisms and Developing Treatments Poster Presentations

Stroke in the Elderly and Young: Challenges for the Next Decade Poster Presentations

Frontiers in Child Neurology: Cultivating Careers, Transitioning Care, and Highlighting Scientific Developments Poster Presentations

Platform Session

Aging and Dementia: Therapeutics and Management

Multiple Sclerosis: Animal Models and In Vitro Studies

Neurology Education

Health Disparities and Sex Differences in Stroke

Movement Disorders: Parkinson's Disease and Atypical Parkinsonian Syndromes: Biomarkers

Global Health

Stroke Clinical Trials

Practice and Policy

Plenary

Contemporary Clinical Issues Plenary

Poster Discussion

Movement Disorders Poster Discussion Session

Poster Session I

Movement Disorders: Health Services/Outcomes Research

Movement Disorders: Cervical Dystonia

Movement Disorders: Dystonia

Movement Disorders: Tics, Tourette's Syndrome, and Other

Movement Disorders: Huntington's Disease

Epilepsy/Clinical Neurophysiology: Health Services and Outcomes Research

Movement Disorders: Miscellaneous

Epilepsy/Clinical Neurophysiology: Geriatric Epilepsy, Epidemiology, and Health Services

Epidemiology of Aging and Dementias

Neuroepidemiology: Aging and Dementia, Epilepsy, and Education

Neuroepidemiology: Cerebrovascular Disease

Cerebrovascular Disease: Epidemiology

Natural History, Outcome, and Epidemiology in Muscle Disorders and Myasthenia Gravis

Natural History and Outcome in Motor Neuron Diseases and Peripheral Neuropathies

Neuroepidemiology: Headache and Sleep

Headache: Health Services/Outcomes Research, Genetics, and Therapeutics

Headache: Other

Cerebrovascular Disease: Risk Factors and Prevention

Ischemic Stroke Outcomes

Acute Endovascular Therapy: Outcomes and Safety

Clinical ICH and ICH Outcomes

Re-admission and Stroke Outcomes

Cardiac Mechanisms and Complications of Stroke

Carotid Disease

Cerebral Venous Sinus Thrombosis

Aneurysms and Subarachnoid Hemorrhage

Cerebrovascular Disease: Health Disparities

Global Health: Non-communicable Disease

Global Health: Infectious Disease, Capacity Building, and Other

Herpes Virus Infections

CNS Tuberculosis and Cryptococcal Meningitis

Other Bacterial Infections

HIV/AIDS

Fungal and Other Infectious Disorders

PML, WNV, Rabies, and Other Viral infections

Practice, Policy, and Ethics

Practice

Practice, Policy, and Ethics: Patient Safety and Quality

Ethics and Policy

MS and CNS Inflammatory Disease: Risk Factors for Disease Progression and Treatment Response

April 17, 2016

ePoster Session

General Neurology and Infectious Disease ePoster Session

INS Data Blitz

New and Emerging Therapeutic Options in Migraine and Other Headache Disorders Data Blitz Presentations

Advances in Acquired and Genetic Muscle Diseases Data Blitz Presentations

Sex-related Factors in Neurological Disease Data Blitz Presentations

INS Poster Session

New and Emerging Therapeutic Options in Migraine and Other Headache Disorders Poster Presentations

Advances in Acquired and Genetic Muscle Diseases Poster Presentations

Sex-related Factors in Neurological Disease Poster Presentations

Platform Session

Neurorehabilitation: New Targets and Therapies

Child Neurology

Neuro Trauma and Sports Neurology

Neuromyelitis Optica and Autoimmune Encephalities

Highlights in Sleep Medicine

Epilepsy: Antiepileptic Drugs and Epidemiology

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Pain and Palliative Care

Poster Discussion

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Poster Session II

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MS and CNS Inflammatory Disease: Treatment Outcome Measures

MS and CNS Inflammatory Disease: Treatment Outcome Measures and Clinical Research

MS and CNS Inflammatory Disease: Treatment of NMO and Other CNS Diseases

MS and CNS Inflammatory Disease: MS Symptoms, Specific Symptoms Treatments, Comorbidities and Cost

Headache: Therapeutics

Aging and Dementia: Therapeutics

Alzheimer's Disease and Mild Cognitive Impairment

Aging and Dementia: Other

General Neurology: Diagnostics and Therapeutics

General Neurology

Treatments of Peripheral Neuropathies and Cramps

Acute Therapy: Thrombolysis and Adjuvant Therapy

Acute Endovascular Therapy: Other Considerations

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Movement Disorders: Parkinson's Disease Therapeutics

Movement Disorders: Therapeutics

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Education Research: Undergraduate Medical Education

Research Methodology and Education: Patient Safety and Quality

Research Methodology and Patient Education

History of Neurology

April 18, 2016

ePoster Session

MS and CNS Inflammatory Disease ePoster Session

INS Data Blitz

Future Directions and Challenges in Stroke Team Action Therapy (STAT) Data Blitz Presentations

The Human Connectome: Implications for Clinical Neurology Data Blitz Presentations

Emerging Technologies for Neurological Research and Care: #Emerging-Tech #Neurologist @AAN Data Blitz Presentations

INS Poster Session

Future Directions and Challenges in Stroke Team Action Therapy (STAT) Poster Presentations

The Human Connectome: Implications for Clinical Neurology Poster Presentations

Emerging Technologies for Neurological Research and Care: #Emerging-Tech #Neurologist
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Platform Session

Autonomic Disorders

Movement Disorders: Parkinson's Disease and Atypical Parkinsonian Syndromes:
Phenomenology

General Neurology

Aging and Dementia: Genetics

Epilepsy/Clinical Neurophysiology: Cognition, Emotion, Women, and Injury

Clinical Outcomes and Treatment Strategies in Multiple Sclerosis

Headache

Movement Disorders: Huntington's Disease

Poster Discussion

MS and CNS Inflammatory Disease Poster Discussion Session

Poster Session III

MS and CNS Inflammatory Disease: Clinical Trials

MS and CNS Inflammatory Disease: Switching and Comparator Studies I

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Clinical Aspects of Myasthenia Gravis and Congenital Myasthenic Syndromes

Acquired Peripheral Neuropathies: Clinical and Pathological Aspects

Clinical Trials in Muscle Diseases and Healthy Volunteers

Clinical Trials and Treatment of Myasthenia Gravis

Motor Neuron Disease: Clinical Trials, Treatment, and Outcome

Neurocritical Care: Clinical Science

Neurocritical Care: Clinical Science and Therapeutics

Neurocritical Care: Patient Safety and Quality

Stroke in the Young

Pediatric Epilepsy

Child Neurology and Developmental Neurology: Epilepsy, Hypoxia, and Stroke

Child Neurology and Developmental Neurology: Other

Neuro-oncology: Pediatric and Rare Tumors

Neurorehabilitation: Rehabilitation After Injury, ALS, and Parkinson Disease

Neurorehabilitation

Neuro Trauma and Sports Neurology

Neuroepidemiology: Global Health, Neuro Trauma, and CNS Inflammation

Neuroepidemiology: Movement Disorders, MS, and Stiff Person Syndrome

Movement Disorders: Parkinson's Disease Surgical Interventions

General Neurology

General Neurology: Clinical Practice

April 19, 2016

ePoster Session

Aging, Dementia, Cognitive, and Behavioral Neurology ePoster Session

INS Data Blitz

Sleep, Clocks, and Alzheimer's Disease Data Blitz Presentations

Remyelination and Repair in Multiple Sclerosis Data Blitz Presentations

INS Poster Session

Sleep, Clocks, and Alzheimer's Disease Poster Presentations

Remyelination and Repair in Multiple Sclerosis Poster Presentations

Platform Session

Movement Disorders. Essential Tremor and Tardive Dyskinesia

Clinical Trials and Experimental Therapies in Neuromuscular Diseases

Pediatric Multiple Sclerosis

Movement Disorders: Ataxias and Other Hyperkinetic Movement Disorders

Stroke Risk, Outcomes, and Complications

Neuroepidemiology

Neuro-oncology

Behavioral and Cognitive Neurology

Poster Discussion

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Imaging, Diagnosis, and Management: Other Dementias

Behavioral and Cognitive Neurology: Markers of Cognition

Behavioral and Cognitive Neurology: Clinical Imaging Correlates

Behavioral and Cognitive Neurology: Health Services and Assessment

EEG and Clinical Neurophysiology

MRI and Ultrasonography Studies in Peripheral Neuropathies

Imaging Studies in Muscle Diseases and Others

Imaging Studies and Clinical Features in Motor Neuron Disease

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Headache: Imaging and Other

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MS and CNS Inflammatory Disease: MRI Brain and Spinal Cord Atrophy Measures and Correlations in Multiple Sclerosis

MS and CNS Inflammatory Disease: Neuromyelitis Optica Spectrum Disorders: Imaging and Differential Diagnosis

MS and CNS Inflammatory Disease: Neuroimaging

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Epilepsy/Clinical Neurophysiology: Intraoperative Monitoring, Intracranial, and Long-term EEG

Epilepsy and Clinical Neurophysiology: Psychogenic Non-epileptic Seizures, Quality of Life, and Emotions

Epilepsy/Clinical Neurophysiology: Status Epilepticus

Epilepsy/Clinical Neurophysiology: Co-morbidities

Epilepsy/Clinical Neurophysiology: Patient Safety and Quality

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Neuro-oncology: Quality of Life

Neuro-oncology: Neuro-Imaging

Neuro-ophthalmology/Neuro-otology

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Movement Disorders Poster Session: Miscellaneous

Movement Disorders: Other

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Non-Atherosclerotic Arteriopathies

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General Neurology: Imaging in Clinical Diagnosis

April 20, 2016

ePoster Session

Neuromuscular Disease and Epilepsy ePoster Session

INS Data Blitz

Neurocritical Care and Neuroscience Crossroads: From Bench To Bedside Data Blitz Presentations

Amyloid and Beyond: From Bench to Bedside Data Blitz Presentations

INS Poster Session

Neurocritical Care and Neuroscience Crossroads: From Bench To Bedside Poster Presentations

Amyloid and Beyond: From Bench to Bedside Poster Presentations

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Aging and Dementia: Pathology and Imaging

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Clinical Trials Plenary

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Neuromuscular and Clinical Neurophysiology Poster Discussion Session

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Pathomechanism and Biomarkers in Muscle Diseases and Myasthenia

Biomarkers and Clinical Features of Motor Neuron Disease and Biomarkers in Peripheral Nerve Disorders

Genetics of Hereditary Motor Neuron Disease and Spastic Paraplegia

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Neuroepidemiology: Neuro-oncology and ALS

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Autonomic Disorders: Autonomic Neuropathies

Autonomic Disorders: Miscellaneous

Autonomic Disorders: Orthostatic Hypotension

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Child Neurology and Developmental Neurology: Genetics

Epilepsy/Clinical Neurophysiology: Genetics

Aging and Dementia: Neurogenetics

Aging and Dementia: Biomarkers

Aging and Dementia: Atypical Dementia

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MS and CNS Inflammatory Disease: Genetics and Therapeutics MOA

MS and CNS Inflammatory Disease: Neuromyelitis Optica Spectrum Disorders: Biomarkers and Animal Models

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April 21, 2016

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INS Data Blitz

Sports-related Concussion: Vision and Vestibular Insights Data Blitz Presentations

Practical Approaches to Narrowing the Epilepsy Treatment Gap Data Blitz Presentations

INS Poster Session

Sports-related Concussion: Vision and Vestibular Insights Poster Presentations

Practical Approaches to Narrowing the Epilepsy Treatment Gap Data Blitz Presentations

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MRI and OCT Outcomes in Multiple Sclerosis

Critical Care

IV-tPA and Endovascular Therapy

Neuro-ophthalmology/Neuro-otology

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Telestroke and Other Innovations and TIA

In-Hospital Stroke and Stroke Complications

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Intracerebral Hemorrhage and Cerebral Amyloid Angiopathy

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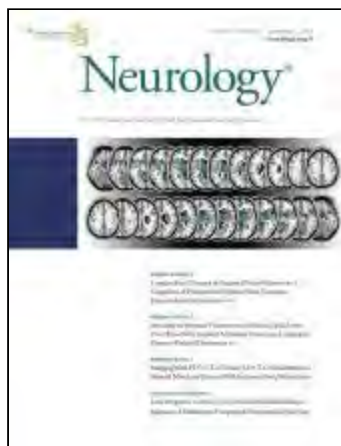
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EXHIBIT 1029

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April 05, 2016; 86 (16 Supplement) APRIL 19, 2016

Intravenous Administration of Ganaxolone Attenuates Electroencephalographic Seizures in a Diazepam Resistant Model of Status Epilepticus (P4.212)

Michael Saporito, Julia Tsai, Albena Patroneva

First published April 4, 2016,

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Abstract

Objective: These studies were designed to evaluate the potential of ganaxolone (GNX) for the treatment of status epilepticus (SE). Further studies were conducted to clarify the activities of GNX on the human progesterone (PGR) receptor. **Background:** Ganaxolone is an analog of the neurosteroid GABA modulator allopregnanolone (ALLO) and is in development for treatment of epilepsy. **Methods:** SE was induced by lithium chloride and pilocarpine administration to Sprague-Dawley rats. Seizure response was measured by electroencephalographic recordings through cortical electrodes. Compounds were administered via IV injections 15 or 60 minutes after SE onset. Seizure response was measured for 5 hrs. GNX and ALLO activities on PGR function were evaluated in HEK-293 cells containing the human PGR receptor. **Results:** Lithium-pilocarpine induced seizures were sustained for 6 hrs. This seizure activity was resistant to diazepam (10 mg/kg), but GNX (12 or 15 mg/kg; bolus IV) elicited a complete block of SE when administered 15 or 60 min after SE onset. The GNX antiepileptic activity was durable, with activity observed for at least 5 hrs. ALLO (15 mg/kg; IV) also blocked SE when administered 15 minutes after SE onset. However, the duration of antiepileptic activity was brief (<1 hr). Further, when administered 60 min after SE onset, ALLO only produced a minimal block of the seizure. GNX was devoid of any PGR activity, whereas ALLO (EC₅₀=270 nM) elicited a partial agonist response. **Conclusion:** GNX produced an anti-epileptic response in a diazepam resistant model of SE with IV injection. The GNX response was more durable and effective than ALLO. GNX is also available as an oral formulation allowing the possibility that GNX can be administered orally after SE to prevent subsequent seizure activity. Finally, data is presented showing that GNX is devoid of PGR activities, indicating that the risk of progesterone-mediated side-effects are minimal.

Disclosure: Dr. Saporito has nothing to disclose. Dr. Tsai has nothing to disclose. Dr. Patroneva has received personal compensation for activities with Marinus Pharmaceuticals, Inc.

Tuesday, April 19 2016, 8:30 am-7:00 pm

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EXHIBIT 1030

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Neurology®

April 05, 2016; 86 (16 Supplement) APRIL 17, 2016

Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus (P2.020)

Michael Saporito, Julia Tsai, Albena Patroneva, Steve White, Cameron Metcalf, Melissa L. Barker-Haliski

First published April 4, 2016,

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Abstract

OBJECTIVE: To test IV ganaxolone in a clinically translatable rodent model of status epilepticus (SE). **BACKGROUND:** Ganaxolone (GNX) is a synthetic analog of the endogenous neurosteroid GABA modulator allopregnanolone (ALLO) and is in development for treatment of epilepsy and other neuropsychiatric conditions. **DESIGN/METHODS:** Convulsive SE (CSE) was induced by the administration of lithium chloride and pilocarpine to male Sprague-Dawley rats. GNX (6, 9, 12 mg/kg) or ALLO (15 mg/kg) were administered via IV bolus injections at the time of CSE onset (time 0) or 15, 30 or 60 minutes after CSE onset, as measured by the first observed Racine Stage 3 seizure. Animals were observed for the presence of CSE (stage 3 or greater) for an additional 2 hours after compound administration. Animals that did not exhibit a convulsive seizure during that time period were considered protected. Twenty-four hours after CSE onset, surviving rats were sacrificed and blood collected for bioanalysis. **RESULTS:** Pilocarpine administration induced CSE in all animals. Vehicle administration did not affect seizure activity and notable (~50[percent]) death was observed 24 hours after CSE onset. GNX was able to halt CSE and produced a dose-dependent reduction in CSE at all time points. The ED₅₀ when administered at the onset of CSE (0 min time point) was 2.2 mg/kg, and at 60 min after CSE onset, the ED₅₀ was 6.2 mg/kg. Near complete survival was noted 24 hours after CSE onset for ALLO and all doses of GNX evaluated. **CONCLUSIONS:** IV bolus GNX produced a dose-dependent anti-convulsant effect. Administration of GNX promoted survival with activity similar to that observed with ALLO in a rat model of CSE. GNX reduced seizure activity when administration was delayed until 30 min and up to at least 60 minutes after CSE onset, a period of SE typically refractory to benzodiazepines.

Disclosure: Dr. Saporito has received personal compensation for activities with Marinus Pharmaceuticals, Inc. as a consultant. Dr. Tsai has nothing to disclose. Dr. Patroneva has received personal compensation for activities with Marinus Pharmaceuticals, Inc. Dr. White has received research support from Marinus Pharmaceuticals, Inc. Dr. Metcalf has received research support from Marinus Pharmaceuticals, Inc. Dr. Barker-Haliski has received research support from Marinus Pharmaceuticals, Inc.

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Ganaxolone Administered Intravenously Prevents Behavioral Seizures and Promotes Survival in the Rat Lithium-Pilocarpine Model of Status Epilepticus (I11.003)

Michael Saporito, Julia Tsai, Albena Patroneva, Steve White, Cameron Metcalf, Melissa L. Barker-Haliski

First published April 4, 2016,

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Abstract

OBJECTIVE: To test IV ganaxolone in a clinically translatable rodent model of status epilepticus (SE). **BACKGROUND:** Ganaxolone (GNX) is a synthetic analog of the endogenous neurosteroid GABA modulator allopregnanolone (ALLO) and is in development for treatment of epilepsy and other neuropsychiatric conditions. **DESIGN/METHODS:** Convulsive SE (CSE) was induced by the administration of lithium chloride and pilocarpine to male Sprague-Dawley rats. GNX (6, 9, 12 mg/kg) or ALLO (15 mg/kg) were administered via IV bolus injections at the time of CSE onset (time 0) or 15, 30 or 60 minutes after CSE onset, as measured by the first observed Racine Stage 3 seizure. Animals were observed for the presence of CSE (stage 3 or greater) for an additional 2 hours after compound administration. Animals that did not exhibit a convulsive seizure during that time period were considered protected. Twenty-four hours after CSE onset, surviving rats were sacrificed and blood collected for bioanalysis. **RESULTS:** Pilocarpine administration induced CSE in all animals. Vehicle administration did not affect seizure activity and notable (~50[percent]) death was observed 24 hours after CSE onset. GNX was able to halt CSE and produced a dose-dependent reduction in CSE at all time points. The ED50 when administered at the onset of CSE (0 min time point) was 2.2 mg/kg, and at 60 min after CSE onset, the ED50 was 6.2 mg/kg. Near complete survival was noted 24 hours after CSE onset for ALLO and all doses of GNX evaluated. **CONCLUSIONS:** IV bolus GNX produced a dose-dependent anti-convulsant effect. Administration of GNX promoted survival with activity similar to that observed with ALLO in a rat model of CSE. GNX reduced seizure activity when administration was delayed until 30 min and up to at least 60 minutes after CSE onset, a period of SE typically refractory to benzodiazepines.

Disclosure: Dr. Saporito has received personal compensation for activities with Marinus Pharmaceuticals, Inc. as a consultant. Dr. Tsai has nothing to disclose. Dr. Patroneva has received personal compensation for activities with Marinus Pharmaceuticals, Inc. Dr. White has received research support from Marinus Pharmaceuticals, Inc. Dr. Metcalf has received research support from Marinus Pharmaceuticals, Inc. Dr. Barker-Haliski has received research support from Marinus Pharmaceuticals, Inc.

Wednesday, April 20 2016, 1:00 pm-5:30 pm

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Michael Saporito, Julia Tsai, Albenia Patroneva, et al.
April 04, 2016

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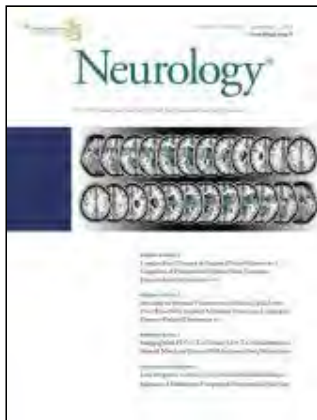
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