GARNETT McKEEN LABORATORY, INC.

INVESTIGATOR-INITIATED LAMC CLINICAL STUDIES
(11 studies; 8 INDs issued – numbers included)

- 2022–present: – David Conway RPA-C, MPAS (Compassionate Community Physicians P.C.) In this 2022 project low-dose LAMC (1/4 tsp/day) was utilized in a geriatric patient population to alleviate fatigue. A number of patients experienced unresolved wounds and infections. The clinical observation demonstrated that, after two weeks, this low dose of LAMC potentiated the immune system in chronically infected patients, allowing them to now respond to their treatment interventions. Mr. Conway noted decreases in respiratory infections, as well as skin and oral infections resolving.
- 2021: Dr. Raghav Govindarajan (Department of Neurology, University of Missouri Medical Center) This was an open-label, prospective study of ALS –associated fatigue (IND #152212). Nine patients were enrolled in this Amyotrophic Lateral Sclerosis pilot study, 7 men and 2 women, with 8 limb onset patients and 1 bulbar. Each patient took 4 teaspoons of LAMC supplement daily, over a 6-month interval. Monthly, patients were administered the ALS Quality of Life-50 (ALSQ-50), Modified Fatigue Impact Scale (MFIS) and the Montgomery and Asberg Depression Rating Scale (MADRS). The ALSQ-50 initially improved, but was not sustained over the 6 months, however, the fatigue scale and depression scales were statistically improved over the 6-month period.
- 2014: Dr. Lauren Krupp (Stony Brook Medical Center) - A Multiple Sclerosis-associated fatigue IND study (#112015) was recently completed at Stony Brook University Medical Center. Each patient took 4 teaspoons per day for 6 weeks. The patients were tested at their baseline visit and at the end of 6 weeks using three Multiple Sclerosis Fatigue Scales (Fatigue Severity Scale (FSS); PROMIS Fatigue; Multiple Sclerosis Fatigue Impact Scale (MSFIS)). There was a statistically significant decrease in each scale, leading the Principal Investigators to conclude that the product was “well tolerated and was associated with a clear reduction in fatigue severity and fatigue impact”.
- 2013: Dr. Rick Williams (Virginia Tech College of Osteopathic Medicine) – IND (#111268) was granted for this Phase II (safety and efficacy) study to examine the concurrent therapeutic benefit of the LAMC formulation in multiple myeloma patients (PAMS study). This study did not meet its recruitment goals.
- 2013: Drs. Candice Perkins and Agnes Kowalska (Stony Brook Medical Center) – DESSTINNI A was a non-randomized, open-label, un-blinded, prospective IND study (#107857) to evaluate safety and tolerability of 8 teaspoons of Poly MVA taken daily, over a 26-Week interval, followed by an 8-week washout period. All patients in this 2013 study received the standard of care therapy for their astrocytoma. It was reported that that more than half of the patients demonstrated an improved appetite and less fatigue. Additionally, observations included patients that had less constipation, improved breathing and improved infections (i.e. resolution of unresolved surgical site infection, alleviated bed sores). The team shared that all the patients exceeded the median survival time. Of the 10 patients who reached a clinical “safety” study endpoint: 3 patients showed a decrease in their primary tumor, 2

stopped growth (one of them showed resumed growth on the washout MRI), 3 who had stopped the Poly MVA at various points of the study all progressed, and two progressed. ○ 2010: Dr. Priyadarshini Kulkarni (Cipla Cancer Palliative Care and Training Centre) - A Palliative Care Study was conducted by the Indian pharmaceutical company Cipla Ltd. (Mumbai, India). Patients took the PdLA supplement Rejeneril-A for 24 days, followed by a 12 day clearance period. The following parameters demonstrated statistically significant patient improvement: Cognitive Functioning, Emotional Functioning, Social Functioning, Fatigue, Sleep Disturbances, and Appetite Loss.

- 2009: Dr. Gary Blick (CIRCLE MEDICAL LLC)) – Based on his pilot study demonstrating alleviation of HIV-associated fatigue and improved quality of life in AIDS patients, Dr. Blick applied for an IND (#107266) for the project entitled REFRESH (Rejeneril for Fatigue Dose Ranging Efficacy Study in HIV/AIDS). This IRB approved study was a prospective, multicenter, randomized, open-label, dose-ranging, comparative study. Since Stony Brook's DESSTINI-A glioblastoma study was approved shortly after this approval, the decision was made to fund that program.
- 2009: Dr. Candice Perkins (Stony Brook University) – The Department of Neurology at Stony Brook University completed a dose-escalation safety study and kinetics profile (DESSTINI) of the Palladium Lipoic Acid formulation (Poly MVA) in preparation for a formal glioblastoma program. This was an IRB approved study, which was monitored by a DSMB (Data Safety and Monitoring Board), as well as, being granted an IND (#77619) from the FDA.
- 2007: Dr. Jeff Mueller (Florida Hospital) – In collaboration with Florida Hospital's Cancer Institute, Dr. Mueller developed a post ovarian cancer treatment dose-escalation study for improved quality of life using the PdLA supplement, Poly MVA. An IND application (#75830) was approved by the FDA (6/07), however, funding restrictions did not allow the study to progress.
- 2006: Dr. Candice Perkins (Stony Brook University) – A university Phase I (SAFETY) study entitled PUNCH (Poly MVA Utilized as Neuroprotection against Chronic Hypertension) of PdLA supplement was completed. 13 research subjects received a single dose of Poly MVA (10 mL/day) for varying time periods. The product was deemed safe and a subsequent IND (#75604) was submitted to the FDA for Poly MVA use to treat the ischemic damage associated with chronic hypertension.
- 2004–2014: Dr. James Forsythe (Century Wellness Clinic) – Dr. Forsythe began collecting observational data in January of 2004 and has over 212 stage IV cancer patients in his observational cohort. His best responders are prostate, breast and lung cancer. The typical oral dosage used is 40 mL or 8 teaspoons per day. Treatment with Poly MVA or Poly MVA + chemotherapy provided a 6-year Overall Survival rate of 32%, while the average 5-year survival rate is 2.1% in all stage IV cancers, as reported in the Clinical Journal of Oncology.

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PRESENTATIONS AND ARTICLES

"Synthetic DNA Reductase" (Garnett), J. Bioinorg. Chem. V. 59, P. 231 Aug. '95, Lubeck

"Charge Relay from Molybdate Oxyradicals to Palladium Lipoic Complex to DNA" (Garnett and Garnett, Conference on Oxygen Intermediates in Nonheme Metallobiochemistry, 1996)

"Developmental Electronic Pathways and Carcinogenesis"(Garnett, Remo, and Krishnan, Sixth International Conference of Bioenergetic Medicine, 2002)

"DNA Reductase: A Synthetic Enzyme with Opportunist Clinical Activity Against Radiation Sickness"(Garnett and Remo, International Symposium on Applications of Enzymes in Chemistry, 2001)

"Increased Pseudoinductance in Paired Mixtures of Biopolymers is a Model for Twin Wire Mutual Inductance in RNA and DNA"(Garnett and Remo, 198th Meeting of Electrochemical Society, Abstract 1152, Phoenix 2000)

"Impedance Spectroscopy of DNA"(Garnett and Garnett, Journal of Inorganic Biochemistry, V.74, 1999)

"Mesophase Interactions Between Biological Polymers"(Garnett and Remo, 200th Meeting of Electrochemical Society, Abstract 1132, 2002)

"Pulsed Electrospinning of Biopolymers"(Garnett and Krishnan, 201st Meeting of Electrochemical Society, Abstract 78, Philadelphia 2002).

"Soluble Sensors of Telephonic Signals" (Garnett and Remo, 200th Meeting of Electrochemical Society, Abstract 185, 2000)

"Synthetic DNA Reductase"(Garnett, Journal of Inorganic Biochemistry, V.59, C48, p.231, 1995)

"Dissipative Impedance in a Doped Liquid Crystal"(Krishnan and Garnett, 1st Spring Meeting of the International Society of Electrochemistry, Abstract P06, Spain 2003)

"Dopant Catalyzed Charge Dissipation in a Liquid Crystal" (Krishnan and Garnett, 203rd Meeting of Electrochemical Society, Abstract 2703, Paris 2003)

"Duplex semiconductor behavior of mercury electrode in aqueous solutions" (Krishnan and Garnett, 226th American Chemical Society National Meeting, Abstract Inor.0028, New York 2003)

"A New Model for DNA Charge Transfer: Variable Electronic Circuitry" (Garnett and Krishnan, 204th Meeting of Electrochemical Society, Abstract 1377, Orlando 2003)

“Modulation of Impedance in DNA Solutions by Ions and Molecules: 1. Effect of Alkali Metal Ions” (Krishnan and Garnett, 204th Meeting of Electrochemical Society, Abstract 1378, Orlando 2003)

“Peroxide Doping of DNA Enables Dissipative Impedance” (Garnett and Krishnan, 204th Meeting of Electrochemical Society, Abstract 1379, Orlando 2003)