

MASARU KANEKO, M.D., CPI

PROFESSIONAL EXPERIENCE

Dr. Kaneko joined SNBL as a Clinical Research Physician after serving two years to the Matsudo Neurology Clinic in Japan as the Vice Director. Prior to this position Dr. Kaneko dedicated 17 years of practice to the care of patients with stroke and neurodegenerative diseases. He completed his residency in neurology and a fellowship in neurophysiology at Indiana University. Dr. Kaneko is a member of the American Board of Psychiatry and Neurology. He is also a member of the Japanese Societies of Neurology and Internal Medicine. Masura brings extensive publication and research experience to SNBL.

December 2006 – present
SNBL Clinical Pharmacology Center, Inc.
800 West Baltimore St. 5th and 6th Floor, Baltimore, Maryland 21201
Research Physician

December 2003 – March 2006
Matsudo Neurology Clinic, Japan
Vice Director

October 1994 – August 1997
Chiba University Hospital, Japan
Staff Neurologist

October 1992 – September 1994
Nakaizu Rehabilitation Center, Japan
Staff Neurologist

EDUCATION & TRAINING

1997 - 2000
Residency, Neurology
Indiana University

2000 - 2001
Residency, Internal Medicine
Indiana University

2001 - 2003

Fellow, Neurophysiology (EEG/Epilepsy & EMG/Neuromuscular)
Indiana University

1991 - 1992

Residency, Neurology
Chiba Emergency Medical Center

1990 - 1991

Residency, Neurology
Kofu City Hospital

1988 - 1990

Residency, Neurology
Chiba University Hospital

1989 - 1989

Residency, Internal Medicine
Chiba University Hospital

1988 - 1988

Residency, Otolaryngology
Chiba University Hospital

1982 - 1988

MD, Chiba University School of Medicine

CERTIFICATIONS & PROFESSIONAL LICENSURE

- Licensed Physician, State of Maryland
- Licensed Physician, State of Florida
- Licensed Physician, Japan
- Licensed Physician, State of Washington
- Licensed Physician, State of Michigan
- Licensed Physician, State of California
- Board Certified – Neurology, Japanese Society of Neurology
- Board Certified – Neurology, American Board of Psychiatry and Neurology
- Board Certified – Internal Medicine, Japanese Society of Internal Medicine
- BLS
- ACLS
- Certified Physician Investigator

PROFESSIONAL AFFILIATIONS & MEMBERSHIPS

- American Academy of Neurology
- Japanese Society of Neurology
- Japanese Society of Internal Medicine
- Neuropsychology Association of Japan

RECENT PUBLICATIONS

- Kaneko M, Yokohari K, Yomoda H, Ohishi Y, Kimura S, Matsushita Y, Ohki T, Kawauchi Y, Kitano K. Severe chronic aphasia improves after a long-term language training. Japanese Society of Neurology Annual Meeting, Kagoshima, Japan, May 2005.
- Kitano K, Moroo I, Nishimura C, Ohki T, Kawauchi Y, Kaneko M. Causes of headache and facial pain. Survey at a community-based neurology clinic- (Japanese Abstract). 2004
- Ohki T, Kawauchi Y, Kaneko M, Kitano K. A study on cases with asymptomatic cerebral microbleeds on T2-star-weighted MRI images (Japanese Abstract). 2004
- Kaneko M, Benson M, Kincaid J. Pattern of neuropathies in primary amyloidosis. Muscle Nerve 2003
- Kaneko M, Asconape JJ, Gerardot JM. Vagus nerve stimulation for the treatment of epilepsy: results of a patient survey on the efficacy of magnet-induced manual activation. Epilepsia 2002
- Kaneko M, Piccardo P, Ghetti B. Gerstmann-Straussler-Scheinker disease with codon 217 mutation in a family of Swedish origin. Indiana University neurology resident's topic paper 2001
- Kaneko M, Kincaid JC. Evaluating double-crush syndrome. Indiana University neurology resident's topic paper 1999
- Kaneko M, Arai K, Hattori T, Imai T. Parahippocampal pathology in Creutzfeldt-Jakob disease. Clinical Neuropathology 1999
- Fukutake T, Kuwabara S, Kaneko M, Kojima S, Hattori T. Sensory impairments in spinal multiple sclerosis: a combined clinical, magnetic resonance imaging and somatosensory evoked potential study. Clinical Neurology & Neurosurgery 1998
- Kaneko M, Kuwabara S, Hatakeyama A, Fukutake T, Hattori T. Guillain-Barre and virus-associated hemophagocytic syndromes contracted simultaneously following Epstein-Barr viral infection. Neurology 1997

RESEARCH EXPERIENCE

2009

- A Phase I Double-Blind, placebo-controlled, single-center dose escalation study to evaluate the safety and tolerability and pharmacokinetics of intramuscular administration of a new oxime
- A Phase I, Double-blind Crossover Study of the Acute Tolerability of Immediate Extended Administration of Methotrexate in Normal Healthy Volunteers.

- A Longitudinal Study in healthy Adult Volunteers Aged 18 to 85 Years to Describe Antibody Levels to Antigens Expressed by *Staphylococcus aureus* and β -Hemolytic Streptococci Species, and to Describe Carriage of These Bacteria
- A Phase 2a Randomized, Double Blind, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of a Trivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine (recombinant) in Healthy Adults

2008

- An open label, single dose, randomized, active controlled, two-period, two-sequence crossover pharmacokinetics study to assess the bioequivalence of the XXXX, a XXXX transdermal formulation versus Emsam 12mg/ day after a single dose in healthy volunteers.
- A phase 1 open label placebo controlled multiple dose study to evaluate the pharmacokinetics of XXXX for injection dosed twice and three times daily in healthy subjects.
- A Randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- A Phase I, Open Label, PET Study in Healthy Subjects Following a Single Oral Dose of XXXX
- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Schizophrenia.
- A placebo-controlled, ascending multiple-dose study to evaluate the safety and pharmacokinetics of XXXX in healthy subjects.
- An Open-Label Formulation Screening Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of a Single Dose and Multiple Doses of Delayed Release XXXX in Healthy Subjects.
- A randomized, open-label study to assess the effect of ketoconazole on XXXX pharmacokinetics and pharmacodynamics.
- A Randomized, Double-Blind, Sequential, Ascending Multiple Dose, Placebo Controlled, Parallel Group Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXXX in Healthy Young Male Subjects.
- A Randomized, Double-Blind, Placebo Controlled Vaccination-Challenge Study of XXXX to Determine Efficacy Against the Symptoms of Moderate to Severe *Campylobacter jejuni* Infection in Normal Healthy Volunteers.
- Single dose pharmacokinetics and safety/tolerability of two formulations of XXXX transdermal systems compared to oral XXXX in healthy volunteers
- An open-label study to assess the effect of XXXX inducers on XXXX pharmacokinetics and pharmacodynamics
- Additional cohort - A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A Three Part Study In Healthy Males and Females Assessing the Relative Bioavailability and Food Effect of Two Formulations of XXXX, the Estimated Bioavailability of XXXX, The Single and Repeat Dose Safety, Tolerability and Pharmacokinetics of Escalating Dose
- A randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- An open-label Phase I multiple dose trial to assess the safety, tolerability and efficacy of capsules containing cross-linked polyelectrolyte giving to ESRD patient.
- A 2-Period, 2-Panel, Double-Blind, Randomized, Placebo-Controlled Pilot Study of Experimental Models for the Assessment of the Perception of Potentially Injurious Heat in Household Settings After the Administration of XXXX in Healthy Subjects
- A Double-Blind, Randomized, Placebo-Controlled, 5-Arm Titration Study to Evaluate the Efficacy and Safety of XXXX When Compared With Valsartan and Olmesartan in Subjects with Essential Hypertension

- A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A multiple-center, single-ascending dose, randomized, observer-blinded, placebo-controlled, study to investigate the safety, tolerability, and pharmacokinetics of XXXX following intravenous administration in individuals with allergic rhinitis.
- A Phase II Dose Finding Study with XXXX in Subjects with Recurrent Episodes of Genital Herpes
- An open label, randomized assessment of the relative bioavailability of a single dose of XXXX administered as a 15mg tablet, one 5 mg tablet or five 1 mg tablets compared with the 15 mg capsule and the effect of a high fat meal on the bioavailability of
- An open-label, dose escalating study to evaluate the safety of intravaginal oxybutynin in subjects with urge urinary incontinence

2007

- A single-center, randomized, double-blind, placebo-controlled, single-dose, dose-escalation study to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic effects of XXXX administered to healthy, postmenopausal volunteers.
- A Phase I, double-blind, placebo-controlled, randomized study to assess the safety, tolerability and pharmacokinetics of single escalating doses of XXX in healthy volunteers
- A phase I study, assessing the pharmacokinetics of two formulations of Oxycodone and XXX compared with Oxycodone XXX consumed after chewing and with Oxycontin.
- An open-label, multiple-dose interaction study between XXXX and Metformin or Probenecid in healthy adult subjects.
- A Phase 1B, randomized, placebo-controlled clinical trial to study the safety and efficacy of XXXX in Hepatitis C infected patients.
- An open-label, non-randomized, one sequence, multi-center study to assess the effects of an oral contraceptive on the pharmacokinetics of XXXX in healthy female subjects
- A Pilot Single-Dose Study of the pharmacokinetics of two XXXX Fentanyl Transdermal Systems Compared to XXXX in Healthy Subjects.
- Single Dose Pharmacokinetics and Safety/Tolerability of Pramipexole Transdermal Systems Compared to Oral Pramipexole in Healthy Volunteers
- Randomized, single-center, open-label, 2-way crossover, 2-arm study with 3 treatments and 2 periods lasting 7 days each, minimum 7 day washout to determine the relative bioavailability of two XXXX Transdermal systems and to assess the wear characteristics
- Multicenter, Randomized, Double-Blind, Placebo-Controlled, Repeat-Dose Study to Determine the Safety, Pharmacokinetic Effects, and Efficacy of XXXX in Patients with Hypercholesterolemia.
- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Alzheimer's disease.
- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Schizophrenia.
- A phase I open-label, single ascending dose study of the safety, nasal tolerability and pharmacokinetics of XXXX intranasal granisetron delivered by XXXX in healthy volunteers.
- A placebo-controlled, ascending single-dose study to evaluate the safety and pharmacokinetics of XXXX in healthy subjects.
- A phase I, double-blinded study to evaluate the safety, tolerability, and immunogenicity of Pandemic Influenza plasmid DNA vaccines administered with the XXXX needle-free System.
- A phase I study to evaluate the safety, tolerability and immunogenicity of the pandemic influenza vaccines XXXX and XXXX.
- Single-dose, randomized, three-period cross over design study of the XXXX compared with the XXXX.

- A Phase II randomized, placebo-controlled clinical trial to study the safety and efficacy of XXXX in hepatitis C infected patients.
- A 52-Week, Randomized, Double-Blind, Parallel-group, Multi-center, Phase IIIB Study Comparing the Long-term Safety of XXXX Actuations Twice Daily to XXXX Actuations Twice Daily in Adult and Adolescent African American Subjects with Asthma
- Multi-center, randomized, double-blind active controlled parallel group study to investigate plasma folate, red blood cell folate and homocysteine levels during a 24 week oral administration of an OC containing folate compared to OC alone.
- A randomized, Double-Blind, Active-and Placebo-Controlled, Parallel- Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of XXXX Immediate-Release Formulation in Subjects Awaiting Primary Joint Replacement Surgery for End-Stage
- Blood draw to obtain the PBMC layer of cells from whole blood from MS patients
- A Multicenter, randomized, double-blind study to compare the efficacy and safety of patient-initiated XXXX to XXXX in immunocompetent adults with recurrent genital herpes.
- A Prospective, Multi-center Trial of XXXX Compared to Best Standard of Care in Patients with Progressive or Recurrent GBM.
- A Randomized, Double-Blind, Multiple-Site, Placebo Controlled, Parallel Design, Clinical Study to Evaluate the Bioequivalence of XXXX Compared to XXXX in Patients with Moderate to Severe Acne Vulgaris.
- A randomized, double-blind, Phase III study of the efficacy and safety to XXXX in subjects requiring NSAID treatment.
- Analysis of protein or RNA Levels of the Glutamate Transporters, XXXX.
- Efficacy and safety of 2 mg/day of XXXX on Sleep Maintenance Insomnia with a sub-study of the effect of XXXX on stable Type II Diabetes Mellitus: a one year, multi center, randomized, double-blind, placebo-controlled study.
- An Inhaled Mealtime Insulin with the XXXX plus Pioglitazone vs. Pioglitazone alone in Type 2 Diabetes: A 26-Week, Open-Label, Multicenter, Randomized, Parallel Trial to Investigate Efficacy and Safety
- Inhaled Mealtime Insulin with the XXXX Plus Metformin and Glimepiride vs. Rosiglitazone Plus Metformin and Glimepiride in Type 2 Diabetes: A 26-Week, Open-Label, Multicenter, Randomized, Parallel Trial to Investigate Safety and Efficacy

2006

- A Phase I, double blind, placebo-controlled single center trial to assess the safety, tolerability and pharmacokinetics of single dose and multiple dose escalations of XXX in healthy subjects.
- The Relative Bioavailability of Two Amphetamine Transdermal Systems (ATS) to XXXX 10 mg Orally Administered Capsule.