James K. Luu, M.D.

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CURRENT POSITION

2004 - Present	Retina Consultants of Southern Colorado, P.C. Colorado Springs, CO

EMPLOYMENT HISTORY

2002 - 2003	National Retina Institute Towson, MD

EDUCATION

1988 – 1992	Bachelor of Science in Biology, University of California – Irvine Irvine, CA
1992 – 1996	Doctor of Medicine, New York Medical College Valhalla, NY
1996 – 1997	Medicine Internship, UCLA – San Fernando Sylmar, CA
1997 – 2000	Ophthalmology Residency, Stanford University School of Medicine Stanford, CA
2000 – 2002	Retina Fellowship, Glaser – Murphy Retina Treatment Centers Towson, MD

HONORS & AWARDS

1992 – 1992	Alpha Epsilon Delta
1993 – 1996	Trustee's Scholarship
1995 – 1996	Alpha Omega Alpha

HOSPITAL PRIVILEGES

2004 – Present	Penrose-St. Francis Medical Center Colorado Springs, CO
2004 – Present	Memorial Hospital Colorado Springs, CO
2013 – Present	Pinnacle Surgery Center Colorado Springs, CO

LICENSURE

Current	Colorado
Inactive licenses	California, Maryland, Virginia, District of Columbia

PROFESSIONAL SOCIETIES

Alpha Omega Alpha
American Academy of Ophthalmology
American Society of Retina Specialist
Association for Research in Vision and Ophthalmology
Colorado Medical Society
El Paso County Medical Society

CLINICAL RESEARCH

Principal Investigator:

Adverum ADVM-022-02 (NAb)
Blood Specimen Collection Study for the ameasurement of Adeno-Associated Virus (AAV) Neutralizing Antibodies in Subjects with Neovascular (Wet) Age-Related Macular Degeneration

Adverum ADVM-022-01 (Optic)
An Open Label Phase I Study of ADVM-022 (AAV.7m8-aflibercept) in Neovascular (Wet) Age-Related Macular Degeneration

Ampio AP-05-002
A Randomized, Placebo-Controlled, Parallel, Double-Masked Study to Evaluate the Efficacy and Safety of Two Doses of Oral OPTINA in Adult Patients

Chengdu Kanghong KHB-1802 (Panda)
A Multicenter, Double-masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-related Macular Degeneration

Genentech FVF4579g (Harbor)
A Phase III, Double-Masked, Multicenter, Randomized, Active Treatment-Controlled Study of the Efficacy and Safety of 0.5 mg and 2.0 mg Ranibizumab Administered Monthly or on an As-Needed Basis (PRN) in Patients with Subfoveal Neovascular Age-Related Macular Degeneration

Genentech FVF4967g (Shore)
A Multi-Center Randomized Study Evaluating Dosing Regimens for Treatment with Intravitreal Ranibizumab Injections in Subjects with Macular Edema Following Retinal Vein Occlusion

Novartis CRTH258B2301 (Kestrel)

A Two-Year, Three-Arm, Randomized, Double-Masked, Multicenter, Phase III Study Assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Adult Patients with Visual Impairment due to Diabetic Macular Edema

Novartis CRTH258AUS04 (Merlin)

A multicenter, randomized, double-masked Phase 3a study to assess safety and efficacy of brolucizumab 6mg q4 weeks compared to aflibercept 2 mg q4 weeks in patients with neovascular age-related macular degeneration (nAMD) with persistent retinal fluid

Ophthotech OPH1002A (Eclipse)

A Phase 3 Randomized, Double-Masked, Controlled Trial to Establish the Safety and Efficacy of Intravitreous Administration of Fovista (Anti PDGF-B Pegylated Aptamer) Administered in Combination with Lucentis Compared to Lucentis Monotherapy in Subjects with Subfoveal Neovascular Age-Related Macular Degeneration

Ophthotech OPH1004 (Solaris)

A Phase 3 Randomized, Double-Masked, Controlled Trial to Establish the Safety and Efficacy of Intravitreous Administration of Fovista (Anti-PDGF-B Pegylated Aptamer) Administered in combination with Either Avastin or Eylea Compared to Avastin or Eylea Monotherapy in Subjects with Subfoveal Neovascular Age-Related Macular Degeneration

Quark QRK207

A Phase 2/3, Randomized, Double-Masked, Sham-Controlled Trial of QPI-1007 Delivered By Single or Multi-Dose Intravitreal Injection(s) to Subjects with Acute NonArteritic Anterior Ischemic Optic Neuropathy (NAION)

Regeneron R2176-3-AMD-1303

An Open-Label, Dose Escalation Study of the Safety and Tolerability of Intravitreal REGN2176-3 in Patients with Neovascular Age Related Macular Degeneration/Phase 1

Regeneron R2176-3-AMD-1417 (Capella)

A Phase 2, Double-Masked, Randomized, Controlled, Multiple-Dose, Regimen-Ranging Study of the Efficacy and Safety of Intravitreal REGN2176-3 in Patients with Neovascular Age-Related Macular Degeneration

Regeneron VGFT-OD-0605 (View 1)

A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects with Neovascular Age-Related Macular Degeneration

Regeneron VGFTe-AMD-1124, Phase IV (Review)
An Open-Label Study of the Efficacy, Safety and Tolerability of Intravitreal Administration of VEGF Trap-Eye (Intravitreal Aflibercept Injection) in Patients with Neovascular Age-Related Macular Degeneration

Samsung SB11-G31-AMD
A Phase III Randomized, Double-masked, Parallel Group, Multicenter Study to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity between SB11 (proposed ranibizumab biosimilar and Lucentis in Subjects with Neovascular Age-related Macular Degeneration

Sub-Investigator:

Aerpio AKB-9778-CI-5001 (Time-2B)
Phase 2 Double-masked, Placebo-controlled Study To Assess The Safety And Efficacy Of Subcutaneously Administered AKB-9778 15mg Once Daily Or 15mg Twice Daily For 12 Months In Patients With Moderate To Severe Non-Proliferative Diabetic Retinopathy

Alcon C-12-074
Advanced AMD Phase 1 trial-A Multicenter, Open-Label, Single Ascending Dose Study to Assess the Safety, Tolerability, and Serum Pharmacokinetics of Intravitreal CLG561 in Subjects with Advanced Age-Related Macular Degeneration

Alcon LHA510-2201
A Randomized, Double-Masked, Vehicle-Controlled Proof-of-Concept Study for Topically Delivered LHA510 as a Maintenance Therapy in Patients with Wet Age-Related Macular Degeneration

Alcon C-12-006 (Osprey)
A Prospective, Randomized, Double-Masked, Multicenter, Two Arm Study Comparing the Efficacy and Safety of ESBA1008 versus EYLEA in Subjects with Exudative Age-Related Macular Degeneration

Alcon C-10-083 (see)
Safety and Efficacy Study of ESBA1008 versus Lucentis for the Treatment of Exudative Age-Related Macular Degeneration

Alcon/Novartis RTH258-C001 (Hawk)
A Two-Year, Randomized, Double-Masked, Multicenter, Three-Arm Study Comparing the Efficacy and Safety of RTH258 versus Aflibercept in Subjects with Neovascular Age-Related Macular Degeneration

Allegro DME-202B (Del Mar)
A Phase 2 Multicenter, Randomized, Controlled, Double-Masked Clinical Trial Designed to Evaluate the Safety and Exploratory Efficacy of Luminate (ALG-1001) as Compared to AVASTIN in the Treatment of Diabetic Macular Edema

Allergan 206207-024 (Ozurdex)
A Multicenter, Open-label, Randomized Study Comparing the Efficacy and Safety of 700ug Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) to Ranibizumab in Patients with Diabetic Macular Edema/Phase

Allergan 190342-038 (Beacon)
Safety and Efficacy of Brimonidine Posterior Segment Drug Delivery System in Patients with Geographic Atrophy Secondary to Age-related Macular Degeneration

Allergan 150998-004 (Palm)
Evaluation of Abicipar Pegol (AGN-150998) in Patients with Decreased Vision Due to Diabetic Macular Edema

Fast Track/60° Pharmaceuticals 60PH04 (Tafenoquine)
Multisite, Randomized, Double Blind, Placebo-Controlled Study to Assess the Long-Term Safety of Tafenoquine

Genentech/Roche GX28228 (Ladder)
A Phase II, Multicenter, Randomized, Active Treatment-Controlled Study of the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients with Subfoveal Neovascular Age-Related Macular Degeneration

Genentech/Roche GR39821 (HtrA1)
A Phase I, Multicenter, Open-Label, Single-Dose, Dose-Escalation, and Multiple-Dose Study of the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravitreal Injections of RO7171009 in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

Genentech/Roche GR40398 (Rhine)
A phase III, multicenter, randomized, double-masked, active comparator-controlled study to evaluate the efficacy and safety of RO6867461 in patients with diabetic macular edema

Genentech/Roche GR40306 (Tenaya)
A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab In Patients With Neovascular Age-Related Macular Degeneration

Genentech/Roche GX30191 (Omaspect)
A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Lampalizumab in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration who have Completed a Roche-Sponsored Study

Genentech/Roche GX29185 (Spectri)
A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Assess the Efficacy and Safety of Lampalizumab Administered Intravitreally to Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

Genentech/Roche BP29647 (Avenue)
A Multiple-Center, Multiple-Dose and Regimen, Randomized, Active Comparator Controlled, Double-Masked, Parallel Group, 36 Week Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO6867461 Administered Intravitreally in Patients with Choroidal Neovascularization Secondary to Age-Related Macular Degeneration

Genentech/Roche BP30099 (Boulevard)
A Multiple-Center, Multiple-Dose, Randomized, Active Comparator-Controlled, Double-Masked, Parallel Group, 36 Week Study to Investigate the Safety, Tolerability, Pharmacokinetics and Efficacy of RO6867461 Administered Intravitreally in Patients with Diabetic Macular Edema

Genentech/Roche CR39521 (Stairway)
Simultaneous Blockade of Angiopoietin-2 and VEGF-A with the Bispecific Antibody RO6867461 (RG7716) for Extended Durability in the Treatment of Neovascular Age-Related Macular Degeneration

MacTel NHOR Registry
A Natural History Observation and Registry Study of Macular Telangiectasia Type 2

Neurotech pharmaceuticals NTMT-03-A
A Phase III Multicenter Randomized, Sham Controlled, Study to Determine the Safety and Efficacy of Renexus in Macular Telangiectasia type 2

Novartis CLFG316A2203
A Multicenter, Randomized, Sham-Control, Proof-of-Concept Study of Intravitreal LFG316 in Patients with Geographic Atrophy Associated with Age-Related Macular Degeneration

Novartis CRTH258A2301E1 (Hawk)
A 24 week, double-masked, multicenter, two-arm extension study to collect safety and efficacy data on brolucizumab 6 mg drug product intended for commercialization in patients with neovascular age-related macular degeneration who have completed the CRTH258A2301 study

Novartis CRTH258C2301 (Raptor)
An Eighteen-Month, Two-Arm, Randomized, Double-Masked, Multi-Center, Phase III Study Assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Adult Patients with Visual Impairment due to Macular Edema secondary to Branch Retinal Vein Occlusion (RAPTOR)

Novartis CRTH258C2302 (Raven)

An Eighteen-Month, Two-Arm, Randomized, Double-Masked, Multi-Center, Phase III Study Assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Adult Patients with Visual Impairment due to Macular Edema secondary to Central Retinal Vein Occlusion (RAVEN)

Opthea OPT-302-1002

A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with neovascular age-related macular degeneration (wet AMD)

Opthea OPT-302-1003

Phase 1b/2a Study of OPT-302 In Combination With Aflibercept For Persistent Central-involved Diabetic Macular Edema

Pan Optica PAN-01-101

A Phase 1 Open-Label, Multi-Center Trial with Randomization to Dose to Evaluate the Safety and Tolerability of Topical Ocular PAN-90806 in Patients with Neovascular Age-Related Macular Degeneration (AMD)

pSIVIDA PSV-FAI-001

A Phase III, Multi-National, Multi-Center, Randomized, Masked, Controlled, Safety and Efficacy Study of a Fluocinolone Acetonide Intravitreal (FAI) Insert in Subjects with Chronic Non-infectious Uveitis Affecting the Posterior Segment of the Eye

pSIVIDA PSV-FAI-006

A Controlled, Multi-Center Study of the Utilization and Safety of the MK II Inserter and the Safety of the FAI Insert in Subjects with Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Regeneron VGFT-OD-1009 (Vista)

A Double-Masked, Randomized, Active-Controlled, Phase 3 Study of the Efficacy and Safety of Intravitreal Administration of VEGT-Trap-Eye in Patients with Diabetic Macular Edema

Regeneron VGFTe-OD-1411 (Panorama)

A Phase 3, Double-Masked, Randomized Study of the Efficacy and Safety of Intravitreal Aflibercept Injection in Patients with Moderately Severe to Severe Nonproliferative Diabetic Retinopathy

Regeneron VGFTe-RVO-1027 (Vibrant)

A Double-Masked, Randomized, Active-Control Study of the Efficacy, Safety and Tolerability of Intravitreal Administration of VEGF Trap-Eye (Intravitreal Aflibercept Injection) in Patients with Macular Edema Secondary to Branch Retinal Vein Occlusion

Regeneron R910-3-DME-1518 (Ruby)
A Randomized, Double-Masked, Active-Controlled, Phase 2 Study of the Efficacy, Safety and Tolerability of Repeated Doses of Intravitreal REGN910-3 in Patients with Diabetic Macular Edema

Tyrogenex X82-OPH-201
A Randomized, Double-masked, Placebo-controlled, Dose-finding, Non-inferiority Study of X-82 plus prn IVT Anti-VEGF Compared to prn IVT Anti-VEGF Monotherapy in Neovascular AMD/Phase 2b

PREVIOUS RESEARCH

Maggot Debridement Therapy
Assistant to Dr. Ronald Sherman (1990 – 1992)

Assessment of Topical Ketoconazole Ophthalmic Solutions
Assistant to Dr. James Guzek (1996)

Luu, J.K., Ta, C.N., Singh, K. Evaluation of Induced Post-operative Astigmatism Following Combined Trabeculectomy with Cataract Surgery. Presentation AAO (1997)

Luu, J.K., Manche, E. Patient Satisfaction Following Toric PRK Using The Summit Apex Plus Laser. Presentation ISRS (1998)

PUBLICATIONS

Correlation Between Pupil Size and Symptoms of Glare and Haloes Following Toric PRK. Luu, J.K., Manche, E. Presentation ISRS (1998)

Toric PRK for Compound Myopic Astigmatism: The Effect of Preoperative Cylinder Axis. Manche, E., McCulley, T.J., Luu, J.K. Submitted to Invest. Ophthalmology Vis. Sci.

Acute Effects of Sildenafil on the Electroretinogram (ERG) and Multifocal ERG Luu, J.K., Marmor, M.F., McCulley, T.J. Accepted for publication in the American Journal of Ophthalmology.

Clinical Retinal Changes in Response to Sildenafil. Luu, J.K., Marmor, M.F., McCulley, T.J. Submitted to Current Eye Research

Acute Effects of Sildenafil (Viagra) on Blue-on Yellow and White-on-White Humphrey Perimetry. McCulley, T.J, Lam, B.L. Luu, J.K. et al. J. Neuro-Ophthalmology. (Lead/Cover article) 2000; 20:227-28.

PRESENTATIONS:

High Speed ICG Angiographic Characterization of feeder Vessels to Choroidal Neovascularization Associated with Ocular Inflammatory Disease. Velez, G., Baudo, T.A., Luu, J.K. et al. ARVO 2001.

Feeder Vessel Treatment for Age-Related Macular Degeneration (AMD) with Classic Choroidal Neovascularization (CNV). Glaser, B.M, Baudo, T.A, Luu, J.K., et al. ARVO 2001.

Incidence of Predominantly Classic Choroidal Neovascular Membranes (CNV) in Exudative Age-Related Macular Degeneration (AMD): Percentage of New Patients Eligible for Photodynamic Therapy with Verteporfin. Baudo, T.A., Velez, G., Luu, J.K., et al. ARVO 2001.

Internal Tamponade Without tPA for Treatment of Submacular Hemorrhage in Age-Related Macular Degeneration. Luu, J.K, Glaser, B.M., Murphy, R.P., et al. ARVO 2001.

LECTURES

Modern Treatments for Wet AMD. Stanford University Dept. of Ophthalmology (April 2001).

Feeder Vessel Treatment for Wet AMD. ACCME Accredited Course, Chicago (June 2001).

Vascular diseases of the retina. JCAHPO course, New Orleans (November 2001)

CME COURSES

Risk Factors for Macular Degeneration

Macular Holes: Early Identification and Latest Treatment

Identification and Management of Dry Macular Degeneration Feeder Vessel Treatment for Wet AMD

What Do I Need to Know About the Treatment of Retinal Detachments?

Examining the Peripheral Retina and Interpreting the Findings

APPOINTMENTS

Board of Director	Retina Consultants of Southern Colorado (current)
Board of Director	Audubon Surgery Center (ended 2011)
Associate Professor of Ophthalmology	George Washington University (2002 - 2003)
Fellowship Director	National Retina Institute (2002 - 2003)