Seong Young Lee

CURRENT POSITION

Staff Vitreoretinal Surgeon

West Texas Retina Consultants, PA

5441 Health Center Drive

Abilene, Texas 79606 (2004-present)

Staff Investigator

Retina Research Institute of Texas

5441 Health Center Drive

Abilene, Texas 79606 (2004-present)

Staff Investigator

Strategic Clinical Research Group

101 Chuckwagon Trail

Willow Park, TX 76087 (2015-present)

Medical Director
Abilene Surgery Center
5601 Health Center Drive

Abilene, Texas 79606 (2008-present)

Section Chair of Ophthalmology Hendrick Medical Center,

1900 Pine Street

Abilene, Texas 79601 (2005-2006, 2010-2013)

EDUCATION

Fellowship University of Texas Southwestern Medical School at Dallas

Dallas, Texas (2002-2004)

Retina

Residency Medical College of Georgia

Augusta, Georgia (1999-2002)

Ophthalmology

Internship Baylor College of Medicine

Houston, Texas (1998-1999)

Internal Medicine

Medical Degree University of Texas Southwestern Medical School at Dallas

Dallas, Texas (1994-1998)

College Rice University

Houston, Texas (1990-1994)

B.A. in Biochemistry

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HONORS & AWARDS

MCG Ophthalmology Resident Research Award, 2001

Honors in Ophthalmology and Psychiatry Clerkships, 1996-1997

Southwestern Medical Foundation Scholarship for Academic Achievement, 1994-1995

Phi Lambda Upsilon (National Chemical Honor Society), 1994

Rice Class of 1930 Scholarship (Tuition merit scholarship), 1993

Rice University President's Honor Roll, 1990-1994

National Merit Scholarship, 1990-1994

YMCA/King Foundation College Scholarship, 1990-1994

Dallas Morning News/Dallas Mavericks College Scholarship, 1990

National Leadership and Service Award, 1990

Valedictorian, Jesuit College Preparatory School of Dallas, 1990

RETINA RESEARCH INSTITUTE OF TEXAS-RESEARCH

<u>Sub-Investigator</u>, Chengdu Kanghong Biotechnology Co., Ltd. Panda KHB-1801, "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."

Principal Investigator: Eric Zavaleta, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Charles L. Clark, M.D.

October 2018 – Present

<u>Sub-Investigator</u>, **Genentech Stairway CR39521**, "Stairway: Simultaneous blockade of Angiopoietin-2 and VEGF with the bispecific antibody RO6867461 (RG7716) for extended durability in the treatment of Neovascular Age-Related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D. PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

February 2017 - June 2018

Sub-Investigator, Ora Graybug GBV-102-001, "A Phase 1 / 2 Multicenter Study Evaluating the Safety, Tolerability and Efficacy of an Intravitreal Depot Formulation of Sunitinib Malate (GB-102) in Subjects with Neovascular Age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

August 2017 – Present

<u>Sub-Investigator</u>, **Ora Kalvista KVD001-201**, "A randomized sham-controlled double-masked Phase 2a study of the efficacy, safety and tolerability of the intravitreal plasma kallikrein inhibitor, KVD001, in subjects with center-involving diabetic macular edema (ciDME) who have had prior anti vascular endothelial growth factor (VEGF)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

February 2018 - Present

Sub-Investigator, ThromboGenics THR-149-001, "A multi-center study under protocol entitled A Phase I, open-label, multicenter, dose escalation study to evaluate the safety of a single intravitreal injections of THR-149 for the treatment of Diabetic Macular Edema (DME)." Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

May 2018 – Present

Sub-Investigator, Boehringer Ingelheim Pharmaceuticals, Inc. Robin 1386.12, "A randomized, double-masked, placebo-controlled exploratory study to evaluate safety, tolerability, pharmacodynamics and pharmacokinetics of orally administered BI 1467335 for 12 without center-involved Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

May 2018 - Present

Sub-Investigator, Trial Runners Aerpio AKB-9778, "Phase 2 double-masked, placebocontrolled study to assess the safety and efficacy of subcutaneously administered AKB-9778 15MG once daily or 15 MG twice daily for 12 months in patients with moderate to severe Non-Proliferative Diabetic Retinopathy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

November 2017 – Present

Sub-Investigator, Samsung SB11-G31-AMD, "A Phase II 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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

March 2018 – Present

Sub-Investigator, Clearside Tybee CLS1004-201, "Tybee: randomized, double masked, controlled study comparing the safety and efficacy of suprachoroidal CLS-TA with intravitreal aflibercept versus aflibercept alone in subjects with Diabetic Macular Edema."

Principal Investigator: Eric Zavaleta, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Charles L. Clark, M.D. July 2017 –May 2018

Sub-Investigator, Clearside Sapphire CLS1003-301, "A randomized, masked, controlled study the safety and efficacy of suprachoroidal CLS-TA in conjunction with Intravitreal Aflibercept in the subjects with Retinal Vein Occlusion."

Principal Investigator: Eric Zavaleta, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Charles L. Clark, M.D. February 2017– Present

Sub-Investigator, Ophthotech Zimura OPH2007, "A phase 2a open –label trail to assess the safety of Zimura (Anti-C5) administered in combination with Lucentis 0.5mg in treatment naïve subjects with Neovascular Age Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

September 2017-October 2018

<u>Sub-Investigator</u>. Opthea Ltd. 302-1002 WetAMD, "A dose ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in patients with Neovascular Age-Related Macular Degeneration (Wet AMD)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

December 2017-Present

<u>Sub-Investigator</u>, **Opthea Ltd. 302-1003 DME**, "Phase 1b/2a study of OPT-302 in combination with aflibercept for persistent Central-Involved Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

January 2018-Present

<u>Sub-Investigator</u>, **InSite Vision**, **Inc. C-12-305-001**, "A Phase 3, multicenter, randomized, double-masked, parallel-group, comparative study to evaluate the clinical efficacy and safety of ISV-305 (0.1% Dexamethasone) compared to vehicle in the treatment of subjects with Blepharitis."

Principal Investigator: Eric Zavaleta, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Charles L. Clark, M.D.

March 2018–Present

<u>Sub-Investigator</u>, **SciFluor SF0166-C-002**, "A Phase I/II randomized, controlled, double-masked, multicenter clinical trial designed to evaluate the safety and exploratory efficacy of SF0166 Topical Ophthalmic Solution in the treatment of Neovascular Age-Related Macular Degeneration (AMD)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. Octo

October 2016–October 2017

<u>Sub-Investigator</u>, **Allergan Maple 1771-201-008**, "Evaluation of Abicipar Pegol in Patients with Neovascular Age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

June 2018–Present

<u>Sub-Investigator</u>, **Ora ProDex TLC399A2002**, "A Phase IIa Trial of TLC399 (ProDex) in Subjects with Macular Edema due to Retinal Vein Occlusion (RVO): A Double-masked, Randomized Trial to Evaluate Efficacy and Tolerability."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Eric Zavaleta, M.D.

April 2017–Present

<u>Sub-Investigator</u>, Alcon Hawk Extension CRTH258A2301E1, "A 24-week, double-masked, multicenter, two-arm extension study to collect safety and efficacy date on brolucizumab 6mg drug product intended for commercialization in patients with Neovascular age-related macular degeneration who have completed the CRTH258A2301."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Eric Zavaleta, M.D., Charles L. Clark, M.D. February 2018–October 2018

<u>Sub-Investigator</u>, **Kodiak Sciences Inc. KSI-CL-101**, "A Phase I open label, multi-center study to investigate ocular and systemic safety, tolerability, and pharmacokinetics following a single intravitreal administration of KSI-301 in subjects with center involved diabetic macular edema (DME)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

June 2018-Present

<u>Sub-Investigator</u>, **Tryogenix Xcovery II X82-OPH-201**, "A Randomized, Double-Masked, Placebo-Controlled, Dose-Finding, Non-Inferiority Study of X-82 plus prn Eylea compared to prn Eylea monotherapy in Neovascular AMD."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. February 2016–January 2018

<u>Sub-Investigator</u>, Thrombogenics THR-687-001, "A Phase I, open-label, multicenter, dose escalation study to evaluate the safety of a single intravitreal injection of THR-687 for the treatment of diabetic macular edema (DME)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

September 2018–Present

<u>Sub-Investigator</u>, **Mylan Inc. MYL-1701P**, "A Multicenter, Randomized, Double-Masked, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of MYL-1701P and Eylea in Subjects with Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

August 2018–Present

<u>Sub-Investigator</u>, Genentech Omaspect GX30191, "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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

July 2016 – April 2018

<u>Sub-Investigator</u>, **Ora Acucela 4429-203**, "A multi-center, randomized, double-masked, placebo-controlled, pilot study to evaluate effects of Emixustat Hydrochloride on Aqueous Humor Biomarkers associated with Proliferative Diabetic Retinopathy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

April 2016 – January 2018

<u>Sub-Investigator</u>, Regeneron Ruby R910-3-DME-1518, "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."

Principal Investigator: Eric Zavaleta, M.D.

Sub Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D.

March 2016 - December 2017

<u>Sub-Investigator</u>, Genentech Boulevard BP30099, "A multiple-center, multiple-dose, randomized, active comparator-controlled, double-masked, parallel group, 28-week study to investigate the safety, tolerability, pharmacokinetics, and efficacy of RO6867461 administered intravitreally in patients with Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. February 2016 – February 2018

<u>Sub-Investigator</u>, Genentech Chroma GX29176, "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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

February 2016 - May 2018

<u>Sub-Investigator</u>, **Regeneron Onyx R910-3-AMD-1517**, "A randomized, double masked, active controlled Phase II study of the efficacy, safety, and tolerability of repeated doses of intravitreal REGN910-3 in patients with Neovascular age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. February 2016 – December 2017

<u>Sub-Investigator</u>, **Ophthotech Zimura OPH2003**, "A Phase II/III randomized, double-masked, controlled trial to assess the safety and efficacy of intravitreous administration of Zimura (Anti-C5 Aptamer) in subjects with Geographic Atrophy secondary to dry age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

November 2015 – Present

<u>Sub-Investigator</u>, Regeneron Panorama VGFTe-OD-1411.02, "A Phase III, double-masked, randomized study of the efficacy and safety of intravitreal aflibercept injection in patients with moderately severe to severe non-proliferative Diabetic Retinopathy."

Principal Investigator: Sunil S. Patel, M.D. PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

October 2015 – Present

<u>Sub-Investigator</u>, **Daiichi Sankyo Pharma DS7080-A-U101**, "Phase I dose escalation and expansion study of DS-7080a in subjects with Neovascular age-related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D. PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

October 2015 – April 2018

<u>Sub-Investigator</u>, **Opthea OPT-302**, "A Phase I dose escalation study evaluating the safety, pharmacokinetics and pharmacodynamics of OPT-302 in combination with Ranibizumab in subjects with Wet AMD."

Principal Investigator: Sunil S. Patel, M.D. PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

October 2015 - April 2017

<u>Sub-Investigator</u>, Apellis Filly POT-CP121614, "A Phase II, multicenter, randomized, single-masked, Sham-controlled study of safety, tolerability and evidence of activity of intravitreal APL-2 Therapy in patients with Geographic Atrophy (GA)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

September 2015 – April 2018

<u>Principal Investigator</u>, Allegro PVD-202, "A Phase II, randomized, double-masked, placebo-controlled multicenter clinical trial designed to evaluate the safety and efficacy of Luminate in inducing PVD in subjects with Non-Proliferative Diabetic Retinopathy."

Sub-Investigator: Sunil S. Patel, M.D., PhD, Grant P Janzen, M.D., Eric Zavaleta, M.D.

June 2015 – October 2017

<u>Sub-Investigator</u>, Genentech Avenue BP29647, "A multi-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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

June 2015 – October 2017

<u>Sub-Investigator</u>, **Ophthotech OPH1004**, "A Phase III 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."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Eric Zavaleta, M.D. April 2015 – October 2016

<u>Sub-Investigator</u>, Allergan Cedar 150998-005, "Safety and Efficacy of Abicipar Pegol(AGN-150998) in Patients with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

May 2015–Present

<u>Sub-Investigator</u>, Regeneron Pharmaceuticals, Inc.-R2176-3-AMD-1417, "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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. February 2015 – May 2017

Sub-Investigator, F.Hoffmann-La Roche, LTD-GX29639 Proxima, "A Multicenter,

Prospective Epidemiologic Study of the Progression of Geographical Atrophy Secondary to Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. January 2015 – January 2018

<u>Sub-Investigator</u>, **University of Virginia (Paul Yates)**, **TOGA-01**, "A Randomized, Double Masked, Placebo Controlled Study Evaluating ORACEA® in Subjects with Geographical Atrophy Secondary to Non-Exudative Age-Related Macular Degeneration."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Eric Zavaleta, M.D. April 2015 – June 2017

<u>Principal Investigator</u>, Allegro Ophthalmics, LLC DME 202B, "A Phase II Multicenter, Randomized, Controlled, Double-Masked Clinical Trial Designed to Evaluate the Safety and Exploratory Efficacy of Luminate® (ALG-1001) As Compared to Avastin® and Focal Laser Photocoagulation in the Treatment of Diabetic Macular Edema."

Sub-Investigator: Sunil S. Patel M.D. PhD, Grant P. Janzen, M.D., Eric Zavaleta, M.D.

December 2014 – June 2017

<u>Sub-Investigator</u>, **Alcon RTH258-C001**, "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."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D. PhD., Eric Zavaleta, M.D. February 2015 – May 2018

<u>Sub-Investigator</u>, Astellas Pharma Europe- 8232-CL-3001, "A Phase 2, Double-Masked, Randomized, Active Controlled Study to Evaluate the Efficacy and Safety of ASP8232 in Reducing Central Retinal Thickness in Subjects with Diabetic Macular Edema." Principal Investigator: Sunil S. Patel, M.D. PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. January 2015 – December 2016

<u>Sub-Investigator</u>, **Ophthotech Corp.-OPH1006**, "Effect of Anti-VEGF Agents Administered on a Quarterly Maintenance Regimen in Subjects with Neovascular AMD Receiving Anti-PDGF Therapy: An 18 Month Phase 2A Open Label, Randomized Study of Avastin®, Lucentis®, or Eylea®(Anti-VEGF Therapy) Administered in Combination with Fovista®(Anti-PDGF BB PEGylated Aptamer)."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Eric Zavaleta, M.D. January 2015 – January 2017

<u>Sub-Investigator</u>, **F.Hoffmann-La Roche**, **GX29639 Exposure**, "A Phase II, Multicenter, Randomized, Single-Masked, Sham Injection-Controlled Exposure-Response Study of Lampalizumab Intravitreal Injections Administered Every Two Weeks or Every Four Weeks to Patients with Geographical Atrophy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. November 2014 – October 2017

<u>Sub-Investigator</u>, **F.Hoffmann-La Roche**, **Spectri GX29185**, "A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Assess the Efficacy and Safety of Lampalizumab Administered Intravitreally to Patients with Geographical Atrophy Secondary to Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D., Charles L. Clark, M.D.

August 2014 – April 2018

<u>Sub-Investigator</u>, **Allergan 190342-038 Beacon**, "Safety and Efficacy of Brimonidine Posterior Segment Drug Delivery System in Patients with Geographical Atrophy Secondary to Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. November 2013 - October 2018

<u>Sub-Investigator</u>, **Ophthotech OPH1005**, "Sub-Retinal Fibrosis in Neovascular AMD: A 24 Month Phase 2A Open Label Safety Study of Fovista®(Anti-PDGF-BB PEGylated Aptamer) Regimen Administered in Combination with Anti-VEGF Therapy (Avastin®, Eylea®, or Lucentis®) During the Induction and Maintenance Phase of Therapy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D. June 2014 – January 2015

<u>Sub-Investigator</u>, **Ophthotech OPH1002**, "A Phase 3 Randomized, Double-Masked, Controlled Trial to Establish the Safety and Efficacy of Intravitreous Administration of FovistaTM (Anti PDGF-B PEGylated Aptamer) Administered in Combination with Lucentis® Monotherapy in subjects with Subfoveal Neovascular Age-Related Macular Degeneration."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Eric Zavaleta, M.D., Sunil S. Patel, M.D., PhD. August 2013 – March 2017

<u>Sub-Investigator</u>, **Xcovery Vision**, **LLC**. **X82-OPH-102**, "A Phase 1/2 Open-label, Dose Escalation Clinical Trial to Evaluate the Safety and Preliminary Biologic Activity/Efficacy of the VEGFR/PDGFR Inhibitor X-82 administered per Os on Subjects with Neovascular Age-related Macular Degeneration (AMD)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

May 2013 – July 2015

<u>Sub-Investigator</u>, **Genentech Olei GX28198**, "A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of FCFD4514S in patients with Geographical Atrophy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

April 2012 – May 2018

Sub-Investigator, Iconic Therapeutics IT-002, "A Phase II randomized, double-masked, multicenter, active-controlled study evaluating administration of repeated intravitreal doses of hIcon1 in patients with Choroidal Neovascularization secondary to age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

June 2015 – November 2016

Sub-Investigator, Genentech Ladder GX28228, "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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

May 2015 - October 2016

Sub-Investigator, Alcon LMG324-2201, "An Open-Label Single Ascending Dose and Randomized Double-Masked, Ranibizumab Controlled, Safety, Tolerability, and Efficacy Study of Intravitreal LMG324 in Subjects with Neovascular age-related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

2015 - June 2016

Sub-Investigator, 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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

2015 – September 2015

Sub-Investigator, Regeneron Pharmaceutical, Inc.-R910-3-OD-1403.01, "An Open-Label, Dose Escalation study of the Safety and Tolerability of Intravitreal (IVT) REGN910-3 and IVT REGN910 in patients with either Neovascular AMD or DME."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

2015 – November 2015

Sub-Investigator, Clearside Biomedical, Inc., CLS1003-201 Tanzanite, "Safety and Efficacy of Suprachoroidal CLS-TA in Combination with Intravitreal Aflibercept in Subjects with Macular Edema Following Retinal Vein Occlusion."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

2015 - April 2016

Sub-Investigator, National Eye Institute, National Institutes of Health, Department of Health and Human Services-SCORE2, "Study of Comparative Treatments for Retinal Vein Occlusion 2 (SCORE2): A Multicenter, Prospective, Randomized, Phase III, Non-Inferiority Trail of Eyes with Macular Edema Secondary to Central Retinal Vein Occlusion, Comparing Intravitreal Bevacizumab Every 4 Weeks Versus Intravitreal Aflibercept Every 4 Weeks."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D., Eric Zavaleta, M.D.

2014 - January 2016

Sub-Investigator, StemCells, Inc. CL-N01-AMD, "Phase I/II Study of the Safety and Preliminary Efficacy of Human Central Nervous System Stem Cells (HuCNS-Sc) Subretinal Transplantation in Subjects with Geographical Atrophy of Age-Related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

January 2014 – 2016

<u>Sub-Investigator</u>, **PanOptica**, **Inc**. **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)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

January 2014 – 2015

<u>Sub-Investigator</u>, Ampio Pharmaceuticals, Inc. AP-05-002, "A Randomized, Placebo Controlled, Parallel, Double-Masked Study to Evaluate the Efficacy and Safety of Two Doses of Oral OptinaTM in adult Patients with Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

July 2013 - 2015

<u>Sub-Investigator</u>, Regeneron RE-VIEW VGFTe-AMD-1124, "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" Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

February 2013 – November 2015

<u>Sub-Investigator</u>, Regeneron VIBRANT VEGFe-RVO-1027, "A double-Masked, Randomized, Active-Controlled Study of the Efficacy, Safety, and Tolerability of Intravitreal Administration of VEGF Trap-Eye (Intravitreal Aflibercept Injection [IAI]) in Patients with Macular Edema Secondary to Branch Retinal Vein Occlusion

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

May 2012 - 2014

<u>Sub-Investigator</u>, Allergan REACH AGN-150998, "Single and Repeat Dose of the Safety and Efficacy of AGN-150998 in patients with Exudative Age-related Macular Degeneration" Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

July 2011 - 2014

Sub-Investigator, Lpath NEXUS LT1009-Oph-003, "A phase 2A, Multi-Center, Masked, Randomized, Comparator-Controlled Study Evaluating iSonep TM(Sonepcizumab [LT1009]) As either Monotherapy or adjunctive Therapy to Lucentis® or Avastin® Alone for the treatment of subjects with choroidal Neovascularization Secondary to Age-Related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

July 2011 – 2015

<u>Sub-Investigator</u>, **GlaskoSmithKline BAM114341**, "A Phase II, Multi-Centre, Randomized, Double-Masked, Placebo-Controlled, Parallel-Group Study to investigate the Safety, Tolerability, Efficacy, Pharmacokinetics and Pharmacodynamics of GSK933776 in Adult Patients with Geographical Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)." Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

February 2011 – 2016

<u>Sub-Investigator</u>, Regeneron Vista VGFT-OD-1009, "A Double-Masked, Randomized, Active-Controlled, Phase III Study of the Efficacy and Safety of Intravitreal Administration of VEGF Trap-Eye in Patients with Diabetic Macular Edema."

Principal Investigator: Grant P. Janzen, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD.

February 2011 – 2015

<u>Sub-Investigator</u>, Allergan 190342-033D, "A Multicenter, Patient-Masked, Safety Extension Study to evaluate the biodegradation of the brimonidine Tartrate Posterior Segment Drug Delivery System."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2010 - 2014

<u>Sub-Investigator</u>, **DRCR Protocol N**, "An Evaluation of Intravitreal Ranibizumab for Vitreous Hemorrhage Due to Proliferative Diabetic Retinopathy."

Principal Investigator: Sunil S. Patel M.D., PhD.

July 2010 –2016

<u>Sub-Investigator</u>, Alcon Research, Ltd. C-13-001, "A Prospective, Two-Cohort, Single-Masked Study to Evaluate the Effect of ESBA1008 Applied by Microvolume Injection of Infusion in Subjects with Exudative Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

July 2013 - February 2014

<u>Sub-Investigator</u>, Allergan 206207-024, "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" Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

February 2012 – March 2014

<u>Sub-Investigator</u>, **Novartis CLFG316A2202**, "A Multicenter, Randomized, Sham-Controlled, Repeat-Dose Study to Assess the Safety, Tolerability, Serum Pharmacokinetics, and Efficacy of Intravitreal LFG316 in Patients with Neovascular Age-Related Macular Degeneration" Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

February 2012 – December 2013

Sub-Investigator, Alimera FAME C-01-11-008, "An Open Label, Multi-center Extension Study of the Safety and Utility of the New Inserter of Iluvien ® (Fluocinolone Acetonide Intravitreal Insert) 0.19mg and the Safety of Iluvien in subjects with Diabetic Macular Edema" Principal Investigator: Sunil S. Patel, M.D., PhD. March 2011 – November 2013

<u>Sub-Investigator</u>, Allergan BDP 208397-001, "A 12-Month, Multicenter, 2-Stage (Open Label, Dose-Escalation, Followed by Masked, Randomized) Single Dose Study of the Safety and Efficacy of AGN-208397 in Patients with Macular Edema (ME) Associated with Retinal Vein Occlusion (RVO)"

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

April 2011 – May 2013

Sub-Investigator, Pfizer B1181002, "A Phase I, Double-masked, Placebo-controlled study evaluating the Safety and Tolerability, Immunogenicity, Pharmacokinetics and Pharmacodynamics of Multiple Escalating Dosages of RN6G (PF-04382923) in subjects with Advanced Dry, Age-Related Macular Degeneration (AMD) including Geographical Atrophy" Principal Investigator: Sunil S. Patel, M.D., PhD. February 2010 – March 2013

<u>Sub-Investigator</u>, **Pfizer B1181003**, "A Phase 2 Multi-Center, Randomized, Double-Masked Placebo-Controlled, Multi-Dose Study to Investigate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of RN6G (PF-04382923) In Subject with Geographic Atrophy Secondary to Age-Related Macular Degeneration"

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

October 2012 – April 2013

<u>Sub-Investigator</u>, Genentech SHORE FVF4967g, "A Multicenter Randomized Study Evaluating Dosing Regimens for Treatment with Intravitreal Ranibizumab in Subjects with Macular Edema Following Retinal Vein Occlusion."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

February 2011 – January 2013

<u>Sub-Investigator</u>, **Genentech FVF4168g RIDE**, "A phase III, double-masked, multicenter, randomized, sham-controlled study of the efficacy and safety of ranibizumab injection in subjects with clinically significant macular edema with center involvement secondary to diabetes mellitus."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

April 2007 – December 2012

<u>Sub-Investigator</u>, **Lpath Incorporated LT1009-OPH002**, "A Phase 1B Multicenter, Open-Label and Randomized study of ISONEP (Sonepcizumab/LT1009) administered as Intravenous Injections to subjects with PED Secondary to Exudative Age-Related Macular Degeneration or Polypoidal Choroidal Vasculopathy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

March 2011 – November 2012

<u>Sub-Investigator</u>, **Genentech FVF4579g Harbor**, "A Phase III, Double-Masked, Multicenter, Randomized, Active Treatment-Controlled Study of the efficacy and safety of 0.5mg and 2.0 mg Ranibizumab administered monthly or an as-needed basis (PRN) in patients with Subfoveal Neovascular Age-related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

June 2009 – September 2012

<u>Principal Investigator</u>, Alcon C-08-36 (GATE), "The safety and efficacy of AL-8309B ophthalmic Solution for the treatment of Geographical Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

February 2009 – September 2012

<u>Sub-Investigator</u>, **Regeneron VGFT-OD-0819**, "A Randomized, Double Masked, Controlled Phase III Study of the efficacy, safety and tolerability of repeated intravitreal administration of VEGF-Trap in subjects with Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2009 – June 2012

<u>Sub-Investigator</u>, Genentech Mahalo CFD4870g, "A Phase Ib/II, Multicenter, Randomized, Single Masked, Sham-Injection-Controlled study of Safety, Tolerability, and Evidence of Activity of FCFD4514S Intravitreal Injections Administered monthly or Every other month to patients with Geographical Atrophy."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

December 2010 - April 2012

Sub-Investigator, Ophthotech OPH1001, "A PHASE 2, Randomized, Double-Masked, Controlled trial to establish the safety and efficacy of intravitreous injections of E10030 (Anti-PDGF PEGylated Aptamer) given in combination with Lucentis® in subjects with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

March 2010 - March 2012

Sub-Investigator, Ophthotech OPH3000ss, "A phase I ascending dose and parallel group trial to establish the safety, tolerability, and pharmacokinetics profile of multiple intravitreous injections of Volociximab (α5β1 integrin antagonist as monotherapy or in combination with Lucentis® 0.5 mg/eye in subjects with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

October 2010 – December 2011

<u>Sub-Investigator</u>, **Victor Gonzales**, **M.D.**, **PRESERVE**, "Pegaptanib for Retinal Edema Secondary to Diabetic Vascular Disease."

Principal Investigator: Sunil S. Patel, M.D., PhD.

Sub-Investigator: Grant P. Janzen, M.D.

June 2010 – December 2011

<u>Sub-Investigator</u>, Allergan 190342-031D-01, "A Multicenter, Masked, Randomized, Sham Controlled, Parallel-group, 3-month Safety Extension to Evaluate the Safety and Efficacy of Brimonidine Tartrate Posterior Segment Drug Delivery System (Brimonidine Tartrate PS DDS) Applicator System in improving Visual Function in patients with a previous Rhegmatogenous Macular-Off Retinal Detachment."

Principal Investigator: Sunil S. Patel, M.D., PhD.

October 2009 - December 2011

<u>Sub-Investigator</u>, **DRCR Protocol O**, "Comparison of Time Domain OCT and Spectral Domain OCT Retinal Thickness Measurement in Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2009 – October 2011

Sub-Investigator, Allergan 190342-032D-01, "A Multicenter, Masked, Randomized, Sham-controlled, Paired-eyed Comparison, 12-Month (Plus 12-Month Extension) Study to Evaluate the Safety and Effects on Retinal structure and Visual Function of Brimonidine Tartrate Posterior Segment Drug Delivery System (Brimonidine Tartrate PS DDS) Applicator system in Patients with Geographical Atrophy from Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

June 2008 – August 2011

Sub-Investigator, Regeneron VGFT-OD-0605, "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."

Principal Investigator: Sunil S. Patel, M.D., PhD.

July 2007 – July 2011

<u>Sub-Investigator</u>, Alcon C-09-023 (Waltz), "A dose-escalated study of AL-39324 Suspension versus Lucentis® for the treatment of Exudative Age Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

November 2009 – June 2011

<u>Sub-Investigator</u>, **Ophthotech OPH2001**, "A Phase I study to establish the safety and tolerability of ARC1905 (ANTI-C5 APTAMER) in subjects with Dry Age-Related Macular Degeneration." Principal Investigator: Sunil S. Patel, M.D., PhD.

June 2009 – June 2011

<u>Sub-Investigator</u>, Alimera Sciences C01-05-001, "A randomized, double-masked, parallel group, multicenter, dose-finding comparison of the safety and efficacy of ASI-001A $0.5\mu g/day$ and ASI-001B $0.2\mu g/day$ Fluocinolone Acetonide intravitreal inserts to sham injection in subjects with diabetic macular edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

April 2006 – February 2011

Sub-Investigator, Regeneron VGFT-OD-0706, "A Double-Masked, Randomized, Controlled study of the safety and efficacy, Tolerability and Biological effect of repeated Intravitreal Administration of VEGF-Trap in patients with Diabetic Macular Edema (DME)."

Principal Investigator: Sunil S. Patel, M.D., PhD. February 2009 – January 2011

<u>Principal Investigator</u>, Genentech FVF3426g HORIZON, "An open-label, Multicenter extension study to evaluate the safety and tolerability of Ranibizumab in subjects with Choroidal Neovascularization (CNV) secondary to Age-Related Macular Degeneration (AMD) or Macular Edema Secondary to Retinal Vein Occlusion (RVO) who have completed a Genentech-sponsored Ranibizumab study."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

July 2008 – October 2010

Sub-Investigator, Allergan 206207-018, "A 26-week, Open-Label study to asses the safety and efficacy of 700μg Dexamethasone Posterior Segment Drug Delivery System Applicator System in the treatment of Vitrectomized subjects with Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

December 2008 – July 2010

Sub-Investigator, Allergan 206207-019, "A 26-week, Open Label study to asses the safety and efficacy of 700µg Dexamethasone Posterior Segment Drug Delivery System Applicator System as Adjunctive Therapy to Lucentis® in the treatment of subjects with Choroidal Neovascularization Secondary to Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

December 2008 – July 2010

Principal Investigator, Allergan 206207-012-00, "A 52-week, masked, multicenter, randomized, controlled trial (with up to 13 weeks additional follow-up) to assess the safety and efficacy of 700µg dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in combination with laser photocoagulation compared with laser photocoagulation alone in the treatment of subjects with diffuse diabetic macular edema (DME)."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

April 2007 – May 2010

Sub-Investigator, Ophthotech OPH3000, "A phase I ascending dose and parallel group trial to establish the safety, tolerability, and pharmacokinetics profile of multiple intravitreous injections of Volociximab (α5β1 integrin antagonist as monotherapy or in combination with Lucentis® 0.5 mg/eye in subjects with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

July 2008 – May 2010

Sub-Investigator, Ophthotech OPH2000, "A Phase 1, Ascending Dose and Parallel Group Trial to establish the Safety, Tolerability and Pharmacokinetic Profile of Multiple Intravenous Injections of ARC1905 (ANTI-C5 APTAMER) Given either in combination therapy with multiple doses of Lucentis® 0.5 mg/eye, or with one induction dose of Lucentis® 0.5 mg/eye in subjects with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

June 2008 – May 2010

Sub-Investigator, Ophthotech OPH1000, "A Phase I, single ascending dose trail to establish the safety, tolerability and pharmacokinetic profile of intravitreous injection of E10030 (Anti-PDGF PEGylated Aptamer) monotherapy and of E10030 given in combination with Lucentis 0.5 Mg/eye in subjects with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

November 2007 – May 2010

<u>Principal Investigator</u>, Genentech FVF4166g CRUISE, "A phase III, multicenter, randomized, sham injection-controlled study of the efficacy and safety of ranibizumab injection compared with sham in subjects with macular edema secondary to central retinal vein occlusion."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

April 2007 – February 2010

<u>Principal Investigator</u>, Genentech FVF4165g BRAVO, "A phase III multicenter, randomized, sham injection-controlled study of the efficacy and safety of ranibizumab injection compared with sham in subjects with macular edema secondary to branch retinal vein occlusion."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

April 2007 – February 2010

<u>Sub-Investigator</u>, **Jerini J0642701**, "A Phase I open-label study to investigate the safety, tolerability and pharmacokinetic profile of single and repeated doses of JSM6427 following administration by intravitreal injection in patients with Neovascular Age-Related Macular Degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD. September 2007 – September 2009

Sub-Investigator, Alcon C-06-30, "The Natural History of Geographical Atrophy Progression (GAP) Secondary to Age-Related Macular Degeneration (AMD)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2008 – August 2009

<u>Sub-Investigator</u>, **OPKO ACU301C**, "A Phase 3, Randomized, Double-masked, Parallel-assignment study of Intravitreal Bevasiranib Sodium, administered every 8 or 12 weeks as maintenance therapy following three injections of Lucentis® compared with Lucentis® monotherapy every 4 weeks in patients with Exudative Age-Related Macular Degeneration (AMD)."

Principal Investigator: Sunil S. Patel, M.D., PhD.

July 2007 – July 2009

Sub-Investigator, The Standard Care vs. Corticosteroid for Retina Vein Occlusion (SCORE) Study, Two Randomized Trials to Compare the Efficacy and Safety of Intravitreal Injections of Triamcinolone Acetonide with Standard Care to Treat Macular Edema: One for Central Retinal Vein Occlusion and One for Branch Retinal Vein Occlusion."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2004 – June 2009

Principal Investigator, Allergan 206207-016, "A 6-Month, single- masked, multicenter, randomized, controlled study to assess the safety and efficacy of 700µg Dexamethasone posterior segment drug delivery system applicator system as adjunctive therapy to Lucentis compared with Lucentis alone in the treatment of patients with Choroidal Neovascularization secondary to Age-Related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

August 2007 - May 2009

<u>Sub-Investigator</u>, **Allergan SIRIUS**, "A 2- year, Multicenter, randomized, controlled, masked, dose-finding trial to asses the safety and efficacy of multiple intravitreal injections of AGN 211745 in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration"

Principal Investigator: Sunil S. Patel, M.D., PhD.

April 2007 – May 2009

<u>Principal Investigator</u>, Allergan 206207-009-01, "A six-month, phase III, multicenter, masked randomized, sham-controlled trial (with six0month open label extension) to assess the safety and efficacy of 700μg and 350μg dexamethasone Posterior segment drug delivery system (DEX PS DDS) applicator system in the treatment of patients with macular edema following central retinal vein occlusion or branch retinal vein occlusion."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

February 2006 – March 2009

Sub-Investigator, Alcon C0459, "Anecortave Acetate 15mg administered every 3 months versus Anecortave Acetate 15mg administered every 6 months versus Anecortave Acetate 30mg administered every 6 months in patients with exudative age-related macular degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

May 2005 – November 2008

<u>Sub-Investigator</u>, **Eyetech 1023**, "A phase IV, multi-center trial of maintenance intravitreous injections of Macugen® (Pegaptanib Sodium) given every 6 weeks for 48 weeks in subjects with subfoveal neovascular age-related macular degeneration (AMD) initially treated with modality resulting in maculopathy improvement."

Principal Investigator: Sunil S. Patel, M.D., PhD.

June 2006 – October 2008

<u>Sub-Investigator</u>, Anecortave Acetate Risk-Reduction Trial (AART) C-02-60, "Multicenter, double-masked, randomized, parallel groups clinical trial to demonstrate that Anecortave Acetate is safe and effective versus sham in arresting the progression of non-exudative AMD in patients who are at-risk for progressing to exudative AMD."

Principal investigator: Sunil S. Patel, M.D., PhD.

August 2004 – October 2008

<u>Sub-Investigator</u>, **Diabetic Retinopathy Clinical Research Network**, "A Randomized Trial Comparing Intravitreal Corticosteroids and Laser Photocoagulation for Diabetic Macular Edema."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2004 – 2007

<u>Principal Investigator</u>, Alcon C-05-62, "A clinical evaluation of the safety and efficacy of preservative-free Triamcinolone Acetonide sterile suspension for visualization during vitreoretinal surgery."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

August 2007 - October 2007

<u>Sub-Investigator</u>, **DRCR Protocol B**, "A randomized trial comparing intravitreal triamcinolone acetonide and laser photocoagulation for DME."

Principal Investigator: Sunil S. Patel, M.D., PhD.

September 2004 – August 2008

<u>Sub-Investigator</u>, **EYETECH EOP1013**, "A phase 2/3, randomized, controlled, double-masked, multi-center, comparative dose-finding trial in parallel groups, to compare the safety and efficacy of intravitreous injections of 0.3, 0.03, 0.003mg Macugen, given as often as every 6 weeks for 3 years, to sham injections, in subjects with Diabetic Macular Edema involving the center of the macula."

Principal Investigator: Sunil S. Patel, M.D., PhD.

September 2005 – May 2007

<u>Principal Investigator</u>, Alcon C0418, "Clinical evaluation of the safety of Next Generation Ophthalmic Irrigating Solution Compared to BSS Plus for use During Surgery for removal of epimacular membrane and vitrectomy."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

February 2006 – March 2007

<u>Sub-Investigator</u>, **EYETECH EOP1012**, "A phase 3B/4, randomized, active-controlled, double masked, single dummy, multi-center comparative trial, in parallel groups, to compare the safety and efficacy of intravitreous injections of Macugen given every 6 weeks for up to 102 weeks plus sham Photodynamic Therapy to Macugen plus PDT with Visudyne, in subjects with predominantly classic subfoveal choroidal neovascularization secondary to age-related macular degeneration."

Principal Investigator: Sunil S. Patel, M.D., PhD.

March 2005 – February 2007

<u>Principal Investigator</u>, Genaera Corporation MSI-1256F-208, "A Phase 2, Multi-center, Randomized, Controlled, Masked Study of the Effects of Squalamine Lactate in Combination with Visudyne in Patients with Subfoveal Choroidal Neovascularization Associated with Age-Related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD.

December 2004 – 2005

<u>Principal Investigator</u>, Genaera Corporation MSI-1256F-209, "A Phase 2, multi-center, Randomized, Masked, Controlled Study of the MSI-1256F (Squalamine Lactate) for Treatment of Subfoveal Choroidal Neovascularization Associated with Age-Related Macular Degeneration." Sub-Investigator: Sunil S. Patel, M.D., PhD.

December 2004 – 2005

<u>Sub-Investigator</u>, **Eyetech EOP1011B**, "A Phase II randomized, dose-ranging, double-masked, multi-center trial, in parallel groups, to determine the safety, efficacy and pharmacokinetics of intravitreous injections of pegaptanib sodium compared to sham injection for 30 weeks in patients with recent vision loss due to macular edema secondary to CRVO."

Principal Investigator: Sunil S. Patel, M.D., PhD.

August 2004 – 2005

STRATEGIC CLINICAL RESEARCH GROUP-RESEARCH

<u>Principal Investigator</u>, Allergan Beacon 190342-038, "Safety and Efficacy of Brimonidine Posterior Segment Drug Delivery System (PS DDS) in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. May 2004 –November 2017

<u>Principal Investigator</u>, Genentech Chroma GX29176, "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."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. November 2014-2018

<u>Principal Investigator</u>, Genentech GX30191, "A Phase III, 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."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. 2016-2018

Principal Investigator, Allergan Sequoia 150998-006, "Safety and Efficacy of Abicipar Pegol (150998-006) in Patients with Neovascular Age-related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. February 2016- Present

Principal Investigator, Genentech Stairway GX39521, "Stairway: Simultaneous blockade of angiopoietin-2 and Vegf-A with bispecific antibody RO6867461 (Rg7716) for extended durability in the treatment of Neovascular Age-Related Macular Degeneration." Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. January 2017- March 2018

Principal Investigator, Ophthotech OPH2007, "A Phase 2a open-label trial to assess the safety of Zimura (Anti-C5) administered in combination with Lucentis 0.5 Mg in treatment naïve subjects with Neovascular Age-Related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Courtney Crawford, M.D., Ross Lynds, M.D. February 2017-July 2018

Principal Investigator, Regeneron VGFTe-OD-1411, "A Phase 3, double-masked, randomized study of the efficacy and safety"

Sub-Investigator: Sunil S. Patel, M.D., PhD., Grant P. Janzen, M.D., Courtney Crawford, M.D. February 2017- Present

<u>Sub-Investigator</u>, Aldeyra ADX-102-UV-005, "A Phase 3 Randomized, Double-Masked, Vehicle-Controlled Trial to Evaluate the Safety and Efficacy of ADX-102 Ophthalmic Solution in Subjects with Non-Infectious Anterior Uveitis."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

August 2017-Present

Sub-Investigator, Allergan Maple 1771-201-008, "Evaluation of Abicipar Pegol in Patients with

Neovascular Age-related Macular Degeneration."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

May 2018 - Present

<u>Sub-Investigator</u>, Chengdu Kanghong Biotechnology Co., Ltd. Panda KHB-1801, "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."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

August 2018 - Present

<u>Principal Investigator</u>, **Ophthotech Zimura OPH2003**, "A Phase II/III randomized, double-masked, controlled trial to assess the safety and efficacy of intravitreous administration of Zimura (Anti-C5 Aptamer) in subjects with Geographic Atrophy secondary to dry age-related Macular Degeneration."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Courtney Crawford, M.D., Ross Lynds, M.D.

December 2017 - Present

<u>Principal Investigator</u>, Clearside Topaz CLS1003-302, "Topaz: A randomized, masked, controlled trial to study the safety and efficacy of suprachoroidal CLS-TA with intravitreal aflibercept in subjects with retinal vein occlusion."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Courtney Crawford, M.D., Ross Lynds, M.D. August 2018 - Present

<u>Principal Investigator</u>, Genentech, Inc. Yosemite GR40349, "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."

Sub-Investigator: Sunil S. Patel, M.D., PhD., Courtney Crawford, M.D., Ross Lynds, M.D.

September 2018 – Present

<u>Sub-Investigator</u>, **Ophthotech Zimura OPH2005**, "A phase 2b randomized, double-masked, controlled trial to establish the safety and Efficacy of Zimura (Complement C5 Inhibitor) compared to sham subjects with Autosomal Recessive Stargardt Disease."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

December 2017 – Present

<u>Sub-Investigator</u>, **Opthea OPT-302-1002**, "A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, inpatients with neovascular age-related macular degeneration (wet AMD)" ("Study") in accordance with Sponsor's protocol no. OPT-302-1002."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

January 2018 – Present

<u>Sub-Investigator</u>, **Opthea OPT-302-1003**, "Phase 1b/2a study of OPT-302 in combination with aflibercept for persistent central-involved diabetic macular edema."

Principal Investigator: Courtney Crawford, M.D.

Sub-Investigator: Sunil S. Patel, M.D., PhD., Ross Lynds, M.D.

April 2018 – Present

RESEARCH

<u>Sub-Investigator</u>, Anecortave Acetate Risk-Reduction Trial (AART) C-02-60, "Multicenter, double-masked, randomized, parallel groups clinical trial to demonstrate that Anecortave Acetate is safe and effective versus sham in arresting the progression of non-exudative AMD in patients who are at-risk for progressing to exudative AMD." Principal investigator: Yu-Guang He, MD. University of Texas Southwestern Medical Center, Dallas, Texas.

January – July 2004

Sub-Investigator, Anecortave Acetate Posterior Juxtascleral Injection Protocol Number C-01-99, "Multicenter clinical trial to evaluate the safety and efficacy of Anecortave Acetate in maintaining vision in patients with wet AMD as compared to the effectiveness of treatment with Visudyne PDT. "Primary investigator: Yu-Guang He, MD. University of Texas Southwestern Medical Center, Dallas, Texas.

Co-Investigator and author of "Multimodality Transpupillary Thermotherapy and Radiotherapy of Choroidal Neovascular Membranes in Age-Related Macular Degeneration: A Phase I Safety Study." Clinical study to examine the safety of laser thermotherapy and external beam irradiation in the treatment of choroidal neovascular membranes in age-related macular degeneration.

Co-investigator: Dennis M. Marcus, MD. Medical College of Georgia, Augusta, Georgia. July 2000-2002.

Research Assistant. Examined the role of preoperative levels of alpha₂-antiplasmin in identifying patients at increased risk for bleeding during different cardiac surgical procedures. Primary Investigator: Charles Whitten, MD. Department of Anesthesiology, University of Texas Southwestern Medical School, Dallas, Texas. 1995.

Research Assistant. Analyzed changes in cardiac contractile function during hemorrhagic shock and attempted resuscitation. Primary investigator: Dan Meyer, MD. Department of Thoracic and Cardiovascular Surgery, University of Texas Southwestern Medical School, Dallas, Texas. 1992-1994.

PUBLICATIONS

Campochiaro PA, Brown DM, Awh CC, <u>Lee SY</u>, Gray S, Saroj N, Murahashi WY, Rubio RG. Sustained Benefits from Ranibizumab for Macular Edema following Central Retinal Vein Occlusion: Twelve-Month Outcomes of a Phase III Study. Ophthalmology. 2011:118:2041-2049.

Mitchell KT, <u>Lee, S.Y.</u> Current Options for Retinal Detachment Repair. Focal Points: Clinical Modules for Opthalmologists, Volume XXV111 Number 9, Sep 2010.

Scott IU, Ip MS, Van Veldhuisen PC, Oden NL, Blodi BA, Fisher M, Chan CK, Gonzalez VH, Singerman LJ, Tolentino M;SCORE Study Research Group. A randomized trial comparing the efficacy and safety of intravitreal triamcinolone with observation to treat vision loss associated with macular edema secondary to Branch Retinal Vein Occlusion: SCORE Study Report 6 Arch Ophthalmol. 2009 Sep;127(9):1115-28

Ip MS, Scott IU, Van Veldhuisen PC, Oden NL, Blodi BA, Fisher M, Singerman LJ, Tolentino M, Chan CK, Gonzalez VH; SCORE Study Research Group. A randomized trial comparing the efficacy and safety of intravitreal triamcinolone with observation to treat vision loss associated with macular edema secondary to Central Retinal Vein Occlusion: SCORE Study Report 5 Arch Ophthalmol. 2009 Sep;127 (9):1101-14

S.Y.Lee, Dyer D, Callanan D, Bochow T, Abraham P, Lambert HM, Schneiderman T, Potts SL, Walker TM. Clinical evaluation of the safety and efficacy of preservative-free triamcinolone (triesence [triamcinolone acetonide injectable suspension] 40mg/ml) for visualization during pars plana vitrectomy. Retina 2009 29(1):38-45 PMID 18827733

Domalpally A, Blodi BA, Scott Iu, Ip MS, Oden NL, Lauer AK, Van Veldhuisen PC, and SCORE Study Investigator Group. The Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) Study System for Evaluation of Optical Coherence Tomograms: Score Study Report 4 Arch Ophthalmol. 2009; 127 (11): 1461-1467

Diabetic Retinopathy Clinical Research Network. (S.Y. Lee, Participating Clinical Investigator). A Randomized Trail Comparing Intravitreal Triamcinolone Acetonide and Focal/Grid Photocoagulation for Diabetic Macular Edema. *Ophthalmology*, 2008; 115: 1447-1459

S.Y. Lee, P. Jagannathan, A.O. Edwards. "Retinal Pigment Epithelial Rip Following Intravitreal Triamcinolone Acetonide for Exudative Age-Related Macular Degeneration." Submitted for publication June, 2003.

D.M. Meyer, M.E. Jessen, R.Y. Chao, C. Barak, <u>S.Y. Lee</u>. "Recovery of Right Ventricular Function after Severe Hemorrhagic Shock – Resuscitation Using Extracorporeal Assisted Circulation." *Shock*, Supplement 1:8, 1994.

D.M. Meyer, M.E. Jessen, R.Y. Chao, C. Barak, <u>S.Y.Lee</u>. "Effects of Extracorporeal Assisted Circulation on Recovery from Shock." *Circulatory Shock*, Supplement 2: 10, 1993.

BOOK CHAPTER

W.C. Sheils, <u>S.Y. Lee</u>, D.M. Marcus. "Radiation Therapy for Age-Related Macular Degeneration." in *Age-Related Macular Degeneration: Current Treatment Concepts*, edited by W.E. Alberti, G. Richard, R.H. Sagerman. Pp. 189-198. New York: Springer-Verlag, 2000.

ABSTRACT

D.Parver, S.Y. Lee, Y.-G. He and J.P. Mc Culley. Evaluation of Vitreo-Retinal Procedures Combined with Cataract Extraction and Implantation of the Acrysof Natural Intraocular Lens. *Invest Ophthalmol Vis Sci 2004; 45: E-Abstract 331*

Multimodality Transpupillary Thermotherapy and Radiotherapy of Choroidal Neovascular Membranes in Age-Related Macular Degeneration: A Phase I Safety Study. <u>Lee, S.Y.</u>, Sheils, W.C., Redd, J., Samy, C.N., Marcus, D.M. *Invest.Ophthalmol.Vis.Sci.* 2002; 43 (suppl): Abstract #4411

C. Whitten, P. Greilich, D. Young, R. Ivy, <u>S.Y. Lee</u>, P. Allison. "Do Preoperative Levels of Alpha₂-Antiplasmin Vary for Different Cardiac Surgical Procedures?" *American Society of Anesthesiologists: 1997 Abstracts*.

PRESENTATIONS

S.Y. Lee, B. Wall, S.B. McIntosh, C.N. Samy, W.C. Sheils, D.M. Marcus. "Laser Photocoagulation with Adjuvant External Beam Irradiation for Non-Foveal Classic Choroidal Neovascular Membranes in Age Related Macular Degeneration." ARVO Annual Meeting, Fort Lauderdale, Florida, 2001.

S.Y. Lee, W.C. Sheils, J. Redd, C.N. Samy, D. M. Marcus. "Multimodality Transpupillary Thermotherapy and Radiotherapy of Choroidal Neovascular Membranes in Age-Related Macular Degeneration: A Phase I Safety Study." ARVO Annual Meeting, Fort Lauderdale, Florida, 2002.

CERTIFICATION

Diplomate of the American Board of Ophthalmology (Board certified May 2004)

Investigator Education for the Protection of Human Research Subjects with HIPPA Privacy Rule Component (June 28, 2004)

LICENSE

Texas, #K7796, 1999 to present

PROFESSIONAL ORGANIZATIONS

American Academy of Ophthalmology Texas Ophthalmological Association American Society of Cataract and Refractive Surgery American Society of Retina Specialists