RETINA ASSOCIATES OF UTAH CURRENT ACTIVE STUDIES AND PARTICIPATION: (April 2021)

CURRENT STUDIES

Apellis – APL2-304 DRY

A Phase 3, Multi-Center, Randomized, Double-Masked, Sham-Controlled Study to Compare the Efficacy and Safety of Intravitreal Pegcetacoplan Therapy with Sham Injections in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD).

Status: Closed for Enrollment – one patient enrolled.

APL2-305 Gale - DRY

This is the extension study for 304. We could potentially have one patient to rollover.

ISIS 696844—CS5 - DRY

A Phase 2, Placebo-controlled, study for patients with GA secondary to AMD. We have just this week been notified that we have been selected to participate in this new dry study. The sponsor is Ionis Pharma. and uses drug called IONIS-FB-LRX to treat dry AMD.

Status: Open for enrollment. Have 2 enrolled, 1 in screening, and 2 additional scheduled for screening.

ISEEE2008 – GATHER2 – DRY

A Phase 3 Multicenter, Randomized, Double Masked, Sham-Controlled Clinical Trial to Assess the Safety and Efficacy of Intravitreal Administration of Zimura (Complement C5 Inhibitor) in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

Status: Open for enrollment.

Horizon/Explore Gyroscope – GT005-03/Explore GT005-04 – DRY – treatment study for our current Gyroscope study

Horizon - A PHASE II, OPEN-LABEL, OUTCOMES-ASSESSOR MASKED, MULTICENTRE, RANDOMISED, CONTROLLED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TWO DOSES OF GT005 ADMINISTERED AS A SINGLE SUBRETINAL INJECTION IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO DRY AGE-RELATED MACULAR DEGENERATION

Explore - A PHASE 2, OUTCOMES ASSESSOR-MASKED, MULTICENTRE, RANDOMISED STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TWO DOSES OF GT005 ADMINISTERED AS A SINGLE SUBRETINAL INJECTION IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION

Status: Consideration to join.

Archway – GR40548 – CLOSED AND ALL PATIENTS HAVE ROLLED OVER INTO PORTAL

A PHASE III, MULTICENTER, RANDOMIZED, VISUAL ASSESSOR–MASKED,ACTIVE-COMPARATOR STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE RELATED MACULAR DEGENERATION.

Status: Closed for Enrollment/All patients have completed

Portal – GR40549_WET

A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION.

Status: Closed for Enrollment – 17 active patients in follow-up

Pagoda – GR40550 DME

A PHASE III, MULTICENTER, RANDOMIZED, VISUAL ASSESSOR-MASKED, ACTIVE-COMPARATOR STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH DIABETIC MACULAR EDEMA (PAGODA)

Status: Open for enrollment – have enrolled 5 / 3 ACTIVE patients

YOSEMITE — DME

Phase 3 DME study of faricimab. This study has an extension study called Rhone-X. Enrolled 4.

Status: Closed to enrollment.

Rhone – X – DME extention study to Yosemite.

Status: Closed enrollment. Rollover patients only. 1 patient has rolled over. Another possible will be joining shortly.

Regeneron – PHOTON VGFTe-HD-DME-1934 – DME

A RANDOMIZED, DOUBLE-MASKED, ACTIVE-CONTROLLED PHASE 2/3 STUDY OF THE EFFICACY AND SAFETY OF HIGH-DOSE AFLIBERCEPT IN PATIENTS WITH DIABETIC MACULAR EDEMA

Status: Closed to enrollment.

Pavilion – GR41675 NPDR

A PHASE III, MULTICENTER, RANDOMIZED STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF THE PORT DELIVERYSYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NONPROLIFERATIVE DIABETIC RETINOPATHY

Status: Open for Enrollment – have screened 1.

PANDA – WET

Phase 3. Neovascular Age-related Macular Degeneration. Study is closed to enrollment. Have 2 more active patients to complete study. LPV will be Sept 2021.

LUCERNE – WET

Phase 3 112-week study to investigate the efficacy, safety, durability, and pharmacokinetics of faricimab administered at up to 16-week intervals to **treatment-naïve patients with nAMD**. We enrolled 6.

AVONELLE – X WET – This is an extention study for Lucerne patients starting Q3 2021

A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AVONELLE-X)

Sandoz - WET

A RANDOMIZED, DOUBLE-MASKED, ACTIVE-CONTROLLED PHASE 2/3 STUDY OF THE EFFICACY AND SAFETY OF HIGH-DOSE AFLIBERCEPT IN PATIENTS WITH NEOVASCULAR AGE RELATED MACULAR DEGENERATION.

Status: In start-up – waiting on activation

UPCOMING STUDIES:

ADVM-022-08 – WET GENE THERAPY
Phase 3 Study Title A Multi-Center, Randomized, Double-masked, Active Controlled Study of ADVM-022 (AAV.7m8-aflibercept) in Neovascular (Wet) Age-related Macular Degeneration (nAMD)

Status: Budgeting/Contract

Atmosphere – RGX-314-2104 – WET GENE THERAPY

A Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD.

Status: Start up phase – budget/contract

Genentech-ML43000 – CURRENT WET PATIENTS ON TREATMENT

PHASE IIIb/IV, MULTICENTER, OPEN-LABEL, SINGLE-ARM, VISUAL ASSESSOR MASKED STUDY OF THE EFFICACY AND SAFETY OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION PREVIOUSLY TREATED WITH INTRAVITREAL AGENTS OTHER THAN RANIBIZUMAB

Status: budget/contract

GR41984 Balaton (BRVO) (Macular Edema secondary to Branch Retinal Vein Occlusion) **AND GR41986 Comino (CRVO)- GR41986** (Macular Edema due to Central Retinal Vein Occlusion (CRVO) or Hemiretinal Vein Occlusion (HVRO))

Status: Should be activated shortly.

BP41783 Longitude – for nAMD and DME

A LONGITUDINAL, BIOMARKER STUDY, TO EXPLORE THE COMPOSITION OF AQUEOUS HUMOR AND THE ASSOCIATED MULTIMODAL RETINAL IMAGING IN ANTI-VEGF TREATMENTNAÏVE NEOVASCULAR AGE-RELATED MACULAR DEGENERATION AND DIABETIC MACULAR EDEMA, BEFORE AND AFTER AFLIBERCEPT TREATMENT

Status: In start-up finalizing for activation.

Gallego – GR40973 – DRY

A PHASE II, MULTICENTER, RANDOMIZED, SINGLE-MASKED, SHAM−CONTROLLED STUDY TO ASSESS SAFETY, TOLERABILITY, AND EFFICACY OF INTRAVITREAL INJECTIONS OF FHTR2163 IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION.

Status: Updated our feasibility survey; awaiting report back.