PAGODA STUDY

Diabetic Macular Edema

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.

Principal Investigator:
Matthew P. Ohr, MD

Inclusion Criteria:

- Age ≥ 18 years at time of signing Informed Consent Form
- BCVA of ≥ 25 letters (20/320 approximate Snellen equivalent or better), using the ETDRS protocol at the initial testing distance of 4 meters
- HbA_{1c} level of ≤ 10% within 2 months prior to screening or at screening

Exclusion criteria

- Currently untreated diabetes mellitus or previously untreated patients who initiated oral anti-diabetic medication or insulin within 3 months prior to randomization
- Uncontrolled blood pressure (defined as systolic > 180 mmHg and/or diastolic > 110 mmHg while a patient is at rest) at screening
- Renal failure requiring renal transplant, hemodialysis, or peritoneal dialysis, or anticipated to require hemodialysis or peritoneal dialysis at any time during the study

Information about this Study is provided on this website so you can learn about the Study. This may help you decide whether this Study is right for you. It may also be useful in your discussions with your doctor, family and care provider. The information is not intended to be promotional. The drug being studied has not been approved by the FDA, EMA or other regulatory agency for the disease being studied.

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