ForPatients
by Roche

Edema macular diabético

ESTUDIO DE FASE II, MULTICÉNTRICO, ALEATORIZADO, DOBLE ENMASCARADO, CONTROLADO CON COMPARADOR ACTIVO PARA EVALUAR LA EFICACIA, SEGURIDAD, TOLERABILIDAD, FARMACOCINÉTICA Y FARMACODINÁMICA DE RO7200220 ADMINISTRADO POR VÍA INTRAVÍTREA EN PACIENTES CON EDEMA MACULAR DIABÉTICO

A Study to Investigate Vamikibart (RO7200220) in Diabetic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Completo	9 Countries	NCT05151731 2021-003756-16 RENIS IS003788 BP43445

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

A Phase II, Multicenter, Randomized, Double Masked, Active Comparator-Controlled Study to Investigate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7200220 Administered Intravitreally in Patients With Diabetic Macular Edema

Trial Summary:

Study BP43445 is a phase II, multicenter, randomized, double-masked, active comparator-controlled study to investigate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of vamikibart administered intravitreally in participants with diabetic macular edema. Only one eye will be chosen as the study eye. The duration of the study will be up to 76 weeks.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT05151731 2021-003756-16 RENIS IS003788 BP43445
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Diagnosis of diabetes mellitus (Type 1 or Type 2)
- Macular thickening secondary to diabetic macular edema (DME) involving the center of the macula
- Decreased visual acuity attributable primarily to DME
- Ability and willingness to provide written informed consent and to comply with the study protocol
- Willingness to allow Aqueous Humor collection
- For women of childbearing potential: agreement to remain abstinent or use at least one highly effective contraceptive method that results in a failure rate of <1% per year during the treatment period and for at least 12 weeks after the final dose of study treatment

Exclusion Criteria:

- Hemoglobin A1c (HbA1c) of greater than (>) 12%
- Uncontrolled blood pressure, defined as a systolic value greater than (>)180 millimeters of mercury (mmHg) and/or a diastolic value >100 mmHg while a patient is at rest
- Currently pregnant or breastfeeding, or intend to become pregnant during the study
- Prior treatment with panretinal photocoagulation or macular laser to the study eye
- Any intraocular or periocular corticosteroid treatment within the past 16 weeks prior to Day 1 to the study eye
- Prior Iluvien or Retisert implants within 3 years prior to Day 1 to the study eye
- Prior or concomitant treatment with anti-VEGF therapy within 8 weeks prior to Day 1 to the study eye; Vabysmo^TM within 16 weeks prior to Day 1, prior Beovu® is not permitted
- Prior administration of IVT brolucizumab (Beovu®): ever; vamikibart: </=24 weeks prior to Day 1) in either eye
- Any proliferative diabetic retinopathy
- Active intraocular or periocular infection or active intraocular inflammation in the study eye
- Any current or history of ocular disease other than DME that may confound assessment of the macula or affect central vision in the study eye
- Any current ocular condition which, in the opinion of the investigator, is currently causing or could be expected to contribute to irreversible vision loss due to a cause other than DME in the study eye
- Other protocol-specified inclusion/exclusion criteria may apply