ForPatients
by Roche

Huntington Disease (HD)

An Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of RO7234292 (RG6042) in Patients With Huntington's Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	8 Countries	NCT03842969 2018-003898-94 BN40955

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Intrathecally Administered RO7234292 (RG6042) in Patients With Huntington's Disease

Trial Summary:

This study will evaluate the long-term safety and tolerability of RO7234292 (RG6042) in participants who have completed other F. Hoffmann-La Roche, Ltd.-sponsored and/or Genentech-sponsored studies in the Huntington's disease (HD) in the development program for RG6042.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03842969 2018-003898-94 BN40955
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#25 Years	No

Inclusion Criteria:

- Prior enrollment in a Roche-sponsored or Genentech-sponsored study in HD for the RO7234292 (RG6042) development program that made provision for entry into an OLE study
- For women of childbearing potential: agreement to remain abstinent or use contraceptive measures

- For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm
- Patients who were screened and eligible for the placebo-controlled Phase III Study BN40423 but could not be randomized prior to the close of Study BN40423 enrollment due to challenges relating to the COVID-19 pandemic

Inclusion criteria of patients who were screened and eligible for the placebo-controlled Phase III Study BN40423 but could not be randomized prior to the close of Study BN40423 enrollment due to challenges relating to the COVID-19 pandemic:

- Manifest HD diagnosis, defined as a DCL score of 4
- Independence Scale (IS) score >=70
- Genetically confirmed disease by direct DNA testing with a CAP score >400
- Clinical assessment to ensure individual has intact functional independence at baseline to maintain self-care and core activities of daily living (ADLs).

Exclusion Criteria:

- Withdrawal of consent from the preceding study
- Permanent discontinuation of RO7234292 (RG6042) for any drug-related safety concern during the preceding study or meeting of any study treatment discontinuation criteria specified in the preceding study at the time of enrollment into this study
- An ongoing, unresolved, clinically significant medical problem that in the judgment of the investigator would make it unsafe for the patient to participate in this study
- Antiplatelet or anticoagulant therapy within 14 days prior to inclusion or anticipated use during the study, including, but not limited to, aspirin, clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban, and apixaban
- History of bleeding diathesis or coagulopathy
- Platelet count less than the lower limit of normal
- Concurrent participation in any therapeutic clinical trial
- Study treatment (RO7234292/RG6042) is commercially marketed in the patient's country for the patient-specific disease and is accessible to the patient
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 5 months after the final dose of study drug

Exclusion criteria of patients who were screened and eligible for the placebo-controlled Phase III Study BN40423 but could not be randomized prior to the close of Study BN40423 enrollment due to challenges relation to the COVID-19 pandemic:

- Any serious medical condition or clinically significant laboratory, or vital sign abnormality or claustrophobia at screening that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 5 months after the final dose of study drug