The PROOF Trial:

Protocol #: QBGJ398-301

Protocol Title: A Phase 3 Multicenter, Open-Label, Randomized, Controlled Study of Oral Infigratinib Versus Gemcitabine With Cisplatin in Subjects With Advanced/Metastatic or Inoperable Cholangiocarcinoma With FGFR2 Gene Fusions/Translocations: the PROOF Trial

Clinical Trial Overview:

This is a Phase 3, multicenter, open-label, randomized, controlled study to evaluate the efficacy of infigratinib vs gemcitabine with cisplatin based on progression-free survival (PFS) in subjects with advanced/metastatic or inoperable cholangiocarcinoma with FGFR2 gene fusions/translocations.

Subjects will be randomized in a 2:1 ratio to receive oral infigratinib administered once daily for the first 3 weeks (21 days) of a 28-day treatment cycle or gemcitabine with cisplatin given on Days 1 and 8 of a 21-day treatment cycle.

Investigational Drug:

Infigratinib—oral, once daily

Comparator:

Gemcitabine with cisplatin

Primary Endpoint:

Progression-free survival (PFS), as assessed by blinded independent central review (BICR), vs gemcitabine/cisplatin combination

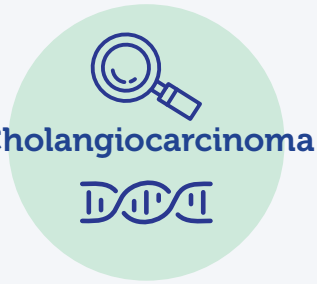
Secondary Endpoints:

- Overall survival (OS) vs gemcitabine/cisplatin combination
- Investigator assessed PFS vs gemcitabine/cisplatin combination
- Overall response rate (ORR), best overall response (BOR), duration of response (DOR), and disease control rate (DCR) vs gemcitabine/cisplatin combination
- Safety and tolerability of infigratinib

Selected Key Eligibility Criteria:

- Have histologically or cytologically confirmed unresectable locally advanced or metastatic cholangiocarcinoma
- Subjects with gallbladder cancer or ampulla of Vater carcinoma are not eligible
- Written documentation of local or central laboratory determination of FGFR2 gene fusions/translocations
- A representative tumor sample available for central FGFR2 fusion/translocation molecular testing
- Full recovery from permitted, prior therapies
- Age ≥18 years
- ECOG performance status ≤1
- Life expectancy >3 months
- No prior liver transplant
- No history or current evidence of extensive tissue calcification
- Sufficient bone marrow, kidney, and liver function
- Normal calcium and phosphorus levels

To see all Inclusion/Exclusion criteria, go to www.clinicaltrials.gov and search for NCT03773302.



To participate or learn more, please contact us at:

PROOF301@QEDTx.com

To find a PROOF Trial site near you, visit:

https://www.qedprooftrial.com/hcp/

The safety and efficacy of infigratinib have not been established. There is no guarantee that infigratinib will receive health authority approval or become commercially available in any country for the uses being investigated.

ECOG=Eastern Cooperative Oncology Group; FGFR=fibroblast growth factor receptor.

Who We Are

QED focuses on precision medicine for FGFR-driven cancers and diseases. Our name is derived from the Latin *Quod Erat Demonstrandum*: "thus, it has been proven."

Our core values are:

- Put patients first
- Think independently
- Be radically transparent
- Every minute counts
- Let science speak

What We Do

With singular focus, QED is devoted to the development of infigratinib. An investigational, selective tyrosine kinase inhibitor, infigratinib is being developed to treat patients with FGFR-driven cholangiocarcinoma, metastatic urothelial carcinoma, and achondroplasia.

Our Parent Company

BridgeBio is a clinical-stage biotech company developing novel, genetically targeted therapies to improve the lives of patients. BridgeBio combines a traditional focus on drug development with a unique corporate model, allowing rapid translation of early-stage science into medicines that treat disease at its source.

Founded in 2015, the company has built a robust portfolio of 16 transformative assets, ranging from preclinical to late-stage development in oncology, cardiology, dermatology, endocrinology, and other therapeutic areas. The company's focus on scientific excellence and rapid execution aims to transform today's discoveries into tomorrow's medicines.

bridgebio

To participate or to learn more, please contact us at:

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QED therapeutics
a bridgebio company