



NEWS RELEASE

qed therapeutics presents data for infigratinib in cholangiocarcinoma in late breaking abstract at the european society of medical oncology 2018 congress

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SAN FRANCISCO, Oct. 19, 2018 /PRNewswire/ — QED Therapeutics today announced the presentation of positive, updated interim data of infigratinib (BGJ398), an orally administered, selective fibroblast growth factor receptor (FGFR) 1-3 tyrosine kinase inhibitor, for the treatment of advanced or metastatic cholangiocarcinoma (bile duct cancer) during a late-breaking poster discussion at the European Society for Medical Oncology (ESMO).

In the open-label trial, which enrolled 71 patients with FGFR2 fusions/translocations, the confirmed overall response rate (cORR) was 26.9% (95% CI 16.8-39.1%) for all patients with the potential for confirmation (n=67) and an additional 56.7% experienced stable disease as their best response, resulting in a disease control rate of 83.6%. For patients who had received one or fewer prior treatment regimens, the cORR was 39.3% (n=28), whereas patients who had received two or more treatment regimens had a cORR of 17.9%. Median progression free survival was 6.8 months (95% CI 5.3-7.6) and median overall survival was 12.5 months (95% CI 9.9-16.6 months).

“These updated data provide the most extensive experience for an FGFR inhibitor in advanced cholangiocarcinoma,” said Milind Javle, M.D., professor, gastrointestinal medical oncology, The University of Texas MD Anderson Cancer Center and investigator on the Phase 2 infigratinib (BGJ398) study. “The high disease control rate and impressive overall survival are promising in a disease with no currently approved targeted treatments.”

“These results show that infigratinib has strong potential to make a real difference in the lives of people with

cholangiocarcinoma,” said Susan Moran, M.D., M.S.C.E., chief medical officer of QED Therapeutics. “Importantly, we have initiated a pivotal, Phase 3 study in first-line cholangiocarcinoma in the hopes of offering patients an upfront chemotherapy-free treatment option.”

The study also demonstrated that infigratinib-associated toxicity is manageable. Most common treatment-emergent adverse events (TEAE) were hyperphosphatemia (73.2%), fatigue (49.3%), stomatitis (45.1%), alopecia (38.0%) and constipation (35.2%). Grade 3/4 TEAEs occurred in 47 patients (66.2%), including hypophosphatemia (14.1%), hyperphosphatemia (12.7%) and hyponatremia (11.3%).

Cholangiocarcinoma affects approximately 8,000 to 10,000 patients a year in the United States. Currently, treatment options are limited, and survival rates are generally poor.

FGFR alterations have been implicated as an oncogenic driver across multiple solid tumors and hematological cancers – including roughly one out of every five cases of cholangiocarcinoma and urothelial carcinoma. Activating mutations in FGFRs are also found in multiple forms of pediatric skeletal dysplasias, including achondroplasia, which affects up to one out of every 15,000 live births.

A Phase 3 study comparing infigratinib to standard of care chemotherapy for first line cholangiocarcinoma has been initiated by QED Therapeutics.

Full poster available at: www.QEDTx.com/ESMO2018/

About QED Therapeutics

QED Therapeutics, a subsidiary of BridgeBio Pharma, is a biotechnology company focused on precision medicine for FGFR-driven diseases. Our lead investigational candidate is infigratinib, an orally administered FGFR1-3 tyrosine kinase inhibitor that has shown meaningful clinical activity in patients with chemotherapy-refractory cholangiocarcinoma with FGFR2 fusions and advanced urothelial carcinoma with FGFR3 genomic alterations. QED is also evaluating infigratinib in preclinical studies for the treatment of achondroplasia and other skeletal dysplasias. We plan to conduct further clinical trials to evaluate infigratinib in additional FGFR-driven tumor types and rare disorders.