Documents

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Infigratinib in patients with advanced cholangiocarcinoma with FGFR2 gene fusions/translocations: The PROOF 301 trial

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Abstract
Cholangiocarcinoma is an aggressive malignancy with poor overall survival. Approximately 15% of intrahepatic cholangiocarcinomas contain FGFR alterations. Infigratinib is an oral FGFR 1-3 kinase inhibitor. Favorable results from a Phase II trial of infigratinib in advanced/metastatic FGFR-altered cholangiocarcinomas has led to its further investigation in the front-line setting. In this article we describe the design, objectives and rationale for PROOF 301, a Phase III multicenter, open label, randomized trial of infigratinib in comparison to standard of care gemcitabine and cisplatin in advanced/metastatic cholangiocarcinoma with FGFR2 translocations. The results of this study have the potential to define a new role for a chemotherapy-free, targeted therapy option in the front-line setting for these patients. © 2020 Future Medicine Ltd.

Author Keywords
cholangiocarcinoma; fibroblast growth factor receptor inhibitor; infigratinib; targeted therapy

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