

For Immediate Release: July 23, 2020

Media Contact: Rachel Darwin 267-622-6624 darwin@nccn.org

NCCN Oncology Research Program Announces Projects Selected for Funding to Study Futibatinib in Tumors with Aberrant FGFR Expression, in Collaboration with Taiho Oncology

Researchers from NCCN Member Institutions will evaluate futibatinib in order to improve treatment for cancers with FGFR aberrations.

PLYMOUTH MEETING, PA [July 23, 2020] — The National Comprehensive Cancer Network® (NCCN®) Oncology Research Program (ORP) today announced four projects selected to receive funding for clinical and pre-clinical evaluation of futibatinib (TAS-120). Futibatinib is an oral, irreversible, selective fibroblast growth factor receptor (FGFR)1–4 Inhibitor. In a phase 1 dose-escalation trial, futibatinib demonstrated tolerability, pharmacodynamic activity, and preliminary antitumor activity in heavily pretreated patients with advanced solid tumors¹. NCCN will provide study oversight while Taiho Oncology is providing drug and funding.

The following projects were selected following formal scientific evaluation by a panel of NCCN experts:

- Phase Ib trial of Olaparib in Combination with Futibatinib in All Solid Tumors with BRCA1/2 Alterations
 - o Jordi Rodon Ahnert, MD, PhD, The University of Texas MD Anderson Cancer Center
- A Phase II Study of Futibatinib and Pembrolizumab in Metastatic Microsatellite Stable Endometrial Carcinoma
 - o Siqing Fu, MD, PhD, The University of Texas MD Anderson Cancer Center
- Phase 2 Study of FRFR4 Inhibitor Futibatinib in Combination with Anti-PD1 Antibody Pembrolizumab in Patients with Advanced or Metastatic Hepatocellular Carcinoma with FGF19 Expression after Firstline Therapy
 - o Nguyen Hoai Tran, MD, Mayo Clinic Cancer Center
- Developing Futibatinib for Use on Novel FGFR Genomic Alterations and in Therapy Combination
 - Sameek Roychowdhury, MD, PhD, The Ohio State University Comprehensive Cancer Center - Arthur G. James Cancer Hospital and Richard J. Solove Research Institute

¹ Bahleda R, Meric-Bernstam F, Goyal L, et al. Phase 1, First-in-Human Study of Futibatinib, a Highly Selective, Irreversible FGFR1-4 Inhibitor in Patients with Advanced Solid Tumors [published online ahead of print, 2020 Jul 2]. Ann Oncol. 2020;S0923-7534(20)39928-2. doi:10.1016/j.annonc.2020.06.018

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Left to right: Drs. Ahnert, Fu, Tran, and Roychowdhury

"This is a really exciting time for such research," said **Wui-Jin Koh, MD, Chief Medical Officer, NCCN**. "There have been some recent discoveries on how FGFR aberrations can impact tumor progression and survival in patients with different cancers, with endometrial cancer being one example. The selected studies offer unique and critical opportunities to learn more about which patients will receive the most benefit from FGFR inhibitors and which approaches are likely to lead to the best outcomes."

"Our support for the National Comprehensive Cancer Network on this important research represents another significant step for Taiho Oncology, as we continue to broaden our collaboration with key investigators in the development of futibatinib." said Martin J. Birkhofer, MD, Senior Vice President and Chief Medical Officer, Taiho Oncology, Inc. "We thank NCCN for their selection of futibatinib for further research and look forward to the generation of data from these studies as we explore the full potential of futibatinib in patients with a variety of solid tumors."

Proposals were peer reviewed by a Scientific Review Committee, which consisted of distinguished oncologists from NCCN Member Institutions. The funded concepts were selected based on several criteria, including scientific merit, existing data, feasibility, and the types of studies needed to further evaluate futibatinib.

The NCCN ORP fosters innovation and knowledge discovery that improves the lives of people with cancer and supports preclinical, translational, and clinical research and quality improvement projects in oncology at NCCN Member Institutions. For more information, visit NCCN.org/orp.

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