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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.

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

The NCCN Oncology Research Program (ORP) recently announced 4 projects selected to receive funding for clinical and preclinical evaluation of futibatinib (TAS-120). Futibatinib is an oral, irreversible, selective fibroblast growth factor receptor (FGFR) 1–4 inhibitor. In a phase I dose-escalation trial, futibatinib demonstrated tolerability, pharmacodynamic activity, and preliminary antitumor activity in heavily pretreated patients with advanced solid tumors.¹ 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
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
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
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

“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.

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

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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 NCCN 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](https://www.nccn.org/orp).

Reference

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 July 2, 2020]. *Ann Oncol*. doi:10.1016/j.annonc.2020.06.018

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NCCN Explores Adoption of Biosimilars in Oncology in Collaboration With Pfizer

NCCN Oncology Research Program (ORP), in collaboration with Pfizer Inc., has announced an open RFP for projects that support innovative approaches to improve the processes related to appropriate biosimilar adoption in oncology. Approved biosimilars are copies of biologic medicines that are similar—even if not completely identical—to the original reference product and have been demonstrated in analytical studies to be highly similar in terms of efficacy and safety profile. Letters of intent (LOIs) are welcome from academic or community centers, patient advocacy groups, or health care professional organizations based in the United States, with the exception of small, physician-owned group practices. LOIs are due on September 9, 2020.

“The creation of a sustainable and competitive marketplace for biologics and biosimilars—in keeping with FDA guidance—can increase treatment options while generating cancer care cost savings,” said Wui-Jin Koh, MD, Chief Medical Officer, NCCN. “A recent RAND corporation study found that if biosimilars became 50% of the market share, it could mean savings of \$150 billion in drug spending between 2017 and 2026.¹ With this RFP, we’re looking for impactful approaches to objectively measure and validate models for supporting and increasing the safe and proper use of biosimilars in oncology.”

“We are enthusiastic about the ability for biosimilars to help increase access to essential medicines and potentially lower the cost of care when utilized,” said Andrew Coop, North America Medical Lead, Pfizer Oncology. “We are thrilled

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to collaborate with NCCN to further explore solutions like biosimilars for people living with cancer.”

Some suggested areas of study include:

- Quality of care and best practices around the appropriate use of biosimilars
- Quality of care and best practices around the perceptions of biosimilars
- Quality/Process improvement projects that impact efficiency and resource utilization
- Educational tools for providers, nurses, pharmacists, administrative units
- Pharmacy and Therapeutic Committee processes
- Pharmacy practices that improve the safety or use of biosimilars
- Electronic medical records and integration of biosimilars
- Tools impacting prescribing behaviors
- Clinical pathway and consensus guidelines development
- Challenges related to payer mandates/insurance issues
- Optimization and integration of processes
- Value/Quality/Cost for patients, clinicians and institutions

Collaboration between institutions is strongly encouraged in order to encourage interactive sharing of knowledge and expertise.

The NCCN ORP fosters innovation and knowledge discovery that improves the lives of people with cancer and supports preclinical, translational, clinical research and quality improvement projects in oncology. For more information, visit [NCCN.org/ORP](https://www.nccn.org/ORP).

Reference

1. Mulcahy AW, Hlavka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. RAND Corporation. Accessed July 10, 2020. Available at: <https://www.rand.org/pubs/perspectives/PE264.html>