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NCCN Announces Selected Projects to Study Neratinib in Collaboration with Puma Biotechnology, Inc.

Research projects will explore the role of neratinib in gastric and gastroesophageal cancers as well as neurofibromatosis 2.

PLYMOUTH MEETING, PA [July 15, 2021] — The National Comprehensive Cancer Network® (NCCN®) Oncology Research Program (ORP) today announced three research projects that have been selected for funding to evaluate neratinib in various tumor types. Neratinib is a type of tyrosine kinase inhibitor (TKI) that works as a dual inhibitor of the epidermal growth factor receptor 1 (EGFR) and human epidermal growth factor receptor 2 (HER2). The research is supported by a grant from Puma Biotechnology, Inc.

"These projects will add to our understanding of the optimal ways to target this pathway and further the management of these diseases, which include rare conditions," said **Crystal S. Denlinger, MD, FACP, Senior Vice President, Chief Scientific Officer, NCCN**. "We congratulate these impressive investigators and look forward to their findings."

The selected projects are:

- Rutika Mehta, MD, MPH, Moffitt Cancer Center
 - Phase 2 study of neratinib in combination with chemotherapy and trastuzumab in HER2 overexpressing gastroesophageal cancers
- Scott Plotkin, MD, PhD, Dana-Farber/Brigham and Women's Cancer Center | Massachusetts General Hospital Cancer Center
 - Phase 2 study of neratinib for adolescents and adults with neurofibromatosis 2 and progressive NF2-related neoplasms: a sub-study of the INTUITT-NF2 platform-basket trial (NCT04374305)
- Namrata Vijayvergia, MD, Fox Chase Cancer Center
 - Multi-center Phase 1 trial of neratinib and fam-trastuzumab deruxtecan in advanced refractory gastric cancer patients

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Left to right: Drs. Mehta, Plotkin, and Vijayvergia

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are pleased to support our partnership with the National Comprehensive Cancer Network in advancing cancer research and we congratulate the selected investigators. We are committed to exploring the efficacy of neratinib in a diverse range of tumor types for the benefit of affected patient populations and we look forward to the insights provided by these studies."

Proposals were peer reviewed by a Scientific Review Committee, which consisted of leading expert medical 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 neratinib. The research projects will commence late 2021 and take place over two years. The NCCN ORP will provide oversight. Puma is providing \$1.4 million in funding and will also supply the neratinib tablets for use in the studies.

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. In an effort to improve collaboration in cancer research, the NCCN ORP also maintains a shared resources website and an informed consent database. For more information, visit NCCN.org/orp.

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About the National Comprehensive Cancer Network

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