The NCCN Oncology Research Program (ORP) strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. Since the program's establishment in 1999, the NCCN ORP has brought millions of dollars in research grants to investigators at NCCN Member Institutions. Research grants are provided to NCCN through collaborations with pharmaceutical and biotechnology companies; these grants are in turn used to support scientifically meritorious cancer research efforts.

NCCN ORP studies typically explore new avenues of clinical investigation and seek answers to important cancer-related questions. All studies are approved and funded through a scientific peer-review process and are overseen by the ORP.

This feature highlights an NCCN study funded through the grant mechanism.

doi: 10.6004/jnccn.2019.0011

For more information on specific trials, including patient selection criteria, use the contact information listed with each study.

For more information on the NCCN ORP, including a complete detailing of the clinical studies currently underway at NCCN Member Institutions, go to www.NCCN.org/clinical_trials/clinicians.asp.

Women's Triple-Negative First-Line Study: A Phase II Trial of Mirvetuximab Soravtansine in Patients With Localized Triple-Negative Breast Cancer (TNBC) With Tumors Predicted Insensitive to Standard Neoadjuvant Chemotherapy, Including a Lead-in Cohort to Establish Activity in Patients With Metastatic TNBC

Principal Investigator: Stacy Moulder, MD

Co-Investigators: Senthil Damodaran, MD; Elizabeth Mittendorf, MD, PhD; W. Fraser Symmans, MD

Condition: Triple-negative breast cancer

Institution: The University of Texas MD Anderson Cancer Center

Patients with triple-negative breast cancer (TNBC) who have residual disease after neoadjuvant chemotherapy (chemo-insensitive disease) have a dismal prognosis, with a 40% to 80% risk of recurrence within 3 years. Thus, exploring novel agents to treat disease that has been identified as chemo-insensitive in the neoadjuvant setting is a viable strategy, because potentially curative chemotherapy is not compromised in this high-risk patient population. Ideally, agents should have demonstrated activity in metastatic disease before use in the neoadjuvant setting. Taken together, the activity of mirvetuximab soravtansine in advanced, heavily pretreated ovarian cancer and the common expression of high levels of folate receptor alpha (FR α) in TNBCs support the rationale to determine the activity of mirvetuximab soravtansine in metastatic breast cancer and, if response is confirmed, evaluating the drug for neoadjuvant treatment of high-risk, chemo-insensitive TNBC.

Patients with metastatic or localized chemo-insensitive TNBC that expresses moderate to high levels of FR α will be enrolled. Two cohorts of patients will be accrued: those with advanced/metastatic TNBC (cohort A) and those with localized, chemo-insensitive TNBC (cohort B). Several biomarkers, including FR α , will be evaluated as potential biomarkers of clinical response to IMGN853 (cohort B only). For purposes of study entry, low FR α expression on the cell surface will be defined as $\geq 25\%$ of cells with $\geq 1+$ expression. TNBC will be defined as estrogen receptor $< 10\%$, progesterone receptor $< 10\%$, and HER2 0 to 2+ using standard immunohistochemistry (IHC). Tumors that are HER2 2+ by IHC must demonstrate nonamplification (ratio < 2) by standard in situ hybridization techniques (chromogenic in situ hybridization or fluorescence in situ hybridization).

Primary Objectives:

- Determine if single-agent mirvetuximab induces response in at least 20% response rate by RECIST criteria in metastatic TNBC
- Determine if single-agent mirvetuximab in the neoadjuvant setting improves rate of excellent pathologic response (complete pathologic response or minimal residual disease) in patients identified as having chemo-insensitive TNBC

Cont. on page xxii.

Cont. from page xx.

Secondary Objectives:

- Determine the radiographic response
- Determine toxicity of mirvetuximab given in cohorts B and A.
- Determine disease-free survival at 3 years in the neoadjuvant setting, and progression-free survival, duration of response, and overall survival at 3 years in metastatic TNBC
- In the neoadjuvant setting, compare disease response to mirvetuximab versus tumors with similar molecular features treated with standard taxane-based chemotherapy

Exploratory Objectives:

- Correlate response to mirvetuximab with expression of FR α /FOLR1 in primary tumors
- Determine if treatment with mirvetuximab alters the tumor microenvironment, making the tumors more susceptible to treatment with immune regulators

Contact: Stacy Moulder, MD • 713-563-0730 •
CR_Study_Registration@mdanderson.org

ClinicalTrials.gov Identifier: NCT03106077

Free Patient Webinar

Tuesday, February 26, 2019
11:00 AM – 12:15 PM

Thursday, February 28, 2019
4:00 – 5:15 PM

Register Now

Know What Your Doctors Know:

Updates in Lung Cancer

Join experts as they discuss updates in non-small cell lung cancer.

Topics will include:

- Biomarker (molecular) testing,
- New treatments, and
- Quality of life.

Each webinar will also include a Question & Answer session. You may submit questions to the presenters during the webinar or in advance.

Presenters

Gregory A. Otterson, MD

*Thoracic Oncologist Professor of Internal Medicine
The Ohio State University Comprehensive Cancer Center -
James Cancer Hospital and Solove Research Institute*

Gina M. Perna, MSN, APRN-CNP, ACNP

*Acute Care Nurse Practitioner
The Ohio State University Comprehensive Cancer Center -
James Cancer Hospital and Solove Research Institute*

Get a Free Book!

Request your FREE copy of NCCN Guidelines for Patients®: Lung Cancer. Free copies are limited to the first 400 requests within the United States.

NCCN.org/patientwebinars

Visit NCCN.org/patientwebinars to register.

Supporters

This activity is supported through the NCCN Foundation, by a contribution from our industry supporters AstraZeneca and Pfizer, Inc. NCCN independently develops and distributes the NCCN Guidelines for Patients. Our industry supporters do not participate in the development of the NCCN Guidelines for Patients and are not responsible for the content and recommendations contained therein.

The NCCN Guidelines for Patients: Lung Cancer are endorsed by:

American Lung Association; Bonnie J. Addario Lung Cancer Foundation; Caring Ambassadors Program, Inc.; Dusty Joy Foundation (LiveLung); Free ME from Lung Cancer; Lung Cancer Action Network (LungCAN); Lung Cancer Alliance; Lung Cancer Initiative of North Carolina; Lung Cancer Research Foundation; and LUNGevity.

JNCCN-N-0264-0119