Highlights of the NCCN Oncology Research Program

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.

An NCCN study funded through the grant mechanism is highlighted below.

Androgen Receptor Targeting in Mantle Cell Lymphoma: A Pilot Trial of Enzalutamide

Principal Investigators: Ajay Gopal, MD, and Victor A. Chow, MD

Condition: Mantle cell lymphoma

Institutions: Fred Hutchinson Cancer Research Center, University of Washington, and Seattle Cancer Care Alliance

This pilot clinical trial is studying the safety and efficacy of enzalutamide, a potent androgen receptor (AR) antagonist, in the treatment of patients with mantle cell lymphoma (MCL) that has returned after a period of improvement (relapsed) or has not responded to previous treatment (refractory). Preclinical studies suggest that ARs are overexpressed in MCL and that AR activation drives tumor growth, which may account for the vast male predominance observed in this disease. Additional preclinical studies have shown that blocking ARs with enzalutamide may slow or prevent tumor growth. This clinical trial is the first to evaluate the use of antiandrogen therapy in MCL.

Patients receive enzalutamide orally once daily in a continuous fashion until disease progression, unacceptable toxicity, or withdrawal from the trial. Patients are evaluated with regular clinical follow-up and interval CT ± PET imaging to determine response to therapy. Additionally, several laboratory studies will be performed on patient blood and tissue samples in order to study the biochemical processes involved in disease response and development of resistance to antiandrogen therapy. After completion of study treatment, patients are followed for up to 5 years.

Primary Objective:

- Perform a preliminary assessment of the efficacy of single-agent enzalutamide, based on overall response rate, in subjects with relapsed/refractory MCL

Secondary Objectives:

- Evaluate the duration of disease control (progression-free survival) in patients with MCL treated with enzalutamide
- Evaluate the safety profile of enzalutamide in MCL
- Gain preliminary data on clinical activity and toxicity of this regimen in male versus female patients

Contact: Heather Rasmussen • 206-606-7140

ClinicalTrials.gov Identifier: NCT02489123

The goal of the Highlights of the NCCN Oncology Research Program (ORP) is to provide readers with more information on the ORP, including studies currently accruing patients.

For more information on specific trials, including patient selection criteria, please 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, please access the NCCN ORP pages at NCCN.org/clinical_trials/clinicians.asp.

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