Journal of the National Comprehensive Cancer Network

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.

A Response-Adapted Clinical Trial of Weekly Carfilzomib With or Without Rituximab for Waldenström's Macroglobulinemia and Marginal Zone Lymphoma

Principal Investigator: Stephen D. Smith, MD

Conditions: Marginal zone lymphoma, recurrent marginal zone lymphoma, recurrent Waldenström's macroglobulinemia, refractory marginal zone lymphoma, refractory Waldenström's macroglobulinemia, Waldenström's macroglobulinemia

Institution: University of Washington/Fred Hutchinson Cancer Research Center

This phase II trial studies how well carfilzomib (CFZ), alone or with the addition of rituximab, works in treating patients with Waldenström's macroglobulinemia (WM) or marginal zone lymphoma (MZL). CFZ acts by altering the balance of proteins inside cells, resulting in programmed cell death (or apoptosis) of tumor cells. Rituximab, a monoclonal antibody, binds to the surface of the cancer cells, triggering the immune system to destroy them while also exerting direct toxic effects.

In this trial, patients first receive CFZ alone for 2 cycles; then, if the lymphoma is not responding, they also receive rituximab treatment. CFZ is given intravenously over 30 minutes on a weekly schedule, days 1, 8, and 15. Treatment cycles occur every 28 days and up to 6 cycles may be given in the absence of disease progression or unacceptable toxicity. Rituximab is added for patients who do not achieve a response to CFZ alone, and is given weekly for 4 doses starting with cycle 3; then once a month for cycles 4 through 6. After completion of study treatment, patients are followed up every 3 months for up to 1 year.

Primary Objective:

- Determine overall response rate of single-agent weekly CFZ, measured after 2 cycles of therapy, in WM and MZL

Secondary Objectives:

- Assess safety and tolerability of single-agent weekly CFZ in patients with WM and MZL, and determine the tolerability of weekly CFZ + rituximab among applicable patients
- Estimate time to best response, response duration, and survival with weekly CFZ for WM and MZL
- Evaluate overall response rate associated with weekly CFZ in a subset of patients with rituximab refractory WM or MZL

Contact: Stephen D. Smith, MD • 206-606-6546 • ssmith50@seattlecca.org

ClinicalTrials.gov Identifier: NCT03269552

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.

doi: 10.6004/jnccn.2018.0028