CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT02899052

A Phase II, Open-Label, Multi-Center Study of Venetoclax in Combination with Carfilzomib and Dexamethasone in Subjects with Relapsed or Refractory Multiple Myeloma

Trial Description:

This international trial will enroll 120 patients with relapsed or refractory (did not respond to) multiple myeloma who have received at least one prior line of therapy.

Trial Objectives:

The overall objective of this study is to evaluate the safety and effectiveness of venetoclax in combination with carfilzomib (Kyprolis®) and dexamethasone (VenKd), compared with a standard treatment of carfilzomib and dexamethasone (Kd).

Trial Design:

- **Part 1:** Evaluate the safety and amount of drug in your body while determining the appropriate doses of venetoclax and carfilzomib to be used in the VenKd combination.
- **Part 2:** Further evaluate the safety and effectiveness of the VenKd combination.
- **Part 3:** Further evaluation of the effectiveness of the VenKd combination.
- **Part 4:** Patients will receive varying doses of the VenKd combination or standard treatment.

Duration of Treatment:

The study consists of 3 phases:

- **Screening Phase:** Lasts up to approximately 28 days.
- **Study Drug Phase:** Patients will receive the assigned treatment until documented disease progression or until other criteria for discontinuation of the study is met. Treatment consists of oral (by mouth) and intravenous (into the vein) medications.
- **Follow-up Phase:** Patients will have one safety follow up visit approximately 30 days after their last dose of treatment. Additional follow-up, for patients who discontinue the study for reasons other than progressive disease, will be conducted every 4 weeks for the first year after completing the study, and then every 12 weeks thereafter. Following progressive disease, either while on treatment or during follow-up, survival follow-up will be conducted every 12 weeks until death, or for 24 months after the last patient's first dose, whichever occurs first.

Key Inclusion Criteria:

- Are 18 years of age or older with confirmed multiple myeloma diagnosis, measurable disease, and is relapsed or refractory (did not respond to) to the most recent line of therapy.
- Test positive for the t(11;14) translocation biomarker.
- Has received at least one prior line of therapy (a line of therapy consists of ≥1 complete cycle of a single agent, a regimen consisting of a combination of several drugs, or a planned sequential therapy of various regimens).
- Have not received treatment with carfilzomib, dexamethasone, venetoclax, or other BCL-2 inhibitors.
- Meet additional study criteria.

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INTERNATIONAL MYELOMA FOUNDATION

International Myeloma Foundation
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Key Exclusion Criteria:

- Pre-existing condition that is contraindicated (such as Grade 3 or 4 peripheral neuropathy or significant cardiovascular disease).
- History of other active malignancies, including myelodysplastic syndrome (MDS), within the past 3 years prior to study entry.

Venetoclax is being clinically investigated as a treatment for patients with multiple myeloma and is not approved by the FDA or other global regulatory health authorities. Safety and efficacy have not been established for this unapproved use.

Locations Enrolling Patients and Contact Information:

Contact ABBVIE CALL CENTER at **844-663-3742** or **abbvieclinicaltrials@abbvie.com** for specific site information.

United States, Alabama
Univ of Alabama at Birmingham – Main Campus /ID# 151405
Birmingham, Alabama 35233

United States, Arkansas
University of Arkansas for Medical Sciences /ID# 151399
Little Rock, Arkansas 72205

United States, Florida
Memorial Healthcare System /ID# 224862
Hollywood, Florida 33021-3513

United States, Georgia
Emory University, Winship Cancer Institute /ID# 161710
Atlanta, Georgia 30322

United States, Illinois
University of Chicago DCAM /ID# 151395
Chicago, Illinois 60637-1443

United States, Indiana
Indiana Blood & Marrow Transplantation /ID# 218862
Indianapolis, Indiana 46237

United States, Maine
Central Maine Medical Center /ID# 218856
Lewiston, Maine 04240

United States, Maryland
University of Maryland School Medicine /ID# 159721
Baltimore, Maryland 21201

United States, Missouri
Washington University – School of Medicine /ID# 222651
Saint Louis, Missouri 63110

Oncology Hematology Associates (OHA)
Springfield /ID# 218855
Springfield, Missouri 65807-5287

United States, North Carolina
Duke University Medical Center /ID# 162062
Durham, North Carolina 27710-3000

United States, Pennsylvania
University of Pennsylvania /ID# 151768
Philadelphia, Pennsylvania 19104-5502

United States, Texas
UT Southwestern Medical Center /ID# 218336
Dallas, Texas 75390-7208

Baylor Scott & White Medical Center – Temple /ID# 218252
Temple, Texas 76508-0001

United States, Utah
University of Utah /ID# 151397
Salt Lake City, Utah 84112-5500

United States, Wisconsin
Aurora Health Care, Aurora Cancer Center /ID# 209612
Wauwatosa, Wisconsin 53226-3436

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