CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT03539744

A Phase III, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

(CANOVA)

Trial Description:

This international trial will enroll 244 patients with relapsed or refractory (did not respond to previous treatment) multiple myeloma who have received at least two prior lines of therapy, including lenalidomide (Revlimid®) and a proteasome inhibitor. Patients will be randomly selected by a computer to one of two treatment groups called study "arms." Patients will know which arm they have been assigned to. There will be approximately 122 patients in each arm of the study.

Trial Objectives:

The overall objective of this study is to evaluate the safety and effectiveness of venetoclax plus dexamethasone (VenDex) compared with pomalidomide plus dexamethasone (PomDex) in participants with t(11;14)-positive relapsed or refractory multiple myeloma.

Trial Design:

- Patients in the experimental arm will receive venetoclax taken by mouth once daily plus dexamethasone taken by mouth once every week for each 28-day cycle.
- Patients in the comparator arm will receive pomalidomide taken by mouth once daily on Days 1–21 for each 28-day cycle plus dexamethasone taken by mouth once every week for each 28-day cycle.

Both treatments consist of oral (by mouth) medications which are taken at home.

Duration of Treatment:

The study consists of 3 phases:

- **Screening Phase:** Lasts up to approximately 21 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.
- **Follow-Up Phase:** Patients will have one treatment completion visit prior to commencing other therapies. If this visit predates 30 days, then a safety follow up visit will be completed. If a patient were to stop treatment without progression being documented, follow up will be conducted every 4 weeks until progression. After progression, patients will then be followed every 12 weeks.

Key Inclusion Criteria:

- Are 18 years of age or older.
- Have relapsed or refractory multiple myeloma with measurable disease.
- Test positive for the t(11;14) translocation biomarker.
- Previously received at least two prior lines of therapy, including lenalidomide, and a proteasome inhibitor.
- Relapsed or refractory to lenalidomide therapy.
- Meet additional study criteria.

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INTERNATIONAL MYELOMA FOUNDATION

International Myeloma Foundation
12650 Riverside Drive, Suite 206, North Hollywood, CA 91607 USA
Telephone: 800.452.CURE *(USA & Canada)* 818.487.7455 *(worldwide)* • TheIMF@myeloma.org • myeloma.org

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(continued)

Key Exclusion Criteria:

- Previous treatment with venetoclax or other B-Cell Lymphoma 2 (BCL-2) inhibitor or pomalidomide.
- Evidence of ongoing graft-versus-host disease (GvHD) if prior stem cell transplant (SCT).
- Prior treatment with any of the following: allogeneic or syngeneic SCT within 16 weeks prior to randomization; or autologous SCT within 12 weeks prior to randomization.

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, Arizona
University of Arizona Cancer Center
North Campus /ID# 218407
Tucson, Arizona 85719-1478

United States, California
VA Central California Health Care System /ID# 200047
Fresno, California 93703

University of California, Los Angeles /ID# 171524
Los Angeles, California 90095

United States, Colorado
Rocky Mountain Regional VA Medical Center –
Eastern Colorado Health Care System /ID# 222904
Aurora, Colorado 80045

United States, Florida
Mayo Clinic – Jacksonville /ID# 200075
Jacksonville, Florida 32224

Cleveland Clinic Foundation – Florida /ID# 208884
Weston, Florida 33331-3609

United States, Maryland
University of Maryland School of Medicine /ID# 217422
Baltimore, Maryland 21201

United States, Massachusetts
Boston Medical Center /ID# 223606
Boston, Massachusetts 02118

United States, Michigan
Karmanos Cancer Institute /ID# 201377
Detroit, Michigan 48201

Henry Ford Hospital /ID# 171531
Detroit, Michigan 48202

United States, Minnesota
Mayo Clinic /ID# 201091
Rochester, Minnesota 55905-0001

United States, Ohio
Fairview Hospital – Moll Pavilion /ID# 208919
Cleveland, Ohio 44111-5605

Cleveland Clinic Main Campus /ID# 202247
Cleveland, Ohio 44195

United States, Texas
MD Anderson Cancer Center
at Texas Medical Center /ID# 200060
Houston, Texas 77030-4000

United States, Utah
Huntsman Cancer Institute /ID# 218406
Salt Lake City, Utah 84112-5500

United States, Washington
VA Puget Sound Health Care System /ID# 222708
Seattle, Washington 98108

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