CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT03314181

A Phase I/II, Multicenter, Dose-Escalation and Expansion Study of Combination Therapy with Venetoclax, Daratumumab and Dexamethasone (with and without Bortezomib) in Subjects with Relapsed or Refractory Multiple Myeloma

Trial Description:

This international trial will enroll approximately 104 patients with relapsed or refractory (did not respond to) multiple myeloma who have received at least one prior line of therapy, including an immunomodulatory agent. In Part 3, patients will be randomly selected by a computer to one of three treatment groups called study "arms." Patients will know which arm they have been assigned to.

Trial Objectives:

The overall objective of this study is to evaluate the safety and effectiveness of venetoclax in combination with daratumumab (Darzalex®), and dexamethasone at two dose levels, in comparison to daratumumab, bortezomib (Velcade®) and dexamethasone.

Trial Design:

The study consists of 3 parts with only Part 3 open to enrollment:

- **Part 3:** Patients will receive venetoclax in combination with daratumumab and dexamethasone (VenDd) or daratumumab, bortezomib, and dexamethasone (DVd).

Duration of Treatment:

Each part of 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 may consist of oral (by mouth), subcutaneous (under the skin), and/or intravenous (into the vein) administration of medications.
- **Follow-up Phase:** Patients will have one safety follow up visit approximately 30 days after their last dose of treatment. Additional follow-up on disease status, for patients who discontinue the study treatment for reasons other than progressive disease, will be conducted every 4 weeks for the first year after completing the study treatment, 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 that is relapsed or refractory (did not respond to) to the most recent line of therapy.
- Test positive for the t(11;14) translocation biomarker.
- Have received at least one line of therapy, including an immunomodulatory agent (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).
- Meet additional study criteria.

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INTERNATIONAL MYELOMA FOUNDATION

International Myeloma Foundation
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(continued)

Key Exclusion Criteria:

- Previous venetoclax or other B-Cell Lymphoma 2 (BCL-2) inhibitor.
- Prior daratumumab or other anti-CD38 antibody therapy exposure that meets ANY of the following criteria*:
  - Failure to achieve at least a PR to most recent therapy with daratumumab or other anti-CD38 therapy.
  - Daratumumab or other anti-CD38 antibody therapy was discontinued due to toxicity.
  - Relapse within 60 days of intensive treatment (at least every other week) of daratumumab or other anti-CD38 antibody therapy.
  - Prior treatment with daratumumab or other anti-CD38 antibody within 6 months prior to first dose of study drug.
- Participant is refractory to any proteasome inhibitor, defined as progression on or within 60 days of the last dose of a proteasome inhibitor-containing regimen.
- Participant has had prior treatment with proteasome inhibitor within 60 days prior to first dose of study drug.
- Treatment with anti-myeloma monoclonal antibodies within 6 weeks prior to first dose.
- Central Nervous System (CNS) involvement.

* NOTE: Sites must have Protocol Amendment 5 approved to allow prior exposure to daratumumab or other anti-CD38 antibody therapy.

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, Florida
Moffitt Cancer Center /ID# 169614
Tampa, Florida 33612-9416

United States, Georgia
Emory University, Winship Cancer Institute /ID# 165427
Atlanta, Georgia 30322

United States, Illinois
University of Chicago Medical Center /ID# 165429
Chicago, Illinois 60637-1443

United States, Massachusetts
Dana-Farber Cancer Institute /ID# 166886
Boston, Massachusetts 02215

United States, New Jersey
Hackensack University Medical Center /ID# 225111
Hackensack, New Jersey 07601

United States, New York
Weill Cornell Medicine/NYP /ID# 167605
New York, New York 10021-4872

United States, North Carolina
Atrium Health Carolinas Medical Center /ID# 164948
Charlotte, North Carolina 28203

Duke University Medical Center /ID# 165104
Durham, North Carolina 27710-3000

Wake Forest Baptist Health /ID# 224447
Winston-Salem, North Carolina 27157

United States, Oregon
Oregon Health & Science University /ID# 166822
Portland, Oregon 97239

United States, Washington
University of Washington /ID# 164884
Seattle, Washington 98109

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