

CLINICAL TRIAL FACT SHEET

ARROW

Clinicaltrials.gov Identifier: NCT02412878

A Randomized, Open-label, Phase III Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib (Kyprolis®) in Combination with Dexamethasone, Comparing Once-weekly Versus Twice-weekly Carfilzomib Dosing

Trial Description: The US Food and Drug Administration approved carfilzomib as a twice-weekly intravenous (IV) injection for patients with relapsed and refractory myeloma who have received prior treatment with bortezomib (Velcade®) and an immunomodulatory agent (IMiD, i.e., thalidomide, lenalidomide, or pomalidomide). The ARROW study is designed to potentially provide patients and physicians greater convenience with a once-weekly dosing schedule.

The ARROW trial is evaluating approximately 460 patients with relapsed and refractory myeloma who have had at least 2, but not more than 3, prior therapies, including both Velcade and an IMiD.

Trial Objective: To compare once-weekly carfilzomib dosing in combination with dexamethasone to twice-weekly carfilzomib dosing in combination with dexamethasone in patients with relapsed and refractory myeloma who have been treated previously with Velcade and an IMiD.

Measuring Trial Outcome: This trial will determine the response to treatment, or “overall response rate,” of patients receiving once-weekly carfilzomib + weekly dexamethasone versus twice-weekly carfilzomib + weekly dexamethasone.

Assigned Interventions: Patients will be randomly assigned to one of two treatment groups:

- Arm 1 – once-weekly carfilzomib at 20 mg/m² on Day 1 of Cycle 1; 70 mg/m² on Days 8 and 15 of Cycle 1, and on Days 1, 8, and 15 of all subsequent cycles. Dexamethasone 40 mg once weekly.
- Arm 2 – twice-weekly carfilzomib at 20 mg/m² on Days 1 and 2 of Cycle 1; 27 mg/m² on days 8, 9, 15 and 16 of Cycle 1, and on Days 1, 2, 8, 9, 15, and 16 of all subsequent cycles. Dexamethasone 40 mg once weekly.

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International Myeloma Foundation

12650 Riverside Drive, Suite 206, North Hollywood, CA 91607 USA

Telephone: 800-452-CURE (2873) (USA & Canada) 818-487-7455 (worldwide) • TheIMF@myeloma.org • myeloma.org

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Key Inclusion Criteria:

- Relapsed multiple myeloma
- Refractory multiple myeloma defined as meeting 1 or more of the following:
 - Nonresponsive to most recent therapy (stable disease or progressive disease while on treatment), or
 - Disease progression within 60 days of discontinuation from most recent therapy
- At least 2 but no more than 3 prior therapies for myeloma (A line of therapy is a planned course of treatment including sequential induction, transplantation, consolidation, and/or maintenance.)
- Prior exposure to an immunomodulatory agent (IMiD)
- Prior exposure to a proteasome inhibitor (PI)
- Documented response of at least partial response to a prior therapy (PR, or at least a 50 % reduction in the amount of monoclonal protein)

Key Exclusion Criteria:

- Waldenström macroglobulinemia
- Multiple myeloma of Immunoglobulin M (IgM) subtype
- POEMS syndrome (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes)
- Plasma cell leukemia (high levels of plasma cells in the circulating blood)
- Myelodysplastic syndrome
- History of, or current, amyloidosis
- Active congestive heart failure or certain other types of heart disease

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Recruiting Locations: Additional sites will be opening soon. Please contact the International Myeloma Foundation InfoLine at 818-487-7455 (worldwide) or 800-452-2873 (toll-free in US and Canada), or clinicaltrials.gov for up-to-date site information.

UNITED STATES

Arizona

Mayo Clinic, Scottsdale

Maryland

Center for Cancer and Blood Disorders, Bethesda

Maryland Oncology Hematology, P.A., Rockville

New Jersey

John Theurer Cancer Center at Hackensack University Medical Center, Hackensack

Pennsylvania

Western Penn Hospital, Pittsburgh

Texas

Blood and Cancer Center of East Texas, Tyler

CANADA

Ontario

The Ottawa Hospital Regional Cancer Centre, Ottawa

Nova Scotia

Queen Elizabeth II Health Science Centre, Halifax

HUNGARY

Bekes

Bekes County Pandy Kalman Hospital, Gyula

ITALY

Piacenza

Guglielmo da Saliceto Hospital, Piacenza

JAPAN

Tokyo

National Center for Global Health and Medicine, Shinjuku-ku

National Hospital Organization Disaster Medical Center, Tachikawa-city

Fukuoka

National Hospital Organization Kyushu Cancer Center, Fukuoka-shi

Aichi

Nagoya City University Hospital, Nagoya

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