

Carfilzomib Fact Sheet

Overview

Carfilzomib is a selective, next-generation proteasome inhibitor currently being evaluated in clinical trials as a single-agent or in combination with other therapies, for the treatment of relapsed or newly diagnosed multiple myeloma.^{1,2}

Carfilzomib received accelerated approval from the U.S. FDA in July 2012 and is marketed as Kyprolis® (carfilzomib) for Injection.¹ The treatment is also approved in Israel,³ Argentina⁴ and Mexico.⁵ Kyprolis is indicated for patients with multiple myeloma who have already received at least two other treatments including bortezomib and an immunomodulatory agent (lenalidomide and/or thalidomide), and whose disease has progressed on their last therapy or within 60 days of their last therapy.²

What is a proteasome inhibitor?

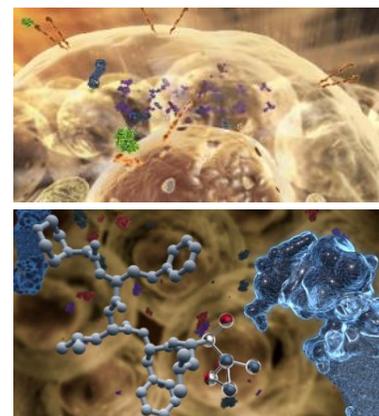
Proteasomes play an important role in cell function and growth by breaking down proteins that are damaged or no longer needed. Inhibition of the proteasome is a well-characterized approach to treating certain hematological malignancies, and affects several critical pathways in cancer, including apoptosis, otherwise known as programmed cell death.¹

Study results of interest

The pivotal Phase 3 ASPIRE clinical trial comparing carfilzomib, lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with relapsed multiple myeloma recently concluded. Results from the study met its primary endpoint of progression-free survival (PFS). The secondary endpoints evaluated included overall survival (OS), overall response rate (ORR), duration of response (DOR) and health-related quality of life (HR-QoL) measures and safety.⁶

Ongoing global carfilzomib Phase 3 clinical trials*

*Click on the links below to view the study summaries on www.clinicaltrials.gov



Description	Primary Endpoint	Secondary Endpoint	Select Enrollment Criteria
ENDEAVOR – Relapsed multiple myeloma; Head-to-head comparative			
Carfilzomib with dexamethasone vs. bortezomib with dexamethasone in relapsed myeloma	To compare PFS in patients with relapsed multiple myeloma treated with of carfilzomib and dexamethasone versus bortezomib and dexamethasone ⁷	Additional outcomes to be evaluated include OS, ORR, complete response rate and safety ⁸	Following treatment with 1-3 prior regimens ⁷
CLARION – First-line; Head-to-head comparative			
Carfilzomib with melphalan and prednisone vs. bortezomib with melphalan and prednisone in newly diagnosed myeloma	To compare PFS in patients with newly-diagnosed transplant ineligible symptomatic multiple myeloma treated with carfilzomib, melphalan and prednisone versus bortezomib, melphalan and prednisone ⁹	Additional outcomes to be evaluated include OS, ORR, complete response rate and safety ⁹	Newly diagnosed, transplant-ineligible ⁹

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Additional Information

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Forward-Looking Statements

This fact sheet contains forward-looking statements that are based on Amgen Inc. and its subsidiaries current expectations and beliefs and are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including those related to: expected clinical or regulatory results or practices; development of Amgen's product candidates, including anticipated regulatory filings; and current scientific theories and research regarding the diseases or conditions targeted by the product candidates. Forward-looking statements involve significant risks and uncertainties, including those more fully described in the Risk Factors found in the most recent Annual Report on Form 10-K and periodic reports on Form 10-Q and Form 8-K filed by Amgen with the U.S. Securities and Exchange Commission, and actual results may vary materially. Except where otherwise indicated, Amgen is providing this information as of November 2014, and does not undertake any obligation to update any forward-looking statements contained in this fact sheet as a result of new information, future events, or otherwise.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Onyx Pharmaceuticals, Inc.

Based in South San Francisco, California, Onyx Pharmaceuticals, Inc., an Amgen subsidiary, is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways.

For more information about Onyx, visit the company's website at www.onyx.com. Onyx Pharmaceuticals is on Twitter. Sign up to follow our Twitter feed @OnyxPharm at <http://twitter.com/OnyxPharm>.

1. About Kyprolis. Available at: <http://www.kyprolis.com/about-kyprolis>. Accessed November 2014.
2. Kyprolis Prescribing Information. Available at: <http://www.kyprolis.com/prescribing-information>. Accessed November 2014.
3. Israel Drug Registry. http://www.old.health.gov.il/units/pharmacy/trufot/PeruTrufa.asp?Reg_Number=151%2021%2033948%2000&NewTruf=2&safe=. Accessed November 2014
4. Varifarma Press Release. March 2014. Available at: <http://www.varifarma.com.ar/noticias/5/90/Lanzamiento-Kyprolis-Carfilzomib-en-Argentina/>. Accessed November 2014.
5. Amgen Press Release. Available at: <http://www.lasalud.mx/permalink/13981.html>. Accessed December 2014.
6. Stewart AK, et al. Carfilzomib, lenalidomide, and dexamethasone vs lenalidomide and dexamethasone in patients with relapsed multiple myeloma: interim results from ASPIRE, a randomized, open-label, multicenter phase 3 study. American Society of Hematology [oral presentation]. 2014.
7. Phase 3 Study With Carfilzomib and Dexamethasone Versus Velcade and Dexamethasone for Relapsed Multiple Myeloma Patients (ENDEAVOR). ClinicalTrials.gov. Accessed October 2014: <http://clinicaltrials.gov/ct2/show/NCT01568866>
8. Onyx Pharmaceuticals Initiates Phase 3 Kyprolis™ Head-to-Head Comparison Trial vs. Velcade® in Patients with Relapsed Multiple Myeloma [Press Release]. Available at: <http://www.onyx.com/view.cfm/608/onyx-pharmaceuticals-initiates-phase-3-kyprolis-head-to-head-comparison-trial-vs-velcade-in-patients-with-relapsed-multiple-myeloma>
9. Phase 3 Study of Carfilzomib, Melphalan, Prednisone vs Bortezomib, Melphalan, Prednisone in Newly Diagnosed Multiple Myeloma (CLARION). ClinicalTrials.gov. Accessed October 2014: <http://clinicaltrials.gov/ct2/show/NCT01818752>