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Amneal and Shilpa Medicare announce US FDA approval of ready-to-use oncology product

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Product is expected to launch with a unique J-code in the second quarter of 2025



US-based Amneal Pharmaceuticals, Inc. and Karnataka-based Shilpa Medicare have announced US Food and Drug Administration (FDA) approval of BORUZU, a new presentation of bortezomib for ready-to-use subcutaneous administration or intravenous (IV) administration.

This new ready-to-use oncology product reduces the compounding preparation steps typically required with administration.

BORUZU (bortezomib injection), a proteasome inhibitor, is used for the treatment of multiple myeloma and mantle cell lymphoma. This product references the branded product Velcade, a lyophilised powder requiring reconstitution before use.

Shilpa developed the molecule and Amneal will manufacture and commercialise the product. BORUZU is expected to launch with a unique J-code in the second quarter of 2025.

“This second NDA approval in the US market from our novel injectable portfolio is a testament of our capabilities and commitment to introduce pharmacy efficient solutions that enhance preparation and have the potential to reduce patient wait times. This development exemplifies Shilpa’s constant endeavour to work towards introducing novel first of its kind pharmaceutical products that help improve the healthcare requirements of a large patient pool,” said Vishnukant Bhutada, Managing Director of Shilpa Medicare.