Vizient Commends the FDA on Its Recent Approval of the First Neulasta Biosimilar

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RVNG, Texas—(BUSINESS WIRE) [12]—Vizient [13] today applauds the U.S. Food and Drug Administration (FDA) on its announcement yesterday that it approved the first biosimilar to Neulasta (pegfilgrastim) and The overall progress in authorizing more competitive versions of commonly used, high cost biologics.

Vizient has long been a vocal proponent of biosimilar approval, adoption and use and has continued to provide education to encourage understanding of this developing market. Vizient published a blog [14] on the subject, as well as a letter in the Journal of Clinical Oncology titled “Clarifying Our Understanding of Biosimilars in Oncology: Response to ASCO Statement.” Biosimilar competition strengthens the healthcare market via increasing access to biologic therapy through lowering costs for patients and providers.

The FDA defines a biosimilar as, “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.” While more streamlined than the approval pathway for originators, a biosimilar evaluation is both thorough and rigorous and maximizes the capabilities of analytical characterization to yield a product that is highly similar to the reference biologic in terms of safety, purity and potency.

Additionally, biosimilars approved in highly regulated markets like the U.S. and in Europe, have yielded the same clinical performance as their branded, original counterparts. Therefore, we believe biosimilars have the potential to significantly lower the expense for biologic drugs that are currently cost prohibitive for many, while simultaneously maintaining a high level of quality and improved clinical outcomes.

Vizient is the nation’s largest health care performance improvement company serving a diverse membership that includes academic medical centers, pediatric facilities, community hospitals, integrated health care delivery networks and non-acute health care providers.

About Vizient, Inc.

Vizient, Inc., the largest member-driven health care performance improvement company in the country, provides innovative data-driven solutions, expertise and collaborative opportunities that lead to improved patient outcomes and lower costs. Vizient’s diverse membership base includes academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers.

Organization, Company designation from the MedAssets’ Spend and Clinical Resource Management (SCM) segment, including Sg2, which was acquired in 2016. In 2018, Vizient again received a World’s Most Ethical Company designation from the Ethisphere Institute. Vizient’s headquarters are in Irving, Texas, with locations in Chicago and other cities across the United States. Please visit www.vizientinc.com, as well as our newsroom [15], blog [16], Twitter [17], LinkedIn [18] and YouTube [19] pages for more information about the company.

Language:
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Vizient applauds the @US_FDA for its approval of the first #biosimilar to #neulasta which will bring new competition to the biologic therapy market. #pegfilgrastim #hospitals


Links: