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Bristol-Myers Squibb recalls carmustine for injection

Singapore: Bristol-Myers Squibb initiated a voluntary global recall of 10 lots of BiCNU (carmustine for injection) previously manufactured by Ben Venue Laboratories, a former, third-party contract manufacturer for the company.

The precautionary recall of BiCNU, a chemotherapeutic agent administered to patients in a hospital or other clinical setting, is being initiated following the discovery of one overfilled vial of BiCNU during routine testing. An overfilled vial of BiCNU represents a significant risk to patients due to the nature of product administration and could result in patients receiving a dose greater than prescribed. There have been no reported adverse events associated with this issue.

BiCNU is used as a therapy for treatment of brain tumors, multiple myeloma, Hodgkin's disease and non- Hodgkin's lymphoma. Potential adverse events include myelo suppression, pulmonary toxicity and renal abnormality, as well as increased incidence of other adverse events known to be caused by carmustine. In the hematopoietic stem cell transplantation (HSCT) setting, which has been reported as an off-label use, BiCNU is administered using a high dose regimen and this may lead to fatal outcomes in certain individuals.

This recall is being conducted in the US, Canada and countries within Europe, Latin America and Asia Pacific for lots previously manufactured by Ben Venue. Bristol-Myers Squibb does not anticipate a product shortage resulting from the recall as current supply is secured through another manufacturer.

Bristol-Myers Squibb is committed to ensuring patient safety and is working to resolve this issue quickly and appropriately. The company is notifying regulatory authorities in impacted countries and is issuing recall communications to hospitals and healthcare professionals who may have received the product from recalled lots.