

## **NextSource Biotechnology Announces FDA Short Supply release of the formally known Bristol Myers Squibb (CeeNu®) Brand Oncology product now currently marketed under the NextSource Biotechnology Lomustine (CCNU) label Exclusively in the United States**

MIAMI, Jan. 24, 2014 /PRNewswire/ -- NextSource BioTechnology, LLC, (NSB), an emerging Specialty Pharmaceutical Manufacturing and Marketing Company focused on Consolidating, Re-Branding and Launching "Matured & Orphan Drugs," has announced its most recent product Lomustine (CCNU), formerly known as CeeNu® by Bristol-Myers Squibb (BMS), which has officially been removed from the U.S. Food & Drug Administration (FDA) Drug Shortage List. As a result of this new status, Lomustine (CCNU) is now readily available through NextSource's Nationwide Authorized Distribution supply chain. Please visit us at: [http://www.nextsourcebiotechnology.com/authorized\\_distributors.aspx](http://www.nextsourcebiotechnology.com/authorized_distributors.aspx)

Due to the successful product re-launch and market availability of Lomustine (CCNU), there is no longer a need for continued use of the unregulated compound equivalent product. Pharmacies currently compounding this product are doing so against the FDA Code of Federal Regulations.

Lomustine (CCNU) will continue to be distributed under the current name, while the pending FDA "Brand" name is under review for approval. Lomustine (CCNU) is the first of many "Matured Drugs" to be launched under the NextSource Biotechnology portfolio.

*"Our launch of LOMUSTINE," said Robert DiCrisci, President, CEO of NextSource Biotechnology, "is an example of the NextSource commitment to work proactively with the FDA in an effort to prevent the discontinuation of existing and future drugs that are vital in the application of a well balanced treatment plan of traditional proven therapies and New therapy options that healthcare providers and patients in the hospital settings require under the new healthcare guidelines."*

### **About Lomustine (CCNU) - INDICATIONS AND USES**

Lomustine (CCNU) is an oral chemotherapy medication that is used to treat **Primary** and **Metastatic** Brain Cancer. Lomustine belongs to a class of drugs known as nitrosourea anti-tumor alkylating agent. Unlike the more common nitrogen mustard alkylating agents, Lomustine (CCNU) **crosses the blood-brain barrier** quite effectively due to its high lipid solubility and the relative lack of ion-ization at physiological pH and is used in the treatment of both primary and metastatic brain tumors in patients. It works by bonding with DNA of rapidly dividing cells causing breakage of the DNA strands and eventually, the death of the cancer cell.

Lomustine (CCNU) has been shown to be useful as a single agent in addition to other treatment modalities, or in an established combination therapy with other approved chemotherapeutic agents in the following:

**Brain tumors-** Both primary and metastatic, in patients who have already received appropriate surgical and/or radio therapeutic procedures.

**Hodgkin's disease-** secondary treatment in combination with other approved drugs in patients who relapse while being treated with primary therapy or who fail to respond to primary therapy.

**About our Partner:** CordenPharma is an expert Contract Manufacturing partner helping leading pharmaceutical and biotechnology companies link their requirements for product success with their patients' healthier lives. CordenPharma has subsequently been the long-term manufacturing partner of the Lomustine product for both NextSource Biotechnology and **Bristol Myers Squibb (CeeNu®)**.

Formed as a pharmaceutical branch of [International Chemical Investors Group](#) in 2006, CordenPharma provides specialized technologies that are ideal for the development and manufacturing of oral, sterile, highly potent and antibiotic pharmaceutical Drug Products, their Active Pharmaceutical Ingredients, and associated Global Supply Chain and Packaging Services.

## References

1. Lomustine Package Insert: [www.nextsourcebio.com](http://www.nextsourcebio.com)
2. U.S. Food and Drug Administration (FDA) Current Resolved Drug Shortages Index. Available at: <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050793.htm>
3. Press Release: [http://www.nextsourcebiotechnology.com/news\\_and\\_media.aspx](http://www.nextsourcebiotechnology.com/news_and_media.aspx)

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