Bristol Myers Squibb™

Drug Shortage Staff
Attn: CAPT Valerie Jensen, R.Ph., USPHS (Ret.)
Food and Drug Administration
WO 22, Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 14, 2022

Dear CAPT Jensen,

Bristol-Myers Squibb Company ("BMS" or "the company") is writing in response to the Food and Drug Administration ("FDA") Letter dated February 2, 2022, concerning the company's notification to FDA of an insufficient supply for Abraxane® for Injectable Suspension Paclitaxel (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), for intravenous use (NDC: 68817-134-50).

BMS is committed to the reliable supply of high quality, life-saving medicines like ABRAXANE to patients who need them, in the United States and around the world. BMS worked diligently and with full transparency with FDA to resolve the manufacturing constraints that led to global supply challenges for ABRAXANE. The chronology of events outlining the steps taken by BMS to notify DSS of the situation is provided below. BMS remains dedicated to open and timely communication with the Drug Shortage Staff (DSS) on supply issues and takes our reporting obligations seriously.

As per our most recent communication on 10 Mar 2022 to DSS, the drug product manufacturing site has returned to operations. Inventory levels are expected to be at or above(b) (4) coverage through 2Q-2022 for the US market.

Chronology of events

As noted in your letter, there was an unanticipated event at the primary drug product manufacturing site for ABRAXANE in April 2021. Given the planned mitigation strategies, which included obtaining additional supplies from an alternate, ex-US drug product manufacturing site, it was concluded that there was low risk of a meaningful disruption of supply of ABRAXANE in the United States. After further evaluation, BMS recognized the potential for a supply disruption and a notification was sent to DSS on 18 Jun 2021. It is important to clarify that the outreach by DSS to BMS on 11 Jun 2021 described in the 02 Feb 2022 letter to BMS was related to a potential 10% shortfall of the market for paclitaxel injection, not ABRAXANE, an albumin bound form of paclitaxel. These are two different drugs, which have different indications, and are not interchangeable.

On 03 Sep 2021, the Company informed DSS that delays in receipt of packaging components at the alternate drug product manufacturing site resulted in additional constraint for supply. That notification stated that there was potential impact for patient supply from 24 Sept through 29 Sep 2021 due to unanticipated delays in receipt of these supplies. That communication also identified potential for additional supply risk in Nov 2021. The Company informed wholesalers as well as health care provides of the anticipated disruption, in parallel with the FDA communications. On 13 Sept, BMS provided DSS with a copy of the letter that was being sent to Healthcare Providers. On 29 Sep 2021, DSS requested information necessary to post the ABRAXANE supply status on the FDA Drug Shortage website. That information was provided on 30 Sep 2021.

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Following the initial drug shortage notification, the Company has continued to update DSS on activities at the site to enable return to operations. Approximately 25 updates, as well as numerous responses to requests for information, have been provided to DSS since the original notification on 18 Jun 2021. The Company has also updated DSS on efforts to obtain additional supplies from the alternate drug product manufacturing site and is very appreciative of the support from the FDA drug shortage staff.

Conclusion

BMS understands the importance of ABRAXANE to patients and is committed to supplying this life-saving therapy to patients. BMS prioritized resources at the primary manufacturing site to resolve the manufacturing constraints and to return the site to operation as quickly as possible. BMS has been and will continue to be fully transparent with DSS on the ABRAXANE supply situation in compliance with the Federal Food, Drug, and Cosmetic Act Section 506C and remains dedicated to open and timely communication with the Drug Shortage Staff on emerging supply issues.

Sincerely,

Annie Sturgess

Annie Sturgess, Ph.D.
Vice President, Global Regulatory Sciences-CMC