BeiGene Announces Supply Update for ABRAXANE® in China

- NMPA has suspended the importation, sales and use of ABRAXANE in China supplied by Celgene Corporation, a Bristol Myers Squibb (BMS) company
- As the marketing agent for ABRAXANE in China, BeiGene is working with BMS to restore supply in China

BEIJING, China, and CAMBRIDGE, Mass., March 25, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immunoncology drugs for the treatment of cancer, today announced that, on March 25, 2020, the China National Medical Products Administration (NMPA) suspended the importation, sales and use of ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China supplied to BeiGene by Celgene Corporation, a Bristol Myers Squibb (BMS) company. This suspension is based on inspection findings at BMS’s contract manufacturing facility in the United States. As a result, BeiGene expects a disruption in ABRAXANE supply in China and is working closely with BMS to restore supply as soon as possible, including through BMS’s remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply.

“As the marketing agent for ABRAXANE in China, we are extremely disappointed by this interruption in drug supply,” said John V. Oyler, Chairman, Co-Founder, and Chief Executive Officer of BeiGene. “At BeiGene, the quality of our medicines is of the utmost importance, and we hold ourselves and our partners to the highest global industry standards. We are working with BMS to determine corrective actions for this situation as quickly as possible. We remain focused on the ongoing launches of our other products in China and the United States and the development of potential new treatments for patients worldwide.”

BeiGene and Celgene, now a BMS company, entered into an exclusive license and supply agreement for ABRAXANE and two other cancer medicines in China in 2017 as part of a broader strategic collaboration. Under the terms of the agreement, BeiGene is responsible for promoting and distributing ABRAXANE in China and BMS is responsible for manufacturing the drug in compliance with regulatory requirements, maintaining the drug registration and import license, and supplying packaged drug product for the China market.

In addition to the ongoing remediation efforts at the current manufacturing site with the contract manufacturer, BMS has applied for NMPA approval to source its supply for the China market from an alternative BMS manufacturing facility for ABRAXANE, which is currently under review.

The NMPA’s findings concerning BMS’s contract manufacturing site do not impact any other products marketed by BeiGene. No other BeiGene products are manufactured at this site.

For information on the manufacturing of ABRAXANE or other BMS inquiries, please contact: media@bms.com or +1 609-252-3345.

About BeiGene
BeiGene is a global, commercial-stage research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 3,500 employees in the United States, China, Australia, and Europe, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. In the United States, BeiGene markets and distributes BRUKINSA™ (zanubrutinib) and in China, the Company markets its anti-PD-1 antibody tislelizumab and markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) under a license from Celgene Logistics Sàrl, a Bristol Myers Squibb company, and plans to market XGEVA® (denosumab) in collaboration with Amgen. For more information please visit www.beigene.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the disruption of ABRAXANE supply in China and efforts to restore supply as soon as possible; and BeiGene’s plans to the continue development and launches of its other products. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the ability of BMS and its contract manufacturer to successfully remediate the existing manufacturing site or of BMS to obtain approval for an alternative site; the NMPA’s inspection of the manufacturing site to be used by BMS; the NMPA’s withdrawal of its suspension or reinstatement of approval to import, sell and use ABRAXANE in China; BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene’s limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the coronavirus on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors" in BeiGene’s most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.
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XGEVA® is a registered trademark of Amgen.