EUSA Pharma and BeiGene Announce Acceptance of a Biologics License Application for QARZIBA®▼ (Dinutuximab Beta) in China

HEMEL HEMPSTEAD, England, BEIJING, China, and CAMBRIDGE, Mass. November 9, 2020 - EUSA Pharma (UK) Limited and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) today announced that the Biologics License Application (BLA) for QARZIBA®▼ (dinutuximab beta) was accepted by the China National Medical Products Administration (NMPA) and granted priority review. Dinutuximab beta is a targeted immunotherapy approved by the European Medicines Agency (EMA) for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma with or without residual disease. High-risk neuroblastoma is an aggressive neoplasm and the most common childhood solid tumour that originates outside of the brain. Dinutuximab beta is listed in the first batch of New Drugs in Urgent Clinical Need Marketed Overseas by the NMPA.

“Dinutuximab beta represents an important biologic, which is already available to patients with high-risk neuroblastoma in Europe,” commented Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. “For paediatric patients fighting this disease in China, we are hopeful that dinutuximab beta will soon be available as a new treatment option. Our collaboration with EUSA and the progress thus far demonstrate our joint commitment to bringing high-quality therapies to the people who need them.”

Lee Morley, Chief Executive Officer of EUSA Pharma, said, “This milestone brings us and BeiGene closer to delivering on our promise of bringing innovative cancer and rare disease therapies to patients around the world. We look forward to working with BeiGene and the NMPA to potentially make dinutuximab beta available in China.”

About QARZIBA®▼ (dinutuximab beta)

QARZIBA®▼ is a monoclonal antibody that is specifically directed against the carbohydrate moiety of disialoganglioside 2 (GD2), which is overexpressed on neuroblastoma cells. Dinutuximab beta was approved by the European Commission in 2017 and is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures. In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, dinutuximab beta should be combined with interleukin-2 (IL-2).

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a world-class biopharmaceutical company focused on oncology and rare disease. The company has extensive commercial operations in the United States and Europe, alongside a direct presence in select other markets across the globe. EUSA Pharma is led by an experienced management team with a strong record of building successful pharmaceutical companies and is supported by significant funding raised from leading life science investor EW Healthcare Partners. For more information please visit www.eusapharma.com.

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,700+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

BeiGene 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 potential approval, launch and opportunity of QARZIBA® in China, future development and potential commercialization activities of the products under the agreement with EUSA, and other information that is not historical information. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including 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, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, 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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