EUSA Pharma and BeiGene Announce Exclusive Development and Commercialization Agreement for SYLVANT® and QARZIBA® in Greater China

- SYLVANT® and QARZIBA® recently listed for fast-track approval in China –
- Expands EUSA’s global product offering; broadens BeiGene’s portfolio –

HEMEL HEMPSTEAD, England, CAMBRIDGE, Mass. and BEIJING, China, Jan. 13, 2020 - EUSA Pharma (EUSA) and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) today announced that they have entered into an exclusive development and commercialization agreement for the orphan biologic products SYLVANT® (siltuximab) and QARZIBA® (dinutuximab beta) in Greater China.

Under the terms of the agreement, EUSA has granted BeiGene exclusive rights to SYLVANT® in Greater China, and to QARZIBA® in mainland China. Under the agreement, BeiGene will fund and undertake all clinical development and regulatory submissions in the territories, and will launch and commercialize both products once approved. EUSA will receive an upfront payment and be eligible to receive payments upon the achievement of regulatory and commercial milestones up to a total of $160 million. EUSA will also be eligible to receive tiered royalties on future product sales.

“Our teams are excited to work with EUSA to commercialize SYLVANT and QARZIBA, two important biologics which are already available to patients with rare diseases outside of China,” said Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. “This collaboration further demonstrates our commitment to bringing high quality therapies to people in China and around the world.”

Lee Morley, Chief Executive Officer of EUSA Pharma, said, “This exclusive agreement with BeiGene represents an important milestone for EUSA as we deliver on our promise to bring our innovative cancer and rare disease therapies to patients around the world. BeiGene brings to our collaboration exceptional development and commercialization capabilities in China and a clear focus on delivering innovative, targeted oncology medicines. We look forward to working together over the coming months to ensure these important orphan products are made available to Chinese patients.”

SYLVANT® is currently approved in more than 40 countries worldwide for the treatment of idiopathic multicentric Castleman’s disease (iMCD), a rare, life-threatening and debilitating orphan condition of the lymph nodes and related tissues. QARZIBA® is the only EMA approved targeted immunotherapy for the treatment of high-risk neuroblastoma, an aggressive neoplasm and the most common childhood solid tumor that originates outside of the brain. Both products have been listed for fast-track approval in China by the National Medical Products Administration (NMPA) via its Review and Approval Procedures for Urgently-Needed Pharmaceutical Drugs Developed Overseas.

Jefferies International Limited acted as exclusive advisor to EUSA on the transaction.

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 SYLVANT® (siltuximab)
SYLVANT® is a monoclonal antibody that blocks the action of interleukin-6 (IL-6), a multifunctional cytokine detected at elevated levels in iMCD patients. SYLVANT® is approved in a number of jurisdictions and indicated for the treatment of patients with multicentric Castleman’s disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. iMCD is a rare, life-threatening and debilitating lymphoproliferative disorder, which causes abnormal overgrowth of immune cells and shares many symptomatic and histological features with lymphoma.

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, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 3,300 employees in China, the United States, 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 has received approval to market its anti-PD-1 antibody tislelizumab and markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) under a license from Celgene Logistics Sarl, a Bristol-Myers Squibb company, and plans to market XGEVA® (denosumab) under a license from Amgen. For more information please visit www.beigene.com.

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 future development and potential commercialization activities of the specified products under the agreement with EUSA, potential payments payable to EUSA, the speed and outcome of drug development plans, 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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ii XGEVA® is a registered trademark of Amgen