Celgene Corporation Enters Into Global Strategic Immuno-Oncology Collaboration with BeiGene to Advance PD-1 Inhibitor Program for Solid Tumor Cancers

- Celgene accelerates its immuno-oncology strategy in solid tumors with acquisition of worldwide rights, rest of world outside Asia, to BeiGene's PD-1 inhibitor BGB-A317; Pivotal BGB-A317 solid tumor studies planned for 2018
- Collaboration maximizes potential for best-in-class PD-1-based immuno-oncology combinations in solid tumors by leveraging BGB-A317's differentiated profile and Celgene’s novel pipeline assets and global oncology expertise
- BeiGene to acquire Celgene’s commercial operations in China and exclusive license to Celgene's China cancer commercial portfolio (ABRAXANE®, REVLIMID®, VIDAZA®)
- BeiGene to receive $263 million in upfront license fees and $150 million equity investment

SUMMIT, N.J. & BEIJING--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) and BeiGene, Ltd. (NASDAQ:BGNE) entered into a strategic collaboration to develop and commercialize BeiGene's investigational anti-programmed cell death protein 1 (PD-1) inhibitor, BGB-A317, for patients with solid tumor cancers in the United States, Europe, Japan and rest of world outside Asia. BeiGene will retain exclusive rights for the development and commercialization of BGB-A317 for hematological malignancies globally and for solid tumors in Asia (with the exception of Japan). BeiGene will acquire Celgene's commercial operations in China and gain an exclusive license to commercialize Celgene's approved therapies in China - ABRAXANE®, REVLIMID® and VIDAZA®.

BGB-A317 is an advanced clinical-stage investigational PD-1 inhibitor, which has been dosed in over 500 patients. Initial clinical data suggest that BGB-A317 is well tolerated and exhibits anti-tumor activity across a range of solid tumor types. BGB-A317 has high affinity and specificity for PD-1 and may be differentiated from the currently approved PD-1 antibodies through an engineered Fc region, potentially minimizing interactions with other immune cells that may exert a negative impact on effector T-cell function. BGB-A317 is being developed as a monotherapy and in combination with other therapies for the treatment of solid tumor cancers. It is currently in two pivotal trials in China, and global pivotal studies of BGB-A317 are planned for initiation in 2018. Celgene and BeiGene will collaborate in the global development of BGB-A317. In addition, BeiGene retains the right to develop BGB-A317 in hematology and in combination with its other portfolio compounds.

"The acquisition of BGB-A317 significantly accelerates and expands our opportunity to develop and deliver novel T-cell checkpoint inhibitor-based therapies in solid tumor cancers to patients worldwide and adds to our ongoing PD-L1 FUSION™ program in hematological malignancies,” said Mark J. Alles, Chief Executive Officer of Celgene. "China is an important market for Celgene, and our collaboration with BeiGene positions us exceptionally well to optimize research, manufacturing, and the long-term commercial potential of our portfolio in China."

"This strategic partnership with Celgene is a transformational event for BeiGene, transitioning us into a commercial-stage company and preparing us well for the potential future launch of our internally developed compounds, some of which are already in pivotal trials in China,” said John V. Oyler, Co-founder, CEO, and Chairman of BeiGene. "Aligned in our mission and therapeutic focus, we believe that we have forged a promising alliance with Celgene that will help both companies fulfill their ultimate commitments of bringing new, life-altering treatments to patients in China and worldwide."

BeiGene will acquire Celgene's operations in China. BeiGene will also license and assume commercial responsibility for Celgene's approved therapies in China, consisting of ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), REVLIMID® (lenalidomide) and VIDAZA® (azacitidine). In addition, BeiGene is granted licensing rights in China to CC-122, under the same terms and conditions as the approved commercial products. CC-122 is a next generation CelMOD currently in development by Celgene for lymphoma and hepatocellular carcinoma. BeiGene plans to expand manufacturing and commercial operations in China in preparation for the potential approvals of BGB-A317 and future innovative therapies developed by BeiGene in greater China.

Celgene will maintain a strategic and R&D presence in China dedicated to long-term commercial activities, regulatory affairs and clinical development of new therapies in the country. Celgene will also continue supporting BeiGene with management
of the REVLIMID® Risk Minimization Program.

Upon closing, BeiGene will receive upfront licensing fees totaling $263 million, and in addition Celgene will acquire an equity stake in BeiGene by purchasing 32.7 million, or 5.9 percent, of BeiGene's ordinary shares at $4.58 per share, or $59.55 per BeiGene's American Depositary Shares (ADS), representing a 35% premium to an 11-day volume-weighted average price of BeiGene's ADS. BeiGene is eligible to receive up to $980 million in development, regulatory and sales milestone payments and royalties on future sales of BGB-A317.

The transactions have been approved by the boards of directors of Celgene and BeiGene. Both companies expect to complete the transaction during the third quarter of 2017, subject to the expiration or termination of applicable waiting periods under all applicable antitrust laws and satisfaction of other usual and customary closing conditions.

BGB-A317 is not approved in any country for any indication.

About BGB-A317

BGB-A317 is an investigational humanized monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an important role in downregulating the immune system by preventing the activation of T-cells. BGB-A317 has high affinity and specificity for PD-1. It is believed to be differentiated from the currently approved PD-1 antibodies, as the engineering of its Fc region is believed to minimize potentially negative interactions with other immune cells. BGB-A317 is being developed as a monotherapy and in combination with other therapies for the treatment of various cancers.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on social media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 400 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for the treatment of cancer. BeiGene is working to create combination solutions aimed at having both a meaningful and lasting impact on cancer patients.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Celgene and BeiGene undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in Celgene's Annual Report on Form 10-K and other reports filed with the Securities and Exchange Commission, with respect to Celgene's forward-looking statements, and BeiGene's Annual Report on Form 10-K and other reports filed with the Securities and Exchange Commission, with respect to BeiGene's forward-looking statements.

Source: Celgene Corporation and BeiGene, Ltd.

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