Juno Therapeutics' and Celgene Corporation's Investigational Drug JCAR017 Granted Breakthrough Therapy Designation from FDA and Priority Medicines Eligibility from EMA for Relapsed/Refractory Diffuse Large B-cell Lymphoma

-- Early results recently announced with JCAR017 in non-Hodgkin lymphoma and pediatric acute lymphoblastic leukemia

-- Pivotal DLBCL trial expected to begin in 2017

SEATTLE & SUMMIT, N.J.--(BUSINESS WIRE)-- Juno Therapeutics, Inc. (NASDAQ: JUNO) and Celgene Corporation (NASDAQ: CELG), today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to investigational drug JCAR017 for the treatment of patients with relapsed/refractory (r/r) aggressive large B-cell non-Hodgkin lymphoma (NHL), including diffuse large B-cell lymphoma (DLBCL), not otherwise specified (de novo or transformed from indolent lymphoma), Primary Mediastinal B-cell Lymphoma (PMBCL) or Grade 3B Follicular Lymphoma. In addition, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT) have granted JCAR017 access to the Priority Medicines (PRIME) scheme for r/r DLBCL.

JCAR017 uses a defined CD4:CD8 cell composition and 4-1BB as the costimulatory domain, which differentiates it from other CD19-directed CAR T product candidates in clinical development. Earlier this month, data from multiple phase I studies with JCAR017 in non-Hodgkin lymphoma and pediatric acute lymphoblastic leukemia were presented at the 58th American Society of Hematology Annual Meeting.

"The Breakthrough Therapy designation from the FDA and PRIME eligibility from EMA for JCAR017 highlight the need for new treatment options for patients with DLBCL, particularly for the significant number of patients who do not respond to initial therapy or with relapsed disease," said Mark J. Gilbert, M.D., Juno's Chief Medical Officer. "Early data with JCAR017 in a range of B-cell malignancies has been encouraging and we look forward to initiating a pivotal trial in patients with relapsed or refractory DLBCL in the U.S. in 2017."

"The encouraging news of the FDA Breakthrough Therapy and EMA PRIME designations reflect the agencies' emphasis on accelerating the development and assessment of potential new options for serious blood cancers like DLBCL," said Jay Backstrom, M.D., Chief Medical Officer and Head of Global Regulatory Affairs for Celgene. "We will continue to work closely with our partners at Juno and with the agencies to move the JCAR017 program forward in the interest of patients with relapsed or refractory DLBCL."

The Breakthrough Therapy designation and PRIME eligibility were granted by the FDA and EMA, respectively, on the basis of early clinical results with JCAR017 in r/r DLBCL. According to the FDA, Breakthrough Therapy designation is intended to expedite the development and review of medicines with early evidence of potential clinical benefit in serious diseases. PRIME was launched by the EMA earlier this year and enables accelerated assessment of therapeutic applications that target an unmet medical need, focusing on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options.

JCAR017 is not approved in any country. FDA's Breakthrough Therapy designation and access to EMA's Priority Medicines scheme does not constitute or guarantee a future approval.

ABOUT JUNO

Juno Therapeutics is building a fully integrated biopharmaceutical company focused on re-engaging the body's immune system to revolutionize the treatment of cancer. Founded on the vision that the use of human cells as therapeutic entities will drive one of the next important phases in medicine, Juno is developing cell-based cancer immunotherapies based on chimeric antigen receptor and high-affinity T cell receptor technologies to genetically engineer T cells to recognize and kill cancer. Juno is developing multiple cell-based product candidates to treat a variety of B-cell malignancies as well as solid tumors. Several product candidates have shown compelling clinical responses in clinical trials in refractory leukemia and lymphoma conducted to date. Juno's long-term aim is to leverage its cell-based platform to develop new product candidates
that address a broader range of cancers and human diseases. Juno brings together innovative technologies from some of the world’s leading research institutions, including the Fred Hutchinson Cancer Research Center, Memorial Sloan Kettering Cancer Center, Seattle Children's Research Institute, the University of California, San Francisco, and The National Cancer Institute. Juno Therapeutics has an exclusive license to the St. Jude Children's Research Hospital patented technology for CD19-directed product candidates that use 4-1BB, which was developed by Dario Campana, Chihaya Imai, and St. Jude Children's Research Hospital.

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](http://www.celgene.com). Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

ABOUT THE JUNO-CELGENE COLLABORATION

Celgene Corporation and Juno Therapeutics formed a collaboration in June 2015 under which the two companies will leverage T cell therapeutic strategies to develop treatments for patients with cancer and autoimmune diseases with an initial focus on chimeric antigen receptor (CAR) and T cell receptor (TCR) technologies. In April 2016, Celgene exercised its option to develop and commercialize the Juno CD19 program outside North America and China.

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 Juno 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 the control of either company. 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 the public reports of each company filed with the Securities and Exchange Commission.


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