September 12, 2019 – Summit, N.J. – Celgene Corporation (NASDAQ: CELG) today announced top-line results from the international phase 3, randomized, double-blind, placebo-controlled study, QUAZAR AML-001. The study evaluated the efficacy and safety of investigational therapy CC-486 as maintenance therapy in patients with newly diagnosed acute myeloid leukemia (AML) who achieved first complete response (CR) or complete response with incomplete blood count recovery (CRi) with induction chemotherapy (with or without consolidation). The study demonstrated that maintenance treatment with CC-486 resulted in a highly statistically significant and clinically meaningful improvement in overall survival compared to placebo. The key secondary endpoint of relapse-free survival (RFS) also showed a statistically significant improvement.

CC-486 was well-tolerated and there were no unexpected safety events in QUAZAR AML-001. This phase 3 study enrolled 472 patients, randomized 1:1 to receive either oral CC-486 300mg or placebo once daily for 14 days of a 28-day cycle plus best supportive care until disease relapse.

“AML remains a deadly blood cancer where most patients are not curable and less than 30% of patients survive five years,” said Jay Backstrom, M.D., M.P.H., Chief Medical Officer for Celgene. “The CC-486 QUAZAR AML-001 study is the first phase 3 trial to demonstrate that the addition of maintenance therapy has the potential to extend overall survival in a broad population of patients with newly diagnosed AML who have achieved remission with induction chemotherapy.”

Data from QUAZAR AML-001 will be submitted to a future medical meeting. Celgene also plans regulatory submissions for CC-486 beginning in the first half of 2020.

CC-486 is an investigational compound and not approved for any use in any geography.

About QUAZAR AML-001
Phase 3, randomized, double-blind, placebo-controlled study of CC-486 as AML maintenance therapy in patients who achieved first CR or complete response with incomplete blood count recovery (CRi) with induction chemotherapy (with or without consolidation) The primary endpoint of the study was overall survival. Key secondary endpoints included relapse-free survival (RFS), safety and tolerability, healthcare resource utilization and patient-reported outcomes per the FACIT-Fatigue Scale and EQ-5D

questionnaire. The study enrolled 472 patients, randomized 1:1 to receive either oral CC-486 300mg or placebo once daily for 14 days of a 28-day cycle plus best supportive care until disease progression.

About CC-486
CC-486 is a cytidine nucleoside analogue and incorporates into DNA and RNA. The main mechanism of action is thought to cause DNA hypomethylation and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow. Hypomethylation may restore normal function to genes that are critical for differentiation and proliferation. The antineoplastic effect of CC-486 is hypothesized to cause death of rapidly dividing cells, including cancer cells that are no longer responsive to normal growth control mechanism.

About AML
Acute myeloid leukemia (AML) is a type of cancer in which the bone marrow makes abnormal blast cells that are supposed to grow into different types of blood cells. It may present in multiple subtypes based on the maturity of the cancer cells at diagnosis. There will be an estimated 21,450 new cases of AML in the United States this year, accounting for 1.2% of all cancer cases, with an estimated 10,920 deaths resulting from the disease. There are an estimated 61,048 people living with AML in the United States.

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.

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. We 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 our Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission, including factors related to the proposed transaction between Bristol-Myers Squibb and Celgene, such as, but not limited to, the risks that: management’s time and attention is diverted on transaction related issues; disruption from the transaction make it more difficult to maintain business, contractual and operational relationships; legal proceedings are instituted against Bristol-Myers Squibb, Celgene or the combined company that could delay or prevent the proposed transaction; and Bristol-Myers Squibb, Celgene or the combined company is unable to retain key personnel.

