



September 7, 2017

Celgene Provides Update on the Fusion™ Clinical Program

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on five trials and a full clinical hold on one trial in the Celgene FUSION™ program. The trials are testing IMFINZI™ (durvalumab), an anti-PD-L1 antibody, in combination with immunomodulatory and chemotherapy agents in blood cancers such as multiple myeloma, chronic lymphocytic leukemia and lymphoma.

The decision by the FDA was based on risks identified in other trials for an anti-PD-1 antibody, pembrolizumab, in patients with multiple myeloma in combination with immunomodulatory agents. In the FUSION™ program, the Company has not discerned, at this time, an imbalance in the risk benefit profile; however, the clinical holds allow for additional information to be collected to further understand the risk benefit profile of the program.

Patients enrolled in the trials on partial clinical hold who are receiving clinical benefit from treatment as determined by the investigator, may remain on treatment. Patients enrolled in the trial on full clinical hold will be discontinued from treatment. No new patients will be enrolled into the listed trials.

The trials placed on partial clinical hold are:

- | MEDI4736-MM-001: A Phase IB Multicenter, Open-Label Study to Determine the Recommended Dose and Regimen of Durvalumab Either as Monotherapy or in Combination with Pomalidomide with or without Low-Dose Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma
- | MEDI4736-MM-003: A Phase II, Multicenter, Open-label, Study to Determine the Safety and Efficacy for the Combination of Durvalumab and Daratumumab in Subjects with Relapsed and Refractory Multiple Myeloma
- | MEDI4736-MM-005: A Phase II, Multicenter, Single-Arm, Study to Determine the Efficacy for the Combination of Durvalumab Plus Daratumumab in Subjects with Relapsed and Refractory Multiple Myeloma That Have Progressed While on Current Treatment Regimen Containing Daratumumab
- | MEDI4736-NHL-001: A Phase I/II, Open-label, Multi-center Study to Assess the Safety and Tolerability of Durvalumab as Monotherapy and in Combination Therapy in Subjects with Lymphoma or Chronic Lymphocytic Leukemia. The only arm in this trial for which enrollment is suspended is the arm with the durvalumab, REVLIMID® and rituximab combination.
- | MEDI4736-DLBCL-001: A Phase II, Open-label, Multicenter Study to Evaluate the Safety and Clinical Activity of Durvalumab in Combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, Prednisone (R-CHOP) or with Lenalidomide Plus R-CHOP (R2 CHOP) in Subjects with Previously Untreated, High Risk Diffuse Large B Cell Lymphoma

The trial placed on full clinical hold is:

- | MEDI4736-MM-002: A Phase Ib Multicenter, Open-label Study to Determine the Recommended Dose and Regimen of Durvalumab in Combination with Lenalidomide with and without Low-dose Dexamethasone in Subjects with Newly Diagnosed Multiple Myeloma

The trials that will continue to enroll are:

- | MEDI4736-MDS-001: A Randomized, Multicenter, Open-label, Phase II Study Evaluating the Efficacy and Safety of Azacitidine Subcutaneous in Combination with Durvalumab in Previously Untreated Subjects with Higher-Risk Myelodysplastic Syndromes or in Elderly (> = 65 Years) Acute Myeloid Leukemia Subjects Not Eligible for Hematopoietic Stem Cell Transplantation
- | CC-486-MDS-006: A Phase II, International, Multicenter, Randomized, Open-label, Parallel Group to Evaluate the Efficacy and Safety of CC-486 Alone in Combination with Durvalumab in Subjects with Myelodysplastic Syndromes

Who Fail to Achieve an Objective Response to Treatment with Azacitidine for Injection or Decitabine

In April 2015, Celgene entered into a strategic collaboration with MedImmune, the global biologics research and development arm of AstraZeneca, to develop and commercialize IMFINZI™ for hematologic malignancies. The use of IMFINZI™ in combination with other agents for the treatment of patients with hematologic malignancies is not approved by the FDA, and the safety and efficacy of those combinations have not been established.

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 Securities and Exchange Commission.

Hyperlinks are provided as a convenience and for informational purposes only. Celgene bears no responsibility for the security or content of external websites.



View source version on [businesswire.com](http://www.businesswire.com/news/home/20170907005791/en/): <http://www.businesswire.com/news/home/20170907005791/en/>

Celgene Corporation
Patrick E. Flanigan III, 908-673-9969
Corporate VP, Investor Relations
or
Brian Gill, 908-673-9530
VP, Corporate Communications

Source: Celgene Corporation

News Provided by Acquire Media