December 5, 2016

Acceleron and Celgene Announce Preliminary Results from an Investigator Initiated Phase 2 Study of Sotatercept in Myelofibrosis at the 58th Annual Meeting of the American Society of Hematology

- Preliminary results show that treatment with investigational drug sotatercept can increase hemoglobin and achieve transfusion independence in patients with myelofibrosis -

- Acceleron to host conference call and live webcast on Monday, December 5th at 9:00 a.m. EST (6:00 a.m. PST) -

CAMBRIDGE, Mass. & SUMMIT, N.J.--(BUSINESS WIRE)-- Acceleron Pharma Inc. (NASDAQ:XLRN) and Celgene Corporation (NASDAQ:CELG), today announced preliminary results from an ongoing investigator initiated Phase 2 study with investigational drug sotatercept in patients with myelofibrosis at the 58th Annual Meeting of the American Society of Hematology (ASH) in San Diego, California. Sotatercept is being developed as part of the global collaboration between Acceleron and Celgene.

"These initial and encouraging data support our efforts for further clinical development work with our Acceleron-partnered programs in myelofibrosis," said Michael Pehl, President, Hematology and Oncology for Celgene. "We believe these programs have the potential to address a major unmet need in patients with myelofibrosis."

Highlights of the Sotatercept Myelofibrosis Phase 2 Data Presented at ASH

Results

- 19 patients were enrolled and treated with sotatercept (12 patients at 0.75 mg/kg and 7 at 1 mg/kg) and 14 of these patients have received at least 5 doses of sotatercept and are evaluable for response
- 36% (5/14) of the evaluable patients achieved an anemia response, defined as a composite of RBC-transfusion-independence and hemoglobin response (increase of ≥1.5 g/dL from baseline on every determination consecutively over ≥84 days without RBC transfusions).

Overall Safety

- Most adverse events were grades 1 or 2.
- Adverse events at least possibly related to study drug that occurred include grade 3 hypertension leading to discontinuation, grade 1 myalgia, bone pain, pain in extremity and injection site reaction.
- 13 patients have discontinued from the study: 5 due to no response, 2 proceeded to stem cell transplantation, 2 had MF progression, 1 transformed to AML, 1 each withdrew consent, had unrelated medical problems and hypertension

Sotatercept is an investigational product that is not approved for use in any country.

Acceleron ASH Conference Call Information

Acceleron will host a conference call and live webcast to discuss data presented at the ASH meeting on December 5, 2016, at 9:00 a.m. EST (6:00 a.m. PST). To participate by teleconference, please dial 877-312-5848 (domestic) or 253-237-1155 (international) and refer to the Acceleron ASH Review.

To access the live webcast, please select "Events & Presentations" in the Investors section on Acceleron's website (www.acceleronpharma.com) at least 10 minutes beforehand to ensure time for any downloads that may be required.

An archived webcast recording will be available on the Acceleron website beginning approximately two hours after the event.

About the Phase 2 Study

Data were presented from an ongoing investigator sponsored Phase 2 study of sotatercept in subjects with myelofibrosis at the conference. Subjects enrolled were red blood cell (RBC) transfusion-dependent, have hemoglobin < 10 g/dL on every determination during the 84 days preceding study entry without RBC transfusions, or have hemoglobin < 10 g/dL despite intermittent RBC transfusions without fulfilling the criteria for transfusion dependence. Patients received open-label sotatercept at 0.75 mg/kg or 1 mg/kg, dosed subcutaneously once every three weeks.

The primary outcome measures for the study include anemia response and safety. Anemia response is a composite of RBC-transfusion-independence and hemoglobin response (increase of ≥1.5 g/dL from baseline on every determination consecutively over ≥84 days without RBC transfusions). Subjects must have received ≥5 cycles of sotatercept to be evaluable for response.

About Sotatercept

Sotatercept is an activin receptor type IIA fusion protein that acts as a ligand trap for members in the Transforming Growth Factor-Beta (TGF-β) superfamily involved in fibrosis and late stage erythropoiesis (red blood cell production). Acceleron and Celgene are jointly developing sotatercept as part of a global collaboration. Sotatercept is currently in multiple Phase 2 investigator initiated trials. For more information, please visit www.clinicaltrials.gov.

About Acceleron

Acceleron is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics to treat serious and rare diseases. Its pioneering research platform leverages the powerful biology behind the body's ability to rebuild and repair its own cells and tissues. This approach to drug discovery has generated four therapeutic candidates that are currently in clinical trials. The Company's lead therapeutic candidate, luspatercept, is being evaluated in Phase 3 studies for the treatment of the hematologic diseases, myelodysplastic syndromes (MDS) and beta-thalassemia under a global partnership with Celgene Corp. Acceleron is also advancing clinical programs in the fields of oncology and neuromuscular diseases and has a comprehensive preclinical research effort targeting fibrotic and other serious diseases.

For more information, please visit www.acceleronpharma.com. Follow Acceleron on Social Media: @AcceleronPharma and LinkedIn.

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

Acceleron:

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements about Acceleron's strategy, future plans and prospects, including statements regarding the development of sotatercept, the timeline for clinical development and regulatory approval of Acceleron's compounds, the expected timing for the reporting of data from ongoing trials, and the structure of Acceleron's planned or pending clinical trials. The words "anticipate," "appear," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that preclinical testing of Acceleron's compounds and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that data may not be available when Acceleron expects it to be, that Acceleron or its collaboration partner, Celgene, will be unable to successfully complete the clinical development of Acceleron's compounds, that the development of Acceleron's compounds will take longer or cost more than planned, that Acceleron or Celgene may be delayed in initiating or completing any clinical trials, and that Acceleron's compounds will not receive regulatory approval or become commercially successful products.

Other risks and uncertainties include those identified under the heading "Risk Factors" included in Acceleron's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission (SEC) on February 25, 2016, and other filings that Acceleron has made and may make with the SEC in the future. The forward-looking statements contained in this press release reflect Acceleron's current views with respect to future events, and Acceleron does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Celgene:

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Acceleron and Celgene; the potential of luspatercept as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates ; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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