Exelixis Presents Encouraging Phase 1 Data For XL019, A Novel Selective Inhibitor of JAK2

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ATLANTA, Dec. 10 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL), today reported phase 1 data from an ongoing phase 1 trial of XL019 in patients with myelofibrosis, a myeloproliferative disorder (MPD). XL019 is an investigational small molecule that selectively inhibits the tyrosine kinase JAK2, one of four JAK family members activated in response to cytokines and hematopoietic growth factors. JAK2 is inappropriately activated in the majority of MPD patients and is deregulated in a number of solid tumors, including certain subtypes of lymphoma. Dr. Srdan Verstovsek from the M. D. Anderson Cancer Center, Houston, TX today presented data from an ongoing phase 1 study in an oral presentation session (Abstract #553) at the American Society of Hematology 49th Annual Meeting and Exposition, which is taking place in Atlanta, December 8th-11th.

"We are very encouraged by the results from this ongoing trial that show rapid decrease in spleen size and relief of disease-related symptoms at low doses of XL019. XL019 is a highly selective inhibitor of JAK2 that may have the potential to provide important benefit for patients with myeloproliferative disorders and other diseases driven by JAK2," said Michael Morrissey, Ph.D., president of research and development at Exelixis. "We believe that JAK2 is a critical target in myeloproliferative disorders, and effective inhibition of JAK2 may directly translate into clinical benefit. The strong linkage of JAK2 to MPDs provides a potentially quick route to market, with potential for additional opportunities in larger commercial indications. We are planning to initiate pivotal trials of XL019 in myelofibrosis patients in 2008."

Trial Design

The phase 1 dose escalation study of XL019 is ongoing in subjects with primary myelofibrosis (MF) and post-polycythemia vera/essential thrombocythemia MF. To date nine patients have been enrolled. The primary objective of this study is to determine the safety and tolerability of XL019 when administered orally once daily for 21 days in 28-day cycles. Secondary objectives include evaluation of the pharmacokinetics and pharmacodynamics of XL019, and to evaluate response using the International Working Group for MF consensus response criteria.

Results To-Date

Data (unaudited) from cohort 1 (100mg), cohort 2 (200mg) and cohort 3 (300mg) were presented today and the key findings by investigators include:

-- Preliminary clinical activity observed in most subjects, including: - Reduction in spleen size of 33 to 100% in five of six patients evaluated

- Reduction in erythropoietin-independent colony formation of up to 39% and up to 100% in two patients evaluated

-- Relief of constitutional symptoms, including pruritus, fatigue, back pain and abdominal fullness

-- Reduction in the number of cells with the JAK2 V617F mutation (allele burden)

-- Correlation between XL019 exposure and decreases in phosphorylation of STAT, a marker for JAK activity.

-- XL019 was generally well tolerated.
- Adverse events included Grade 1 nausea, headaches, equilibrium imbalance, dizziness, chest discomfort, visual disturbances, fatigue and hypertension.
- Grade 2 AEs of lightheadedness and decreased sensation in soles and one serious adverse event of confusion in a patient with baseline history of dementia were also observed.

-- No evidence of myelosuppression

The maximum tolerated dose has not been reached. The phase 1 dose escalating clinical trial continues.

About JAK2 and XL019

JAK kinases are activated by cytokines and growth factor receptors and phosphorylate members of the STAT family of inducible transcription factors. JAK2 plays a pivotal role in the cellular response to growth factors that drive blood cell expansion, including erythropoietin and thrombopoietin. Mutational activation of JAK2 is observed in the majority of patients with polycythemia vera, essential thrombocythemia and myelofibrosis, and is thought to drive the inappropriate expansion of blood cells observed in these conditions. Other members of the JAK family play critical roles in regulating immune responses, including the anti-viral and anti-parasitic responses.

XL019 is a potent JAK2 inhibitor (IC50 = 2 nM) with excellent selectivity versus the other members of the JAK kinase family (JAK1 IC50 = 130 nM, JAK3 IC50 = 250 nM, TYK2 IC50 = 340 nM). It is active against both wild type and mutationally activated forms of JAK2, and in preclinical studies showed good oral bioavailability and pharmacodynamic properties. Preclinical safety studies showed that XL019 was well tolerated.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in phase 2 and phase 1 clinical development for cancer and renal disease. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company, Genentech, Wyeth Pharmaceuticals and Daiichi-Sankyo. For

more information, please visit the company's web site at http://www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to the future development and potential efficacy of XL019 and the timing of the initiation of pivotal trials for XL019. Words such as "may," "believe," "provide," "potential," "planning" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the potential failure of our product candidates to demonstrate safety and efficacy in clinical testing; the ability to initiate and complete trials at the referenced times; the ability to conduct clinical trials sufficient to achieve a positive completion; the uncertainty of the FDA approval process; the therapeutic and commercial value of our compounds and risks related to our need for additional financing. These and other risk factors are discussed under "Risk Factors" and elsewhere in our quarterly report on Form 10-Q for the quarter ended September 30, 2007 and our other filings with the Securities and Exchange Commission. We expressly disclaim any duty, obligation or undertaking to release publicly any updates or revisions to any forward- looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

SOURCE Exelixis, Inc.
/CONTACT: Investors, Charles Butler, Director, Corporate Communications & Investor Relations, +1-650-837-7277, cbutler@exelixis.com, or Media, Soleil Harrison, Senior Manager, Corporate Communications, +1-650-837-7012, sharriso@exelixis.com, both of Exelixis, Inc./
/Web site: http://www.exelixis.com /