November 2, 2015

Nivalis Therapeutics Reports Third Quarter and Nine-Month Financial Results for 2015

- N91115 Phase 1b Data Recently Presented at North American Cystic Fibrosis Conference

- Phase 2 Study on Track to Enroll First Patient in Fourth Quarter

BOULDER, Colo., Nov. 02, 2015 (GLOBE NEWSWIRE) -- Nivalis Therapeutics, Inc. (NASDAQ:NVLS), a clinical-stage pharmaceutical company focused on treating people with cystic fibrosis (CF), today reported financial results and recent business highlights for the third quarter ended September 30, 2015.

“Since the successful completion of our initial public offering earlier this year, Nivalis continues to make significant progress in advancing the clinical development of the Company’s lead compound, N91115, a novel stabilizer of the cystic fibrosis transmembrane conductance regulator protein, or CFTR,” said Jon Congleton, president and chief executive officer of Nivalis. “We are pleased to announce that the U.S. Food and Drug Administration has cleared our Phase 2 protocol design which will evaluate the efficacy and safety of N91115 when added to Orkambi™. The Phase 2 study is on track to enroll the first patient prior to the end of this year.”

Third Quarter and Nine-Month Financial Results

For the third quarter ended September 30, 2015, Nivalis reported a net loss of $6.1 million, compared to a net loss of $2.6 million in the same quarter last year. For the nine months ended September 30, 2015, Nivalis reported a net loss of $16.3 million compared to a net loss of $11.2 million in the same period last year. The increased loss in the quarter and nine-month periods was the result of the initiation and completion of the Phase 1b clinical trial, which began in the first quarter of 2015, and related development costs for N91115. In addition, general and administrative costs related to becoming and operating as a publicly-traded company increased during the quarter and nine-month periods, as compared to the same periods last year.

Cash used in operating activities was $13.8 million for the nine months ended September 30, 2015. As of September 30, 2015, Nivalis had approximately $93 million in cash and marketable securities. Nivalis has no outstanding debt and there are 15.5 million shares of common stock issued and outstanding.

Recent Business Highlights and Upcoming Milestones

- **Phase 1b Clinical Study for N91115**

  Results from the Phase 1b clinical study evaluating the safety, tolerability and pharmacokinetic profile of N91115 in participants who were homozygous for the *F508del-CFTR* mutation were presented during an oral presentation and in a poster at the recent North American Cystic Fibrosis Conference. No dose limiting toxicities were observed and N91115 was well tolerated in the study. While not powered to demonstrate statistically significant clinical efficacy, there was a modest reduction in sweat chloride at the highest dose studied, which may suggest a minimum dose for effecting CFTR modulation as well as inform dosing in the subsequent Phase 2 study.

- **Initiation of Phase 2 Clinical Study of N91115**

  The Phase 2 study protocol of N91115 in people with CF who have two copies of the *F508del* mutation was cleared by the U.S. Food and Drug Administration. The twelve-week randomized, double-blind placebo-controlled clinical trial remains on track to begin prior to the end of this year and will evaluate the safety and efficacy of N91115 when added to Orkambi™ (lumacaftor/ivacaftor). The Company expects to enroll the first patient prior to the end of this year, with data from the Phase 2 study available in the second half of 2016.

About Nivalis Therapeutics, Inc.
Nivalis Therapeutics, Inc. (http://www.nivalis.com) is a clinical stage pharmaceutical company committed to the discovery, development and commercialization of therapeutics for people with cystic fibrosis. In addition to developing innovative solutions intended to extend and improve the lives of people with CF, Nivalis plans to utilize its proprietary S-nitrosoglutathione reductase (GSNOR) inhibitor portfolio to develop therapeutics for other diseases.

About N91115
CF is a life-shortening genetic disease that affects an estimated 70,000 people worldwide, predominately in the United States and Europe. CF is characterized by a defect in the chloride channel of human cells known as the “cystic fibrosis transmembrane conductance regulator,” or CFTR, which is caused by mutations in the CFTR gene. N91115 works through a presumed novel mechanism of action called GSNOR inhibition to modulate the unstable and defective CFTR protein responsible for CF. GSNOR inhibition restores GSNO levels thereby modifying the chaperones responsible for CFTR protein degradation. This stabilizing effect increases and prolongs the function of the CFTR chloride channel and leads to an increase in net chloride secretion. Nivalis discovered and owns exclusive rights to N91115 in the United States and all other major markets, including U.S. composition of matter patent protection until at least 2031.

Nivalis Therapeutics has completed a Phase 1a dose-escalation safety study of orally administered N91115 in healthy volunteers, and a Phase 1b safety study in people with CF who have two copies of the *F508del* mutation. In pre-clinical studies, N91115 has been

shown to increase the function of *F508del-CFTR*, the mutant protein that is estimated to be present in approximately 86 percent of people with CF in the United States and Europe.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Nivalis' development plans and potential opportunities, the timing for enrolling patients in, initiating and completing the Phase 2 clinical trial, the timing for announcements of future clinical trial results and expectations that early stage clinical trials will result an approved drug. These forward-looking statements are based on management's current expectations of future events and involve substantial risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by the forward-looking statements. These risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the risk that the timing of site initiation and patient enrollment for our clinical trials may take longer than expected, delays in the timing of regulatory filings and approvals, delays in the commercialization or availability of Orkambi, and other matters that could affect the completion of the clinical development and commercial potential of the company's product candidates. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Nivalis' business in general, see the risk factors contained in the company's prospectus filed with the Securities and Exchange Commission on June 17, 2015, in the company's most recent quarterly report on Form 10-Q and in its other reports filed with the Securities and Exchange Commission. All information in this press release is as of the date of this release, and Nivalis undertakes no duty to update or revise this information unless required by law.

Nivalis Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	4,279	2,164	11,761	9,378
General and administrative expenses	1,822	490	4,507	1,623
Loss from operations	(6,101)	(2,654)	(16,268)	(11,001)
Other income, net	12	35	13	296
Interest expense	-	(392)	-	(845)

Net loss	(6,089)	(3,011)	(16,255)	(11,550)
Gain on extinguishment of convertible debt as a capital transaction	-	378	-	378
Net loss attributable to common stockholders	$ (6,089)	$ (2,633)	$ (16,255)	$ (11,172)
Weighted average shares outstanding	15,451	343	7,322	223
Basic and diluted net loss per share	$ (0.39)	$ (7.68)	$ (2.22)	$ (50.10)

Summary Balance Sheet Data
(in thousands)

	September 30, 2015	December 31, 2014
Cash, cash equivalents and marketable securities	$ 92,651	$ 27,812
Property, plant and equipment, gross	1,634	1,493
Working capital	89,182	26,027
Total assets	93,842	28,543
Stockholders' equity (deficit)	89,377	(15,752)

Contacts:

Investor Relations
John Graziano
1-646-378-2942
jgraziano@troutgroup.com

Media
Lindsay Rocco
1-862-596-1304
lrocco@elixirhealthpr.com

Source: Nivalis Therapeutics, Inc.