

ANADYS PHARMACEUTICALS INITIATES PHASE IIB STUDY OF ANA598 IN HCV PATIENTS

SAN DIEGO, January 4, 2011 -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) announced today that it has initiated the planned Phase Iib study of ANA598 in combination with pegylated interferon and ribavirin. The protocol for the study has been cleared by the United States Food and Drug Administration (FDA) and Health Canada. Patient screening has begun and patient dosing is expected to commence within the next several weeks. In the study ANA598 will be tested in both treatment-naïve patients and treatment-experienced patients who failed a prior course of therapy with interferon and ribavirin. ANA598 is the Company's direct-acting antiviral, or DAA, being developed for the treatment of hepatitis C.

“We are excited to initiate this Phase Iib study of ANA598,” said James L. Freddo, M.D., Anadys' Senior Vice President, Drug Development and Chief Medical Officer. “By establishing safety and efficacy in a greater number of patients, including those who have failed prior HCV treatment, we hope to position ANA598 as a highly attractive HCV agent ready for Phase III development.”

Phase Iib Protocol Design

In the study, approximately 200 chronically infected genotype 1 hepatitis C patients are expected to receive ANA598 200 mg twice a day (bid) in combination with Pegasys[®] (peginterferon alfa-2a) and Copegus[®] (ribavirin, USP) (a current standard of care, or SOC) with a loading dose of 800 mg bid on day 1, while approximately 66 patients are to receive placebo and SOC. Enrollment is expected to include approximately equal numbers of treatment-naïve patients and patients who have failed a prior course of SOC, including difficult to treat prior null-responders. The primary endpoint of the study is Sustained Virological Response 24 weeks after patients conclude all treatment, known as SVR24. Anadys is conducting the study at sites within and outside the United States.

Naïve Arm

Approximately 100 treatment-naïve HCV patients are expected to receive ANA598 in combination with SOC and 33 treatment-naïve HCV patients are to receive placebo plus SOC. Treatment duration for naïve patients will be response-guided; patients who achieve undetectable levels of virus at Week 8 and maintain undetectable levels of virus will be scheduled to conclude all treatment at Week 28. For naïve patients with detectable virus at Week 8 dosing with ANA598, or placebo, and SOC is planned to continue through Week 48. The Company expects to receive Week 8 antiviral response data by the end of the second quarter of 2011, Week 12 antiviral response data in the third quarter of 2011 and Week 24 antiviral response data in the fourth quarter of 2011.

Treatment-Experienced Arm, Including Prior Null Responders

Approximately 80 patients who were partial responders during, or relapsers after, a prior course of therapy with SOC alone are expected to receive ANA598 in combination with SOC, and 33 corresponding patients are to receive placebo plus SOC. Additionally, approximately 28 prior null responder patients are to receive ANA598 in combination with SOC. All treatment-experienced patients who receive ANA598 are scheduled to receive triple combination therapy for 48 weeks. For the treatment-experienced patients, the Company expects to receive Week 12 antiviral response data in the third quarter of 2011 and Week 24 antiviral response data in the fourth quarter of 2011.

About Anadys

Anadys Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to improving patient care by developing novel medicines for the treatment of hepatitis C. The Company believes hepatitis C represents a large unmet medical need in which meaningful improvements in treatment outcomes may be attainable with the introduction of new medicines. Anadys has initiated a Phase IIb study of ANA598, the Company's DAA, added to current standard of care for the treatment of hepatitis C. The Company is also preparing to resume clinical development of ANA773, the Company's oral, small-molecule inducer of endogenous interferons that acts via the Toll like receptor 7, or TLR7, pathway in hepatitis C.

Safe Harbor Statement

Statements in this press release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, references to (i) expectations regarding the timing for commencing patient dosing in the ANA598 Phase IIb study; (ii) the goal of establishing safety and efficacy in a greater number of patients, including those who have failed prior HCV treatment; (iii) the hope to position ANA598 as a highly attractive HCV agent ready for Phase III development; (iv) the scheduled trial design for the Phase IIb study; and (v) Anadys' expectations regarding the timing of receipt of data from the study. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause Anadys' actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. For example, the results of preclinical and early clinical studies may not be predictive of future results, and Anadys cannot provide any assurances that ANA598 will not have unforeseen safety issues, will have favorable results in ongoing or future clinical trials or will receive regulatory approval. In addition, Anadys' results may be affected by competition from other biotechnology and pharmaceutical companies, its effectiveness at managing its financial resources, its ability to enter into transactions around its product candidates, its ability to successfully develop and market products, difficulties or delays in its non-clinical studies or clinical trials, difficulties or delays in manufacturing its clinical trials materials, the scope and validity of patent protection for its products, regulatory developments and its ability to obtain additional funding to support its operations. Risk factors that may cause actual results to differ are more fully discussed in Anadys' SEC filings, including Anadys' Form 10-Q for the quarter ended September 30, 2010. All forward-looking statements are qualified in their entirety by this cautionary statement. Anadys is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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