



## **ANADYS RETAINS LAZARD AS STRATEGIC ADVISOR**

*Company Pursuing Avenues to Maximize Recognition of ANA598 Value*

**SAN DIEGO, May 26, 2010** -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) today announced that it has retained Lazard Frères & Co. LLC as its strategic advisor as it pursues various avenues aimed at value recognition for its stockholders from its non-nucleoside polymerase inhibitor, ANA598, in development for the treatment of hepatitis C. Anadys recently released positive safety and antiviral response data at the conclusion of 12 weeks of dosing ANA598 in combination with pegylated interferon and ribavirin (current standard of care, or SOC) in an ongoing Phase II study.

“The impressive safety and antiviral response data we recently released establish a very attractive profile for ANA598,” said Steve Worland, Ph.D., President and CEO of Anadys. “We look forward to working with Lazard as we pursue options to maximize recognition of the value inherent in the ANA598 program.”

### **Recently Released ANA598 Data**

Anadys recently reported that patients treated with ANA598 at 400 mg bid demonstrated excellent safety through 12 weeks and that 75% of patients at this dose level achieved undetectable levels of virus (<15 /IU/mL) at week 12, known as complete Early Virological Response or cEVR. These data confirmed the positive profile previously reported for ANA598 at 200 mg bid through 12 weeks. Based on comparable antiviral potency and excellent safety at both doses, Anadys has identified 200 mg bid as the optimal dose to advance in combination with current SOC in future clinical trials. Anadys believes that lower doses and once daily dosing also merit exploration, especially in combination with other direct acting antivirals.

In the ongoing Phase II study, a total of approximately 90 treatment-naïve genotype 1 patients have received ANA598 or placebo in combination with Pegasys® (peginterferon alfa-2a) and Copegus® (ribavirin, USP) for 12 weeks at dose levels of 200 mg bid or 400 mg bid, each with a loading dose of 800 mg bid on day one. After week 12, patients are to continue receiving SOC. Patients who achieved undetectable levels of virus at weeks 4 and 12 are to be randomized to stop all treatment at week 24 or 48. The primary endpoint of the study is the proportion of patients who achieve undetectable levels of virus at week 12 (defined as complete Early Virological Response, or cEVR). Additional endpoints include safety and tolerability as well as the proportion of patients with undetectable levels of virus at week 4 (defined as Rapid Virological Response, or RVR). Patients will be followed for 24 weeks after stopping therapy to determine the rate of Sustained Virological Response, or SVR. Approximately 90 patients have been enrolled in this study – with approximately 30 patients receiving ANA598 plus SOC at each dose level and 30 patients receiving placebo plus SOC. The study is being managed by the Duke Clinical Research Institute (DCRI) under the leadership of John McHutchison, M.D. and is being conducted at a number of clinical sites in the United States.

### **About ANA598**

ANA598 is a non-nucleoside inhibitor of the HCV RNA polymerase and is wholly owned by Anadys. Anadys has completed three Phase I clinical studies of ANA598 that have demonstrated potent antiviral activity and good tolerability. In a monotherapy study in treatment-naïve

genotype 1 patients, treatment with ANA598 for three days led to median end-of-treatment declines in viral load ranging from 2.4 to 2.9 log<sub>10</sub> in three separate dose groups. No patient at any dose level in the monotherapy study showed evidence of viral breakthrough while on ANA598, and there were no serious adverse events. Those patients from the monotherapy study who subsequently received pegylated interferon and ribavirin all exhibited further viral load decline, demonstrating that viral variants revealed by brief treatment with ANA598 remain susceptible to current SOC, consistent with prior *in vitro* results.

Anadys has completed two long-term chronic toxicology studies of ANA598 (26 weeks duration in rats and 39 weeks duration in monkeys). The No Observed Adverse Effect Level, or NOAEL, is 1000 mg/kg, the highest dose tested, in both the rat and monkey. The completed toxicology studies support the ongoing Phase II clinical study as well as future clinical studies of longer duration.

Anadys has presented *in vitro* data supporting the use of ANA598 in combination with interferon-alpha as well as with other anti-HCV agents currently in development that act through diverse mechanisms. In particular, data has shown that ANA598 is synergistic *in vitro* with interferon-alpha as well as representative HCV protease and polymerase inhibitors. *In vitro* combination treatment at clinically relevant concentrations of interferon-alpha and ANA598 results in clearance of HCV RNA from cells rather than selection of resistant isolates. Furthermore, ANA598 retains full activity *in vitro* against mutations conferring resistance to protease inhibitors, nucleoside polymerase inhibitors and non-nucleoside polymerase inhibitors that act at binding sites distinct from that of ANA598, while protease and nucleoside polymerase inhibitors retain full activity *in vitro* against mutations conferring resistance to ANA598.

ANA598 has received Fast Track Status from the FDA for the treatment of chronic 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) the Company’s plans to pursue various avenues aimed at value recognition for its stockholders; (ii) the potency and safety profile of ANA598 based on clinical trial data to date; and (iii) the Company’s objective to maximize recognition of value from the ANA598 program. 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 or will continue to have favorable results as the Phase II trial progresses. Also, Anadys cannot provide any assurances that the retention of Lazard and the pursuit of discussions with third parties around a strategic transaction will result in a transaction of a particular structure, on favorable terms, or at all. 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 preclinical 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-K for the year ended December 31, 2009, Form 10-Q for the quarter ended March 31, 2010 and Form 8-K filed on May 26, 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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