



**ANADYS ANNOUNCES COMPLETED 12-WEEK RESULTS FROM PHASE II COMBINATION STUDY OF ANA598 WITH INTERFERON AND RIBAVIRIN**

*Antiviral Potency, Durability and Safety Results Confirm Compelling Profile*

*Company to Review Data During Conference Call at 8:30 AM EDT Today*

**SAN DIEGO, May 21, 2010** -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) today announced completed 12-week results from an ongoing Phase II study, which demonstrated that 75% of hepatitis C patients treated with 400 mg ANA598 twice daily (bid) in combination with pegylated interferon and ribavirin (current standard of care, or SOC) achieved undetectable levels of virus (<15 IU/mL) at week 12, known as complete Early Virological Response or cEVR.

“We are very pleased with the comparable antiviral potency and favorable safety profile demonstrated through 12 weeks for both doses investigated in this study,” said Steve Worland, Ph.D., President and CEO of Anadys. “Coupled with the favorable tolerability profile seen at 200 mg bid, we believe that these results establish ANA598 at 200 mg bid as one of the most attractive agents in Phase 2 HCV development today.”

Anadys also announced additional data for patients in the 200 mg bid dose group who have now completed 24 weeks of treatment – 12 weeks of ANA598 in combination with SOC, followed by an additional 12 weeks of SOC alone. At the 200 mg bid dose level, where 73% of patients achieved a cEVR, 17 of 18 patients who had undetectable levels of virus at week 12 and continued on SOC for an additional 12 weeks remained undetectable at 24 weeks. Additionally, two patients who had low but detectable levels of virus at week 12 achieved undetectable levels of virus at week 24.

***Antiviral Response Through 12 Weeks***

<b>Proportion of Patients (%) with Undetectable Levels of Virus (&lt;15 IU/mL) by Week</b>								
	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 10	Week 12
ANA598 + SOC 200 mg bid	11	22	44	56	65	69	73	73
ANA598 + SOC 400 mg bid	9	27	30	42	56	72	75	75
Placebo + SOC	0	3	9	13	19	38	48	63

In the second cohort a single patient who received ANA598 400 mg bid experienced viral breakthrough (defined as a confirmed increase of >1 log from any prior measurement) between weeks 10 and 12. No other patient who received either dose of ANA598 experienced viral breakthrough.

## ***IL28B Genotyping-Preliminary Assessment***

Based on a preliminary assessment of IL28B genotyping from approximately sixty percent of the patients in the Phase II study, Anadys can now offer additional perspective on the response of the patients who received placebo plus standard of care (control arm) in the study. Recent scientific studies have shown that individuals with the IL28B CC genotype, present in approximately 37% of Caucasian HCV patients and a lower percentage of patients in other ethnic groups, are substantially more responsive to SOC than patients with other IL28B genotypes. In the SOC control arm of the ANA598 study, 56% of the patients who have been genotyped to date are of the CC genotype while in the ANA598-treated arms only 21% of the patients who have been genotyped to date are of the CC genotype. Anadys believes that the high proportion of CC patients in the SOC control arm of the ANA598 Phase II study relative to the overall population likely contributed to a higher cEVR rate than has been seen historically.

## ***Preliminary Safety and Tolerability Assessment Through 12 Weeks***

Both doses of ANA598 demonstrated a favorable safety and tolerability profile through 12 weeks, although conclusions regarding safety and tolerability cannot be made until results in more patients and potentially over longer duration are known. Safety laboratory values were comparable between the ANA598 and control arms. At the 200 mg bid dose level, the incidence of all adverse events was similar between the active and control arms, with reported adverse events being typical for patients treated with interferon and ribavirin. In the 400 mg bid arm, a higher incidence of rash (mostly mild) was seen relative to the 200 mg bid and control arms. The incidence of all other adverse events was comparable between the 400 mg bid and control arms. In the 400 mg bid arm, 59% of patients (20/34) receiving ANA598 400 mg bid developed rash, compared to 41% (12/29) receiving 200 mg bid and 31% (10/32) for patients that received placebo plus SOC. In the 400 mg bid group, 16 of 20 rashes were mild, with one grade 2 rash and three grade 3 rashes. As previously reported, in the 200 mg bid arm, the incidence of rash was comparable with the placebo control arm and also consistent with historical reports of rash incidence due to interferon and ribavirin.

## **Phase II Combination Study**

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<sup>®</sup> (peginterferon alfa-2a) and Copegus<sup>®</sup> (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.

### **Conference Call Webcast and Slides**

Anadys will hold a conference call and webcast today, Friday, May 21, 2010 at 8:30 a.m. Eastern Daylight Time to discuss the completed 12 week results for ANA598 from the ongoing Phase II combination study. A live webcast of the call, including accompanying slides, will be available online at [www.anadyspharma.com](http://www.anadyspharma.com). A telephone replay with slides will also be available approximately one hour after completion of the call. To access the telephone replay, dial 888-286-8010 (domestic) or 617-801-6888 (international), passcode 75833750. The webcast and telephone replay will be available through June 4, 2010.

### **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 compelling profile of ANA598 based on the antiviral potency, durability and safety results seen to date; (ii) the belief that the study results announced today establish ANA598 at 200 mg bid as one of the most attractive agents in Phase 2 HCV development today; (iii) the belief, based on a partial data set, that the high proportion of CC patients in the SOC control arm of the ANA598 Phase II study relative to the overall population likely contributed to a higher cEVR rate in the control arm than has been seen historically; and (iv) the ability for patients to achieve an SVR in the Phase II combination 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 or will continue to have favorable results as the Phase II trial progresses. 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 and Form 10-Q for the quarter ended March 31, 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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**Investor Contact:**

Amy Conrad  
Anadys Pharmaceuticals, Inc.  
(858) 530-3607  
[aconrad@anadyspharma.com](mailto:aconrad@anadyspharma.com)

**Media Contact:**

Ian Stone or David Schull  
Russo Partners, LLC  
(619) 528-2220  
[ian.stone@russopartnersllc.com](mailto:ian.stone@russopartnersllc.com)  
[david.schull@russopartnersllc.com](mailto:david.schull@russopartnersllc.com)