

## ADVENTRX Announces Results From ANX-514 Bioequivalence Study

- Updates guidance regarding strategic transaction process

SAN DIEGO, May 7 /PRNewswire-FirstCall/ -- ADVENTRX Pharmaceuticals, Inc. (NYSE Amex: ANX) today announced results from its bioequivalence study of ANX-514 (docetaxel emulsion). ANX-514 was determined to have comparable overall safety as Taxotere(R), the reference product, with no differences between treatment groups in severe toxicities. However, pharmacokinetic equivalence, the primary endpoint of the study, was not demonstrated based on benchmark regulatory standards.

"Following discussions with clinicians and experts in taxane pharmacokinetics, we believe that the increased blood-levels of docetaxel, which we observed solely during the first hour of a 168-hour observation period, do not affect the safety or efficacy of the drug and are not clinically relevant, and that our pharmacokinetic data should be sufficient to support an NDA for ANX-514," said Brian M. Culley, Chief Business Officer of ADVENTRX. "In addition, we have not fully investigated whether variability with respect to study drug administration and/or blood sample collection may have affected the results. However, the FDA is the final arbiter of safety and efficacy and, following discussion with the Agency, we will have more insight into whether additional pre-clinical and/or clinical activities may be necessary before submitting an NDA for ANX-514."

"The possibility of additional activities creates uncertainty around the cost and timeline to FDA approval of ANX-514, which may adversely impact our on-going strategic transaction discussions," Mr. Culley continued. "Consequently, and in light of our current working capital, we are evaluating both our strategic and non-strategic options."

The study data revealed higher blood-levels of docetaxel during and immediately following infusion of study drug (i.e., during the first hour of treatment) in patients receiving ANX-514 relative to those receiving Taxotere, but, at 10 minutes after the completion of infusion, docetaxel blood-levels were comparable and remained so through the end of the observation period. The Company is analyzing these short-term increased levels, which were the reason ANX-514 was outside the bounds established by the FDA for determining bioequivalence. Analyzing blood-levels at all time points beginning 10 minutes after the completion of drug administration, pharmaceutical equivalence of ANX-514 and Taxotere was observed.

The bioequivalence study of ANX-514 was an open-label, two-period, randomized, crossover comparison of ANX-514 and Taxotere in patients with advanced cancer potentially sensitive to docetaxel. The primary objective was demonstrating the pharmacokinetic equivalence of ANX-514 and Taxotere and determining the safety of a single dose of ANX-514 was a secondary objective. On Day 1, patients were dosed with either ANX-514 or Taxotere and, on Day 22, were dosed with the other drug. Patients were premedicated with corticosteroids prior to treatment on Day 1 and on Day 22. The FDA has indicated that this single bioequivalence study, should it demonstrate pharmacokinetic equivalence between ANX-514 and Taxotere, would provide sufficient data to support an NDA.

Pharmacokinetic equivalence was assessed by a statistical comparison of both the areas under the curve (AUC) and maximum plasma concentrations (Cmax) and determined based on federal regulations and FDA guidance regarding bioequivalence studies. If the upper and lower bounds of the AUC ratio's and the Cmax ratio's 90% confidence interval ranged from 0.80 to 1.25, ANX-514 and Taxotere would be considered to have equivalent pharmacokinetics. Pursuant to the study's protocol and statistical analysis plan, data from 31 patients who received both study drugs, had no major violations of the inclusion/exclusion criteria and had complete pharmacokinetic data were included in the analysis.

About ANX-514 (docetaxel emulsion)

ANX-514 is a novel nano-emulsion formulation of the chemotherapy drug docetaxel, a formulation of which is marketed under the brand name Taxotere. ANX-514 is formulated without polysorbate 80 or other detergents and is intended to reduce the severity and/or incidence of hypersensitivity reactions. Docetaxel is an anti-cancer agent that acts by disrupting the cellular microtubular network that is essential for cell division. Immunosuppressant premedication is recommended for docetaxel therapy to reduce the incidence and severity of hypersensitivity reactions. Docetaxel is approved to treat breast, non-small cell lung, prostate, gastric and head and neck cancers.

About ADVENTRX Pharmaceuticals

ADVENTRX Pharmaceuticals is a biopharmaceutical company whose proprietary product candidates are designed to improve the safety and commercial potential of existing cancer treatments. In December 2008, the Company announced that it is exploring a range of strategic options, including the sale or disposition of one or more of its product candidate programs, a strategic business merger and other transactions that maximize the value of the Company's assets. In January and March 2009, the Company announced headcount reductions and cost containment measures to provide additional time to consummate a strategic transaction or otherwise obtain financing. More information can be found on the Company's web site at [www.adventrx.com](http://www.adventrx.com).

Forward Looking Statements

ADVENTRX cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements that involve risks and assumptions that, if they materialize or do not prove to be accurate, could cause ADVENTRX's results to differ materially from historical results or those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that ADVENTRX will be unable to consummate a strategic transaction on a timeline it believes is acceptable, divests its assets on best-available terms and entirely winds-down its operations; the risk that ADVENTRX will be unable to consummate a strategic or partnering transaction or otherwise raise sufficient capital and will be unable to continue as a going concern, including as a result of negative perceptions of the data from its bioequivalence study of ANX-514; the risk that ADVENTRX's recent cost-containment measures, including the discontinuation of substantially all of its development activities and fundamental business operations and reduction in force to a small, select number of full-time employees, will negatively impact ADVENTRX's ability to consummate a strategic transaction; the potential for regulatory authorities to require additional preclinical and/or clinical activities to support regulatory filings, including prior to the submission or the approval of an NDA for ANX-514, and the impact of increased uncertainty regarding the need for such activities on strategic, partnering and capital-raising transactions; the risk that the performance of third parties on whom ADVENTRX relies to conduct its studies or evaluate the data, including clinical investigators, expert data monitoring committees, contract laboratories and contract research organizations, may be substandard, or they may fail to perform as expected; difficulties or delays in obtaining regulatory approval for ANX-514, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-514 and other challenges by patent holders during the Section 505(b)(2) process; the risk that ADVENTRX's stockholders will not approve a strategic or capital-raising transaction recommended by ADVENTRX's Board of Directors; and other risks and uncertainties more fully described in ADVENTRX's press releases and periodic filings with the Securities and Exchange Commission. ADVENTRX's public filings with the Securities and Exchange Commission are available at <http://www.sec.gov>.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date when made. ADVENTRX does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date on which it was made.

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