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## **Pinney Associates, Inc., and Lifetree Clinical Research Announce a Collaboration to Provide Human Abuse Liability Testing**

Bethesda, MD, and Salt Lake City, UT, March 1, 2011 – Pinney Associates, Inc., science and public health policy consultants with unique expertise in drugs that act on the central nervous system (CNS), and Lifetree Clinical Research, a specialized clinical research organization, focusing on the design, conduct, and interpretation of human abuse liability (HAL) clinical programs, today announced a collaboration to provide the pharmaceutical industry with one-stop comprehensive clinical, regulatory, and post-marketing services for CNS drugs.

This unmatched collaboration will provide pharmaceutical sponsors with access to a broad range of human abuse liability assessment services, including:

- Study design
- Conduct of the study
- Data analysis and interpretation
- Regulatory filings including abuse liability and risk management assessment, data analysis relevant to abuse and scheduling recommendation required under the Controlled Substances Act and the Risk Evaluation and Mitigation Strategy (REMS).

“Human abuse liability testing addresses the FDA requirement to include studies relevant to abuse for CNS-acting drugs. It is a vital component in the development of any CNS drug.” said Jack E. Henningfield, Ph.D., vice president of research and health policy of Pinney Associates. “This research enables companies to make informed decisions about drug development, regulatory submissions, post-marketing activities and risk management. Conducting abuse liability assessments in the early phases of development helps to avoid delays in approval due to requests for additional studies or ongoing discussions about scheduling.”

“Our clinical research staff delivers quality GCP-standard clinical trials necessary for regulatory submissions of CNS drugs,” said Lynn R. Webster, M.D., chief medical director at Lifetree. “We understand the problems in evaluating abuse liability and provide solutions. Timely assessments conducted as early as Phase 1 may yield important information useful for clinical trials designs.”

“Our collaboration with Lifetree unites unrivalled skill and expertise from international leaders in human abuse liability assessment, drug scheduling, and risk management,” said John Pinney, company president of Pinney Associates. “For sponsors, integration of these services enables them to secure product approvals, obtain the appropriate labeling and scheduling, and develop comprehensive risk management that will be reassuring to regulators and facilitate commercial goals.”

“Through this partnership, our high standards for the design, conduct and interpretation of clinical studies will be further strengthened through the advancements, validation and application of human abuse liability assessment,” commented Alice A. Jackson, R.N., president and co-founder of Lifetree Clinical Research. “We are pleased to offer pharmaceutical companies a single source for all their human abuse liability testing needs, including study design, implementation, data analysis, and regulatory strategy.”

“The collaboration with Pinney Associates builds upon a legacy of scientific advancement as pharmaceutical sponsors seek highly specialized services for their emerging human abuse liability needs,” commented Jeffrey Kinell, chief executive officer of CRI which recently acquired Lifetree Clinical Research. “Lifetree’s deep experience in Human Abuse Liability testing combined with CRI’s widely recognized capabilities in the CNS area bring industry leading resources to this collaboration.”

The relationship between Pinney Associates and Lifetree comes at a critical time for companies faced with increasing activity by the FDA on issues that can be addressed through risk mitigation and management efforts, including the interactions between drug ingredients and formulations, and human behavior.

About Pinney Associates, Inc.

**Pinney** Associates’ teams of scientists, public health professionals, and health policy experts help companies get new drugs approved, obtain the appropriate controlled substance scheduling from the Drug Enforcement Administration, and secure switches from prescription to over the counter status. We do this by advising on abuse liability assessments for central nervous system acting drugs, developing required documents for New Drug Application submissions and risk management, and preparing companies for meetings with the Food and Drug Administration and its Advisory Committees. For more detailed information about Pinney Associates, please visit [www.pinneyassociates.com](http://www.pinneyassociates.com).

About Lifetree Clinical Research®

Lifetree Clinical Research® offers multi-therapeutic clinical trials management (CTM) and site expertise in phase I-III clinical trials, with a unique approach to phase I, abuse liability, central nervous system and analgesia. Lifetree Clinical Research® is strategically integrated with Lifetree Pain Clinic in a seamless 25,000-square-foot, 60-bed facility and offers advanced expertise in first-in-human/MTD, bioavailability and bioequivalence, PK/PD/proof of concept, innovative pain model development and Cerebral Spinal Fluid sampling. Site services include PET Scanning, MRS and FMRI Capabilities and on-site pharmacy capable of handling all scheduled drugs I – V. For more detailed information about Lifetree Clinical Research®, please visit [www.lifetreereseach.com](http://www.lifetreereseach.com).

About CRI Worldwide, LLC

CRI Worldwide is a leader in clinical research with specific expertise in Psychiatry, Pediatrics, Pain, and Neurology. CRI specializes in assisting sponsors in the most complex of clinical trials by providing the highest quality services for patients and timely results to sponsors. Operating from facilities in Philadelphia and Mount Laurel, N.J., CRI conducts inpatient and outpatient clinical research trials in patients and in healthy volunteers. The CRI Phase 1 Units are located inside fully accredited medical and psychiatric hospitals. This unique hospital setting ensures the utmost care in patient safety. CRI works with sponsors to assist them in the design and successful execution of drug development plans that expedite the successful transition to Phase II proof of concept. For additional information about CRI, visit the company’s website at [www.criww.com](http://www.criww.com).

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