Liquidia Technologies Announces Positive Phase 1 Data for LIQ865, Sustained-Delivery PRINT® Formulation of Bupivacaine for Post-Surgical Pain Relief

May 24, 2017

Liquidia Technologies, Inc., today announced initial data from its LIQ865 internal clinical development program, which is a PRINT® formulation for the sustained-delivery of free base bupivacaine for post-surgical pain relief. The phase 1 trial, marking the first evaluation of LIQ865 in humans, was a randomized, controlled, double-blind study evaluating the safety, pharmacokinetic profile and pharmacodynamic response of a single-ascending dose in healthy adult males. Topline data indicate that LIQ865 doses were well tolerated and the pharmacodynamic response was consistent with a local anesthetic effect lasting for three or more days.

> "According to the National Institute on Drug Abuse, a component of the National Institutes of Health, 2.1 million people in the United States suffer from substance use disorders related to prescription opioid pain relievers, many of whom began taking opioids as post-surgical patients," said Mike Royal, M.D., LIQ865 Program Leader and Senior Vice President, Clinical Development at Liquidia. "Our intent with LIQ865 is to increase the options for long-lasting, safe, effective post-operative pain relief that can reduce the need for opioids in the early days following surgery."

Liquidia is developing LIQ865 with the goal of providing at least three days of post-surgical pain relief with a single administration, potentially minimizing or avoiding the need for opioid analgesics. There are over 80 million inpatient and outpatient surgeries performed every year, with the majority of surgeries requiring opioids to treat moderate to severe post-operative pain.[i,ii] A minority of these individuals will become long-term users and have the potential for opioid misuse and addiction.[iii], [iv]

"The phase 1 clinical trial results for LIQ865 further validate the remarkably broad applicability of the PRINT technology across virtually any therapeutic area," said Neal Fowler, Chief Executive Officer at Liquidia. "We look forward to providing additional updates on our PRINT technology-enabled clinical programs throughout 2017."

ABOUT THE PHASE 1 TRIAL

This phase 1 randomized, controlled, double-blind study evaluated the safety and pharmacokinetics/ pharmacodynamics of single ascending doses of LIQ865 injection in 28 healthy adult male volunteers. This was a single site study conducted in Copenhagen, Denmark under a Clinical Trial Authorisation and Independent Ethics Committee approval. Each trial participant received active drug in the medial aspect of one calf and control in the other calf.

ABOUT LIQUIDIA TECHNOLOGIES

Liquidia Technologies is a biopharmaceutical company that has pioneered a simple, elegant solution to improve the performance of medicines by precisely engineering drug particles. Through its proprietary PRINT technology, Liquidia has become the only company in the world that can improve the efficacy, safety, or route of administration, of nearly any therapeutic molecule by designing drug particles in a virtually unlimited number of compositions, sizes, or shapes. Combining aspects of biology and medicinal chemistry with polymer science, PRINT technology represents an entirely novel approach to drug development and production, yet one that is also GMP capable, fully-scalable, and highly cost-effective. PRINT® technology-optimized product candidates are in clinical development in inhaled diseases, post-operative pain management and ophthalmology. In addition to advancing product candidates from its own pipeline, Liquidia actively partners with world-class collaborators, including GlaxoSmithKline, to expand the applications for PRINT technology. Liquidia is based in Research Triangle Park, North Carolina. More information is available at www.liquidia.com.

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i Hall, M.J., Schwartzman, A., Zhang, J. & Liu, X. Ambulatory Surgery Data from Hospitals and Ambulatory Surgery Centers: United States, 2010. *National Health Statistics Reports.* February 28, 2017; Number 102.

ii Number, Rate, and Standard Error of All-listed Surgical and Nonsurgical Procedures for Discharges from Short-stay Hospitals, by Selected Procedure Categories: United States, 2010, available at: https://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberrate.pdf (last accessed May 22, 2017).

iii Alam, A., Gomes, T., & Zheng, H. Long-term Analgesic Use After Low-risk Surgery: A Retrospective Cohort Study. *Arch Intern Med*. 2012;172:425-430.

iv Volkow ND. America's Addiction to Opioids; Heroin and Prescription Drug Abuse; presented to the Senate Caucus on International Narcotics Control, National Institute on Drug Abuse, available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (last accessed November 14, 2016).