USPTO Grants Priority Motion To Lipocine And Enters Judgment Against Clarus

SALT LAKE CITY, Jan. 14, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced that the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO") granted Lipocine's Priority Motion in the interference case, Patent Interference No. 106,045, between Clarus Therapeutics, Inc. ("Clarus") U.S. Patent No. 8,828,428 (the "Clarus '428 Patent") and Lipocine Inc. ("Lipocine"), U.S. Patent Application No. 14/713,692 (the "Lipocine '692 Application"), and entered adverse judgment against Clarus. The PTAB ruling cancels all claims of the Clarus '428 patent.

"We are pleased with the judgment ordered by the PTAB which validates the strength of Lipocine's patent portfolio," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine.

About Lipocine

Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in men's and women's health using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes four development programs TLANDO, LPCN 1144, LPCN 1111 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO received a Complete Response Letter from the FDA on May 8, 2018. LPCN 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of non-alcoholic steatohepatitis ("NASH") and is currently being studied in a proof-of-concept MRI PDFF based liver fat imaging clinical study. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in Phase 2 testing. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been completed. For more information, please visit www.lipocine.com

Forward-Looking Statements

This release contains "forward looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding Lipocine's options to enforce and defend our intellectual property, Lipocine's product candidates and related clinical trials and the FDA review process relating to its product candidates, the timing of completion of clinical trials including the definitive phlebotomy study and the ABPM study for TLANDO as well as ongoing LPCN 1144 clinical trials, the path to approvability by the FDA of Lipocine's development programs, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, risks related to our ability to enforce and defend our intellectual property, the risks that the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

SOURCE Lipocine Inc.

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