Lipocine Streamlines Its Infringement Lawsuit Against Clarus Therapeutics

SALT LAKE CITY, Feb. 11, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company, announced today that in an effort to streamline the issues and associated costs for dispute in its infringement lawsuit against Clarus Therapeutics, Inc. ("Clarus") in the United States District Court ("Delaware") related to the infringement of six Lipocine U.S. Patents by Clarus's JATENZO® product, Lipocine has voluntarily dismissed its allegations of patent infringement for expired U.S. Patent Nos. 6,569,463 and 6,923,988. Lipocine continues to vigorously defend its patent rights and maintains its allegations for patent infringement of four U.S. patents – U.S. patent nos. 9,034,858; 9,205,057; 9,480,690; and 9,757,390 – by Clarus's JATENZO® product, which has yet to launch.

About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes TLANDO, LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 and LPCN 1107 development programs. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men and received a Complete Response Letter from the U.S. Food and Drug Administration on November 8, 2019. LPCN 1144, a differentiated oral product of bioidentical testosterone, is currently undergoing Phase 2 clinical testing in biopsy confirmed NASH patients and recently completed a proof-of-concept clinical study demonstrating the potential utility the in treatment of NASH. TLANDO XR (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 has completed Phase 2 testing. LPCN 1148 is a unique oral testosterone product targeted to treat NASH cirrhosis. 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 product candidates and related clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, our product development efforts and future discussions and actions with the FDA related to TLANDO. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, 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, risk related to on-going litigation 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.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 994-7383, mb@lipocine.com or Investors: Hans Vitzhum, Phone: (617) 430-7578, hans@lifesciadvisors.com

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