

Lipocine Announces USPTO Declaration Of Interference Between Lipocine And Clarus Patent Applications

SALT LAKE CITY, Jan. 14, 2021 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO") declared Interference No. 106,128 between Lipocine, Inc. ("the Senior Party") owned U.S. Patent Application and Clarus Therapeutics, Inc. ("the Junior Party") owned U.S. Patent Application. In preparation for the Interference, the USPTO withdrew the Clarus Application from issue.

This follows the pattern of previous Interferences as shown below:

- Interference No. 106,045 decided in Lipocine's favor and resulted in the cancellation of Clarus patent 8,828,428.
- Interference No. 106,120 decided in Lipocine's favor and resulted in the cancellation of Clarus application 15/723,976.

"We are pleased with the actions and judgements 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 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 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, 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. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of 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. For more information. 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, the timing of processes related to intellectual property, and the timing of ongoing litigation. 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, 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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