Lipocine Announces Issuance of US Patent 9,480,690

SALT LAKE CITY, Nov. 07, 2016 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today reported the United States Patent and Trademark Office ("USPTO") issued U.S. Patent number 9,480,690, entitled "High-Strength Testosterone Undecanoate Compositions" on November 1, 2016. The claims in the issued patent relate to dosing regimens associated with the oral administration of Testosterone Undecanoate ("TU") compositions. Bio-reversible TU is the key component in LPCN 1021.

"We are pleased with the patent issuance pertaining to dosing regimens associated with oral product candidates containing TU. We believe this additional patent strengthens our strong existing and pending intellectual property portfolio," said Dr. Mahesh Patel, President and CEO of Lipocine Inc.

About LPCN 1021

LPCN 1021 is a novel twice-a-day oral Testosterone Replacement Therapy product candidate containing Testosterone Undecanoate that is designed to help restore normal testosterone levels in hypogonadal men. Lipocine expects LPCN 1021 will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. Per the IMS Health database, an average of 540,000 prescriptions a month have been dispensed so far in 2016 for testosterone products.

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 three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a twice-daily oral testosterone replacement therapy product candidate, was well tolerated and met the primary efficacy endpoint in Phase 3 testing, which utilized 24-hour pharmacokinetic data for dose adjustments. LPCN 1111, a novel prodrug of testosterone, originated with 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, the potentially first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth, has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA was recently 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 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, the risks that the FDA will not approve LPCN 1021 or any of our other products, risks related to our products, expected product benefits, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the receipt of a CRL from the FDA for LPCN 1021, the receipt of regulatory approvals, the results and timing of clinical trials, including the additional clinical trial for LPCN 1021, 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.

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