Lipocine Presents LPCN 2401 Clinical Data at ObesityWeek®

SALT LAKE CITY, Nov. 4, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery, today announced the presentation of a poster **Treatment with Oral LPCN 2401, a Physiological Regulator of Myostatin, Rapidly Improves Body Composition in Men with Obesity** at the ObesityWeek® annual meeting, taking place in Atlanta, Ga., November 4 to 7. The poster features 20-week data from the previously completed Phase 2 trial and highlights the rapid improvement in body composition in participants with obesity taking LPCN 2401. Data from the study also showed LPCN 2401 improves liver health, as measured by reduction in liver fat content and liver injury markers, in an overweight and obese liver compromised population.

In this Phase 2 trial, men with BMI ≥27 kg/m^2 with metabolic dysfunction associated steatohepatitis were randomized (1:1:1) to one of three treatments:1) LPCN 2401, 2) LPCN 2401 plus vitamin E or 3) placebo, for 36 weeks (NCT04134091). Endpoints included percent change from baseline in lean mass (LM), fat mass (FM), and FM/LM ratio. Other parameters associated with metabolic disorder were also measured.

Key findings:

- As previously disclosed, LPCN 2401 and LPCN 2401+E were shown to increase lean mass, and reduce fat mass and fat to lean mass ratio, at 20 weeks and 36 weeks compared to placebo.
- Treatment with LPCN 2401 and LPCN 2401+E resulted in rapid beneficial effects on liver health (reductions observed in alanine transaminase and aspartate transaminase) starting between 4 and 8 weeks.
- Evaluation of hepatic fat fraction by magnetic resonance imaging (MRI-PDFF) demonstrated significant reductions in liver fat content following 12 weeks of LPCN 2401 and LPCN 2401+E treatment compared to placebo, and this was maintained through week 36.
- LPCN 2401 was well tolerated, with no concerning safety signals observed through 72 weeks of exposure.

About LPCN 2401

LPCN 2401 is an oral formulation comprised of a proprietary anabolic androgen receptor agonist targeted for once daily regimen. Data from preclinical and clinical studies support the potential of LPCN 2401 in preserving lean mass while reducing fat mass (preferentially VAT and android fat) and beneficial liver and bone health effects. As adjunct therapy to incretin mimetics, LPCN 2401 has potential to amplify GLP-1 action, ameliorate loss of muscle mass, improve muscle quality and functionality, and amplify fat mass loss with improved body composition, with no overlapping GI side effects. Moreover, post incretin mimetic discontinuation, LPCN 2401 has potential to attenuate weight gain, prevent "fat overshoot," and accelerate lean mass rebound.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnerships. Our drug candidates represent enablement of differentiated, patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine's clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy, LPCN 2203 an oral candidate targeted for the management of essential tremor, LPCN 2401 an oral proprietary anabolic androgen receptor agonist, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in obesity management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 2401 for obesity management, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of metabolic dysfunction-associated steatohepatitis (MASH). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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 our product candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 2401, and the potential Phase 2 proof-of-concept study for LPCN 2401, potential partnering of our product candidates with third parties, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in

developing product candidates, we may not have sufficient capital to complete the development processes for our product candidates or we may decide to allocate our available capital to other product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our assets, clinical and other studies may not be successful or may not provide results that would support the submission of an NDA, the FDA may 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 for our product candidates, 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.

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