



Lithera

CONTACT: Kenneth W. Locke, Ph.D.
Chief Scientific Officer
Lithera, Inc.
9191 Towne Centre Drive
San Diego, CA 92122
Phone: 858-750-1008
E-mail: klocke@lithera.com

FOR IMMEDIATE RELEASE

**Lithera Reports Positive Clinical Study Results from a Phase IIb Trial
for LIPO-102, a Novel Treatment for Localized Fat Reduction**

SAN DIEGO, Calif. – November 3, 2010 – Lithera, Inc. today announced positive results from a Phase IIb clinical study of LIPO-102, its novel injectable combination of salmeterol xinafoate (SX) and fluticasone propionate (FP) for selective, non-ablative [fat reduction](#).

“LIPO-102 appears to be a well-tolerated, simple and rapid therapy that produces substantial reductions in abdominal fat,” said Mitchel Goldman, M.D., Volunteer Clinical Professor of Dermatology/Medicine University of California, San Diego and the founder and Medical Director of Goldman Butterwick & Associates, Cosmetic Laser Dermatology (San Diego, CA). “For patients interested in a non-surgical option for abdominal fat reduction, LIPO-102 may represent a breakthrough.”

“The simple injectable procedure used in this study was virtually painless and administered in less than 5 minutes,” said John Dobak, M.D., Chief Executive Officer of Lithera. “There was also no recovery period after receiving injections, and therefore, patients were able to resume their normal activities almost immediately.”

LIPO-102 was well-tolerated when administered weekly for 8 weeks into the subcutaneous abdominal fat of healthy subjects and produced dose- and time-related reductions in mean abdominal volume and circumference. The optimal dose of LIPO-102 (0.4 µg SX + 20 µg FP) produced a significant mean reduction in abdominal volume of -268 cc (versus -124 cc for placebo; $p < 0.05$), a significant mean reduction in circumference of approximately -1.5 cm at multiple levels across the abdomen (versus approximately -0.63 cm for placebo; $p < 0.05$) and a cumulative mean reduction in circumference of -10.98 cm (versus -4.39 cm for placebo; $p < 0.05$). Approximately one quarter of the subjects in this treatment group had reductions in abdominal volume greater than 500 cc and mean reductions in circumference of approximately -3.0 cm or greater at multiple levels across the abdomen. The onset of LIPO-102 was rapid with approximately 2/3 of the reduction in abdominal volume observed within 4 weeks. The objective LIPO-102-induced reductions in circumference and volume determined by 3-D photographic imaging were mirrored by significant ($p < 0.05$) patient-reported improvements in the subjective Patient Photonumeric Scale (PPnS) and Patient Global Impression of Change (PGIC) outcome measures. A positive trend was also noted in the patient-reported Abdominal Subcutaneous Adiposity Questionnaire (ASAQ). The safety profile was extremely favorable and not significantly different from placebo.

“This data is exciting because the reductions in abdominal volume with LIPO-102 were comparable to those we target with limited volume liposuction,” said Steven Cohen, M.D., F.A.C.S., Chief of Craniofacial Surgery and Surgical Director of the Craniofacial Center at Children’s Hospital of San Diego and founder of FACESplus™ (San Diego, CA).

One hundred and sixty-four healthy adult, male and female patients with unwanted abdominal adiposity and a body mass index (BMI) less than or equal to 25 kg/m² were enrolled in this double-blind, placebo-controlled study. Subjects were randomized to receive injections of placebo or one of three different doses of LIPO-102 into their anterior abdomen and flanks once weekly for 8 weeks. Safety and efficacy were evaluated weekly for 8 weeks. Abdominal circumference and volume were measured as

a change from baseline using a 3-D photographic imaging system and subjective measures of patient satisfaction were measured using the PPnS, PGIC and ASAQ.

About [LIPO-102](#)

LIPO-102 is being developed as a first-in-class injectable drug product designed to produce local, selective fat tissue reduction ([pharmaceutical lipoplasty](#)). Using FDA-registered drugs approved for use in other indications, LIPO-102 targets and stimulates natural fat tissue metabolism to achieve non-ablative, non-surgical fat tissue reduction in specific locations. LIPO-102 is currently under development for the treatment of symptomatic exophthalmos (protrusion of the eye from the orbit) associated with thyroid-related eye disease (the thyroid condition is also known as [Graves' Disease](#)) and the reduction of abdominal adiposity.

About [Lithera](#)

Lithera is a clinical stage company developing pharmaceutical and biomedical products addressing both medical and lifestyle indications in ophthalmology and aesthetic medicine. Our lead product candidate (LIPO-102) is a novel injectable pharmaceutical product designed to produce local, selective fat tissue reduction (pharmaceutical lipoplasty). Founded in 2007, the Company has assembled an exceptional team of senior executives, employees and advisors and has been financed by top-tier venture capital firms. For more information on Lithera, Inc., please visit www.lithera.com.

Lithera, LIPO-102 and the Lithera logo are trademarks or registered trademarks of Lithera, Inc. Other names and brands may be claimed as the property of others.