Phase 2 Study for the Treatment of Superficial Lipomas

ClinicalTrials.gov Identifier: NCT00608842

Recruitment Status : Completed
First Posted : February 6, 2008
Results First Posted : January 14, 2016
Last Update Posted : January 14, 2016

Sponsor:
Kythera Biopharmaceuticals

Information provided by (Responsible Party):
Kythera Biopharmaceuticals

Tracking Information	
First Submitted Date ICMJE	January 23, 2008
First Posted Date ICMJE	February 6, 2008
Results First Submitted Date ICMJE	December 8, 2015
Results First Posted Date ICMJE	January 14, 2016
Last Update Posted Date	January 14, 2016
Study Start Date ICMJE	November 2007

Actual Primary Completion Date	August 2008 (Final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: December 8, 2015)**	• Number of Participants With Adverse Events (AEs) [Time Frame: Up to 24 weeks] Severity of AEs was determined using the following scale: Mild: The participant was aware of a sign or symptom, but it was easily tolerated; Moderate: Discomfort or interference with usual activity; Severe: Incapacitating, with inability to engage in usual activity. The investigator determined the relationship of each AE to the administration of study material by answering the question: "Was there a reasonable possibility that the event may have been caused by treatment with study material?" A serious AE was an event that constituted a significant medical hazard or side effect, regardless of the investigator's or sponsor's opinion regarding relatedness to study material. Serious AEs included any event that was fatal or life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect or other significant medical hazard. • Number of Participants With Newly Occurring or Worsening Biochemistry/Hematology/Urinalysis Abnormalities [Time Frame: 24 weeks] An abnormality is defined as a value outside the limits of the expanded normal range/notable range. • Number of Participants With Clinically Significant Changes in Vital Signs or Weight [Time Frame: Up to 24 weeks] • Number of Participants With Positive Histopathology Results at Screening [Time Frame: Screening (prior to randomization)] A needle core tissue sample biopsy was performed at screening for all treated lipomas. • Number of Participants With Positive Histopathology Results at Week 20 [Time Frame: Week 20] After the completion of all tests and procedures scheduled for week 20, participants with treated lipomas that remained palpable could have their treated lipomas excised.
Original Primary Outcome Measures ICMJE **(submitted: February 5, 2008)**	Lipoma size reduction [Time Frame: 24 Weeks]
Change History	Complete list of historical versions of study NCT00608842 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: December 8, 2015)**	• Percentage of Participants With Complete Clearance or ≥ 75% Clearance [Time Frame: Baseline and week 20 (8 weeks after last dose)] At randomization 1 to 3 lipomas were selected for treatment. Lipomas were measured in 3 dimensions (longest length, perpendicular width, and height if possible) using digital calipers. Complete clearance indicates target lipoma(s) not present or detectable, and ≥ 75% clearance is defined as a ≥ 75% reduction from baseline in the area of target lipoma(s). For participants with > 1 target lipoma, the total area of all target lipomas was used in the calculation of response.

	• Percent Change From Baseline in the Sum of the Areas of All Treated Lipomas [Time Frame: Baseline and week 12 (last treatment session), week 16 (4 weeks after last treatment), and week 20 (8 weeks after last treatment)] Percent change from baseline was calculated as the baseline total lipoma area - postbaseline total lipoma area / baseline total lipoma area * 100. A positive change indicates a reduction in size.
Original Secondary Outcome Measures ICMJE **(submitted: February 5, 2008)**	Safety: Laboratory tests, ECG, Medical Evaluations [Time Frame: 24 Weeks]
Current Other Pre-specified Outcome Measures	*Not Provided*
Original Other Pre-specified Outcome Measures	*Not Provided*

Descriptive Information

Brief Title ICMJE	Phase 2 Study for the Treatment of Superficial Lipomas
Official Title ICMJE	Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of ATX-101 (Sodium Deoxycholate for Injection) Intralipomal Injections for the Treatment of Superficial Lipomas
Brief Summary	The purpose of this research is to compare the safety and effectiveness of 3 different concentrations of deoxycholic acid for injection against a placebo in the treatment of superficial lipomas.
Detailed Description	A lipoma is a fatty lump typically located on the trunk, shoulder, arms, or legs. For the purposes of this study, only lipomas on the trunk, arms, legs, or neck were treated. (Lipomas on the face, wrists, hands, lower portion of the spine, genitals, ankles, or feet were not treated.)
Study Type ICMJE	Interventional
Study Phase ICMJE	Phase 2
Study Design ICMJE	Allocation: Randomized Intervention Model: Parallel Assignment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment
Condition ICMJE	Lipoma
Intervention ICMJE	• Drug: Deoxycholic Acid Injection Administered via intralipomal injection. Other Names: ◦ sodium deoxycholate ◦ ATX-101 • Drug: Placebo Matching vehicle placebo administered via intralipomal injection.
Study Arms ICMJE	

	• Experimental: Deoxycholic Acid 1% Participants received 1.0% deoxycholic acid administered at a volume dependent on the size of the lipoma, up to a maximum of 4.8 mL per treatment session, at 28-day intervals for up to a maximum of 4 treatments. Intervention: Drug: Deoxycholic Acid Injection • Experimental: Deoxycholic Acid 2% Participants received 2.0% deoxycholic acid administered at a volume dependent on the size of the lipoma, up to a maximum of 4.8 mL per treatment session, at 28-day intervals for up to a maximum of 4 treatments. Intervention: Drug: Deoxycholic Acid Injection • Experimental: Deoxycholic Acid 4% Participants received 4.0% deoxycholic acid administered at a volume dependent on the size of the lipoma, up to a maximum of 4.8 mL per treatment session, at 28-day intervals for up to a maximum of 4 treatments. Intervention: Drug: Deoxycholic Acid Injection • Placebo Comparator: Placebo Participants received matching vehicle placebo administered at a volume dependent on the size of the lipoma, up to a maximum of 4.8 mL per treatment session, at 28-day intervals for up to a maximum of 4 treatments. Intervention: Drug: Placebo
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Completed
Actual Enrollment ICMJE **(submitted: February 5, 2008)**	62
Original Actual Enrollment ICMJE	*Same as current*
Actual Study Completion Date ICMJE	January 2010
Actual Primary Completion Date	August 2008 (Final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • One or more lipomas, based on clinical and histological diagnosis, which are accessible for treatment and assessment, are quantifiable along at least 2 perpendicular diameters, and have the following characteristics: ◦ History of slow growth followed by dormancy, and stable for at least 6 months

	◦ Greatest length multiplied by greatest perpendicular width between 1 and 16 cm^2, inclusive ◦ Discrete, oval to rounded in shape, not hard or attached to underlying tissue ◦ Without changes in overlying skin (ie, inflammation, pain or tenderness, hyperpigmentation) ◦ Located on the trunk, arms, legs, or neck • Signed informed consent. Exclusion Criteria: • Absence of significant medical conditions that could affect safety • History of surgical or deoxycholate treatment for lipomas • Treatment with an investigational agent within 30 days before ATX-101 treatment
Sex/Gender ICMJE	Sexes Eligible for Study: All
Ages ICMJE	18 Years to 65 Years (Adult, Older Adult)
Accepts Healthy Volunteers ICMJE	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	United States
Removed Location Countries	

Administrative Information

NCT Number ICMJE	NCT00608842
Other Study ID Numbers ICMJE	ATX-101-07-05
Has Data Monitoring Committee	No
U.S. FDA-regulated Product	*Not Provided*
IPD Sharing Statement ICMJE	*Not Provided*
Responsible Party	Kythera Biopharmaceuticals
Study Sponsor ICMJE	Kythera Biopharmaceuticals
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	Study Director: Patricia S. Walker, M.D., Ph.D. Kythera Biopharmaceuticals, Inc.
PRS Account	Kythera Biopharmaceuticals
Verification Date	December 2015

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**