
TLC
Pain Management Solutions
George Yeh
President
Delivering Hope for Life

Safe Harbor Statement

This presentation contains forward-looking statements regarding future events and the future performance of Taiwan Liposome Company that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include but are not limited to statements that relate to our business and its future, our strategy, the success of our drug candidates, the safety and efficacy of our drug products, product approvals, market potential, product sales, revenue, development, regulatory and approval timelines, product launches, product acquisitions, capital resources and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact.

Risks that could cause actual results to differ include the possibility that our existing and new drug candidates may not prove safe or effective, the possibility that our existing and new drug candidates may not receive approval from regulatory agencies in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that price and other competitive pressures may make the marketing and sale of our drugs not commercially feasible, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of sustained revenue history, our limited experience in establishing strategic alliances, our limited marketing experience, our customer concentration, the possibility for fluctuations in customer orders, evolving market dynamics, our dependence on third parties for clinical trials, manufacturing, distribution, information and quality control and other risks that are described in further detail in the Company's reports filed with Taipei Exchange. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this presentation except as required by law.

TLC at a Glance

Technology

- World's first multilamellar *and* multivesicular lipid formulation (*BioSeizer*™) in OA and ophthalmology that…
  - can be easy applied to both small/large molecules
  - has both fast onset *and* sustained release capabilities up to 6 months
  - is capable of reproducible and scalable production (>400L)
  - bypasses aseptic manufacturing process » lower COGS
  - has strong intellectual property position – over 100 patents worldwide

Product Pipeline

- 4 clinical assets targeted for pivotal stages by 2019
- Library of 50+ compounds with systemized development process [1 US IND/18mo]

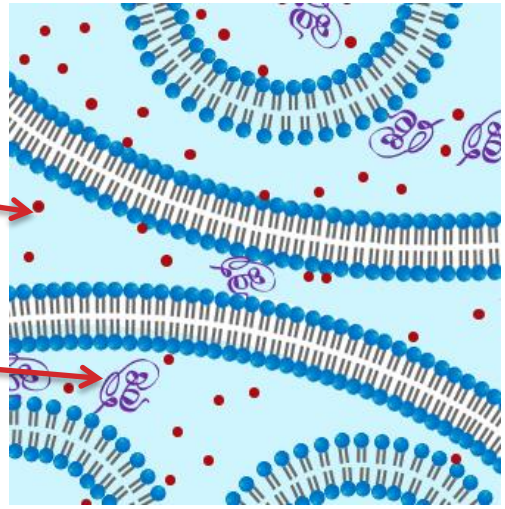
People

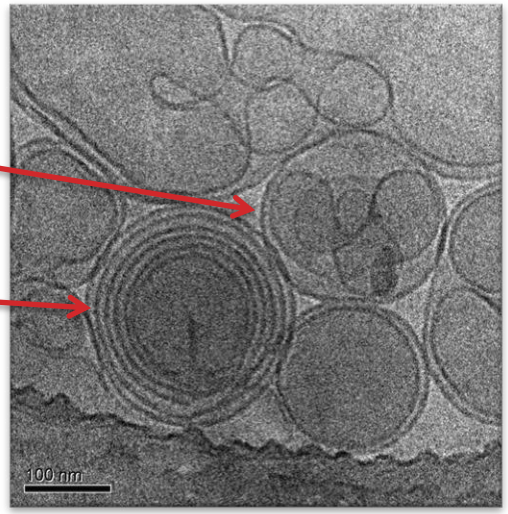
- Over 30 PhDs/MDs on staff; 150+ years of combined experience in in research, development, and manufacturing of lipid formulations
- Led by Dr. Keelung Hong, 35+ years of experience in lipids
  - UC Berkley, Stanford, UCSF Liposome Research Lab
  - Founder / Chairman of TLC (4152:TWO)
  - Founder of Hermes Bio [acquired by Merrimack(NASDAQ: MACK) – Onivyde®]
  - Scientific Advisor to Sequus [acquired by ALZA(NYSE: AZA » JNJ) – Doxil®]

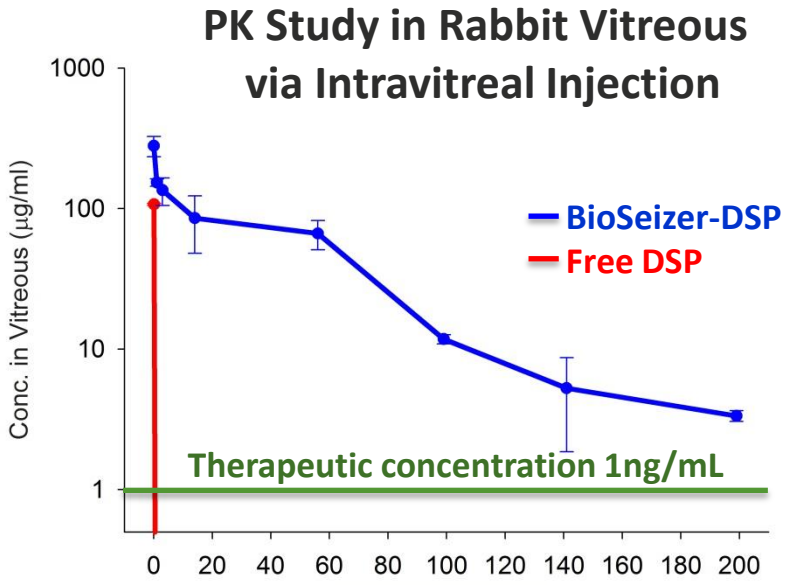
Listed on Taipei Exchange since Dec 2012 (4152:TWO)

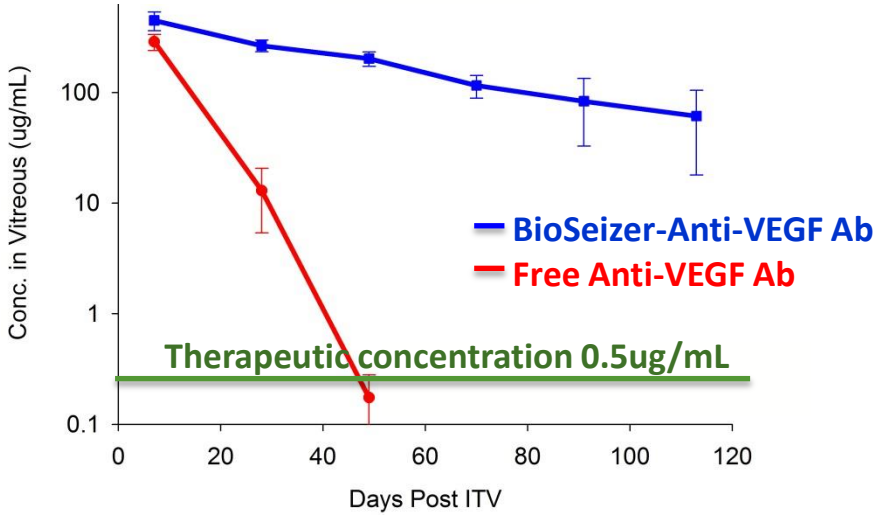
- Awarded "Top 5% in Corporate Governance Evaluation" initiated by TWSE and TPEx

BioSiezer™ Sustained Release Delivery

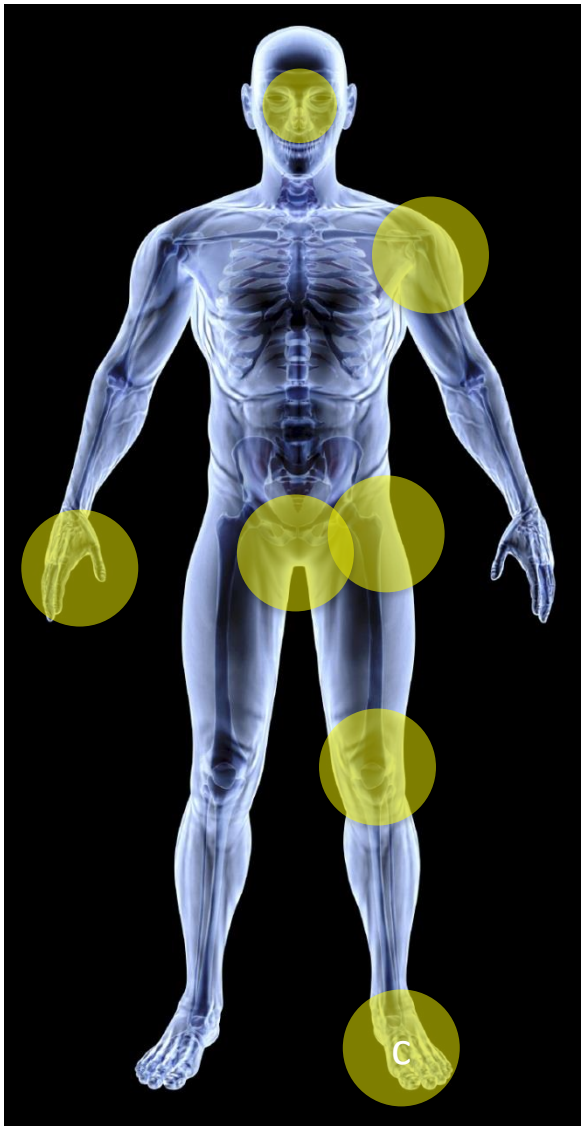








BioSiezer™ Applications



Intravitreal (eye) injection

- *Age-related macular degeneration, diabetic macular edema, retinal vein occlusion*
- Targeting 1 injection/6 months
- Phase II in progress

Intra-articular (joint) injection

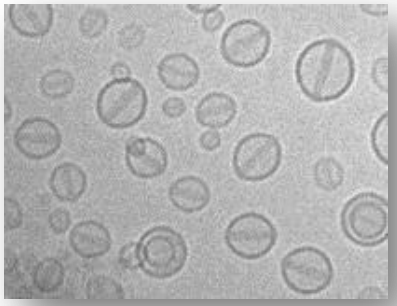
- *Osteoarthritis, rheumatoid arthritis, musculoskeletal injuries*
- Targeting 1 injection/6 months
- Phase II in progress

Local infiltration (nerve endings)

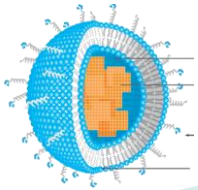
- *Bunionectomy, hemorrhoidectomy, hernia, nerve block*
- Targeting 1 injection/3 days instead of hours
- US IND in Q1 2018

Our proprietary BioSiezer™ technology can also be expanded to other tissues in the human body.

NanoX™ Targeted Delivery

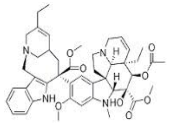


NanoX™
-80-120nm + >90% encapsulated
-Applied both small & large molecules
-No organic solvents (denture targeting moiety
-Robust, scalable, reproducible manufacturing

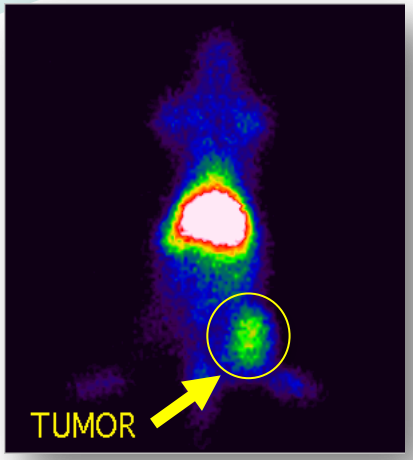


Tissue + Cellular Targeting

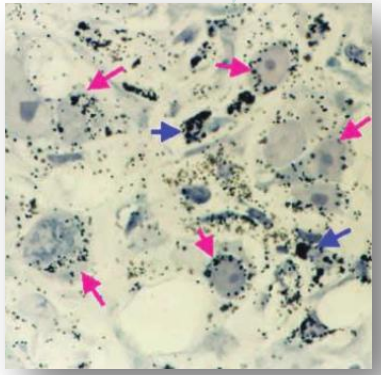
Tissue Targeting



Cytotoxic/Molecular Targeting

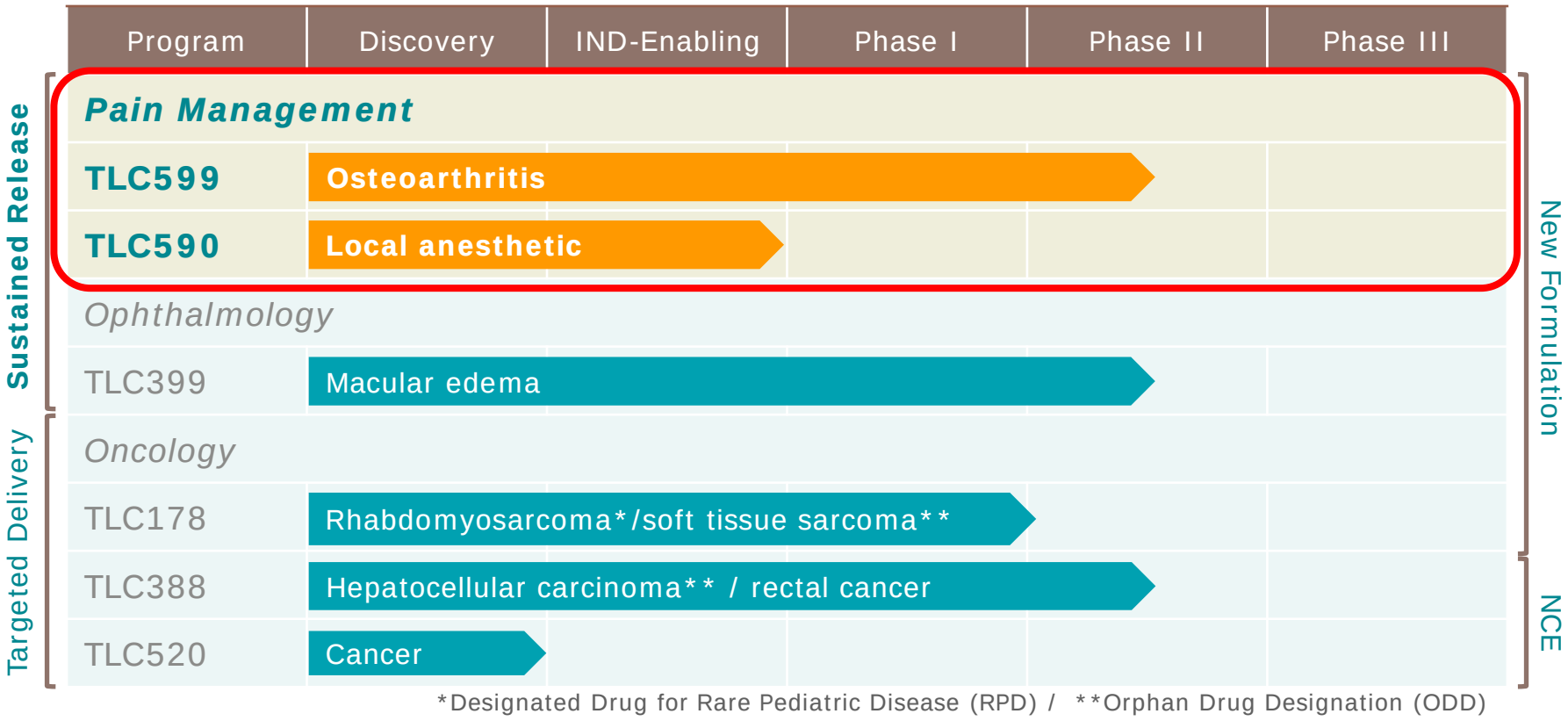


In-111-loaded NanoX™
Nanoparticles deliver drug to tumor to reduce peripheral tox



Antibody conjugated NanoX™
Her 2+ overexpressing cancer cells internalization with variable payload with > 50 molecules/antibody

TLC Pipeline



*Designated Drug for Rare Pediatric Disease (RPD) / **Orphan Drug Designation (ODD)

Approved products in Taiwan:

Ampholipad	ProFlow™	Lipo-Dox™
Systemic fungal infection	PAD, Diabetic neuropathy & ulcer	Breast & ovarian cancer

Osteoarthritis Pain Program

TLC599: BioSeizer™ Sustained Release Dexamethasone for Knee OA

Challenges in IA Treatments for OA

Current IA treatments have short retention and rapid clearance in joint: Drug delivery systems should address shortcomings of rapid clearance by increasing the drug residence time in the synovial cavity and ensuring sustained release and slow absorption of the active substance in the joint. *(Expert Opin. Drug Deliv. 2014; 11(2):269-282)*

Crystal induced synovitis: Microcrystalline aggregates, which are larger in size, induce a stronger inflammatory response. *(CCJM. 2006; 73:897-911; AJO. 2016. Mar/Apr: 108-111).*

Cartilage Cell Death: An human chondrocyte viability in vitro study was evaluated the effect of dexamethasone sodium phosphate, methylprednisolone acetate, betamethasone sodium phosphate and betamethasone acetate, and triamcinolone acetonide.*(Knee Surg Sports Traumatol Arthrosc. 2012; 20:1809–1814)*

Immediate onset is important in OA treatments: Many of the interventions we prescribe-particularly weight loss and exercise-take some time to take effect and with that patients can become discouraged.Having a product with immediate effects provides some much-needed relief from long-standing symptoms for many patients. *(Professor. David Hunter)*

Professor David Hunter

MBBS (Hons), MSc (Clin Epi), M SpMed, PhD, FRACP (Rheum)
Florance and Cope Chair of Rheumatology
Chair of Institute of Bone and Joint Research
Professor of Medicine, University of Sydney

TLC599 Target Product Profile

Product Candidate Information

- World's 1st multilamellar and multivesicular lipid formulation of dexamethasone sodium phosphate (DSP) for osteoarthritis (OA)
- Provides fast onset and sustained release of up to 6 months

Current IA Therapies for Moderate OA

- Corticosteroid injection every 1-3mo : usually only 2-3 weeks efficacy; adverse effects include chondrotoxicity
- Hyaluronic acid injection every 1-4mo : inconclusive efficacy

Regulatory Pathway

- NDA - 505(b)(2)

Developent Stage

- Phase II

TLC599 Competitive Advantages

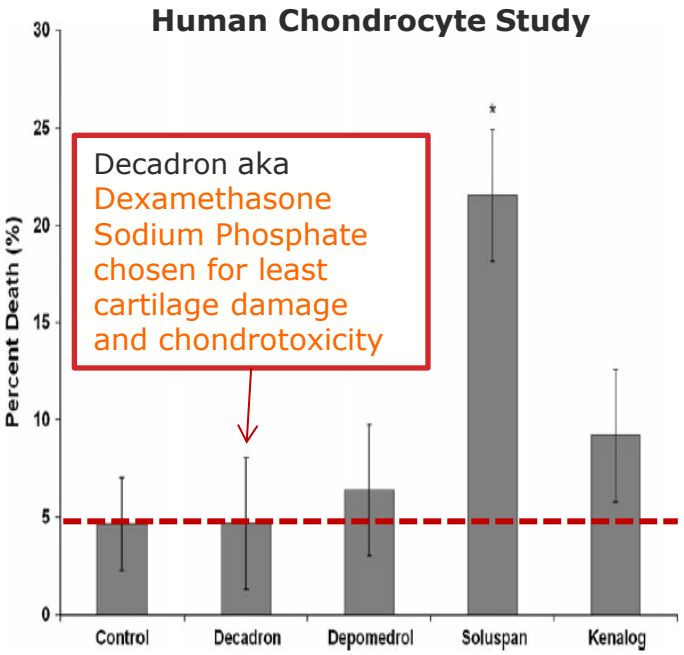
- Better efficacy – fast, immediate onset + sustained pain relief
- High drug potency – no synovial fluid aspiration prior to injection
- Less local & systemic toxicity – minimal cartilage damage & chondrotoxicity + safe cortisol levels
- Better convenience – injection made with small 30G needle and a simple single-vial product with 2-year stability
- Repeat dosing possible
- Streamlined processes to reduce manufacturing cost – lower risk of foreign particulate and bypassed aseptic process
- Worldwide patents well into 2033

TLC599 Design Rationale

Desired Effect	Rationale	TLC599 Design
Fast-acting	Immediate pain relief	Optimized % of free drug to provide immediate therapeutic effect
Long-lasting	Longer drug retention = lower dose frequency	MVV and MLV capable of trapping and controlling release of hydrophilic molecules for up to 6 months
Minimal cartilage damage	Precise choice of API	Soluble steroid with low chondrotoxicity – DSP
Avoid comorbidity	Avoid complications of systemic steroid level in diabetic patients	Retention of steroids in joint leading to low systemic penetration
Optimized particle size	Particles <0.25µm escape freely from joint cavity; particles 1-4µm are phagocytosed by synovial macrophage	Optimized particles (0.4-0.5µm) ensure no escape from joint or phagocytosis; filter filtration process » lower contamination risk » lower COGS
Broader usage for drug administration	To reduce complications such as synovitis, calcifications, or to treat smaller joints	Flexibility in needle sizes: from 21G to 30G

API Selection / Chondrotoxicity

1. In Vitro

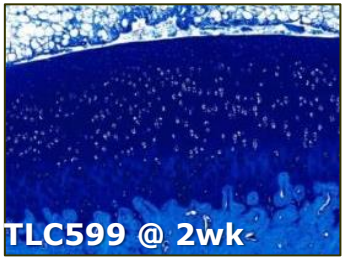


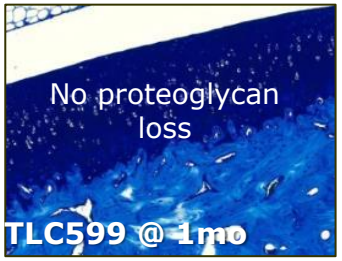
Dragoo et al. Knee Surg Sports Traumatol Arthrosc (2012) 20:1809–1814

2. In Vivo

TLC599 Repeated Doses

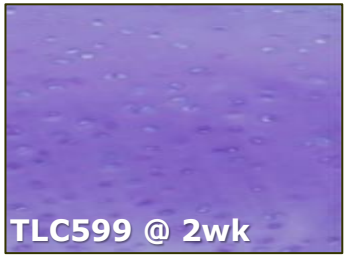
Rabbit: 1.2mg DSP (eq. to 6mg TA)





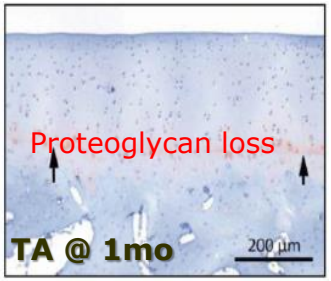
TLC599 Single Dose

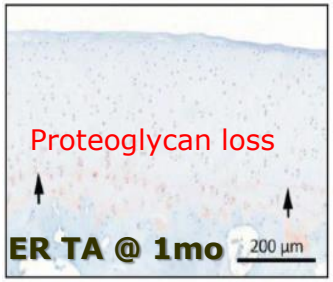
Dog: 12mg DSP (eq. to 60mg TA)



TA & ER TA Single Dose

Dog: 18.75mg TA





Toluidine Blue Stain

Safranin O Stain

3. Human

In a recent study of patients with symptomatic knee osteoarthritis, TA resulted in significantly greater cartilage volume loss.

(JAMA. 2017; 317(19): 1967-1975)

TLC5991001

A Randomized, Open-label, Parallel, Phase I/II Single-Dose Administration Trial of TLC599 in Subjects with Osteoarthritis of the Knee

Study Objectives

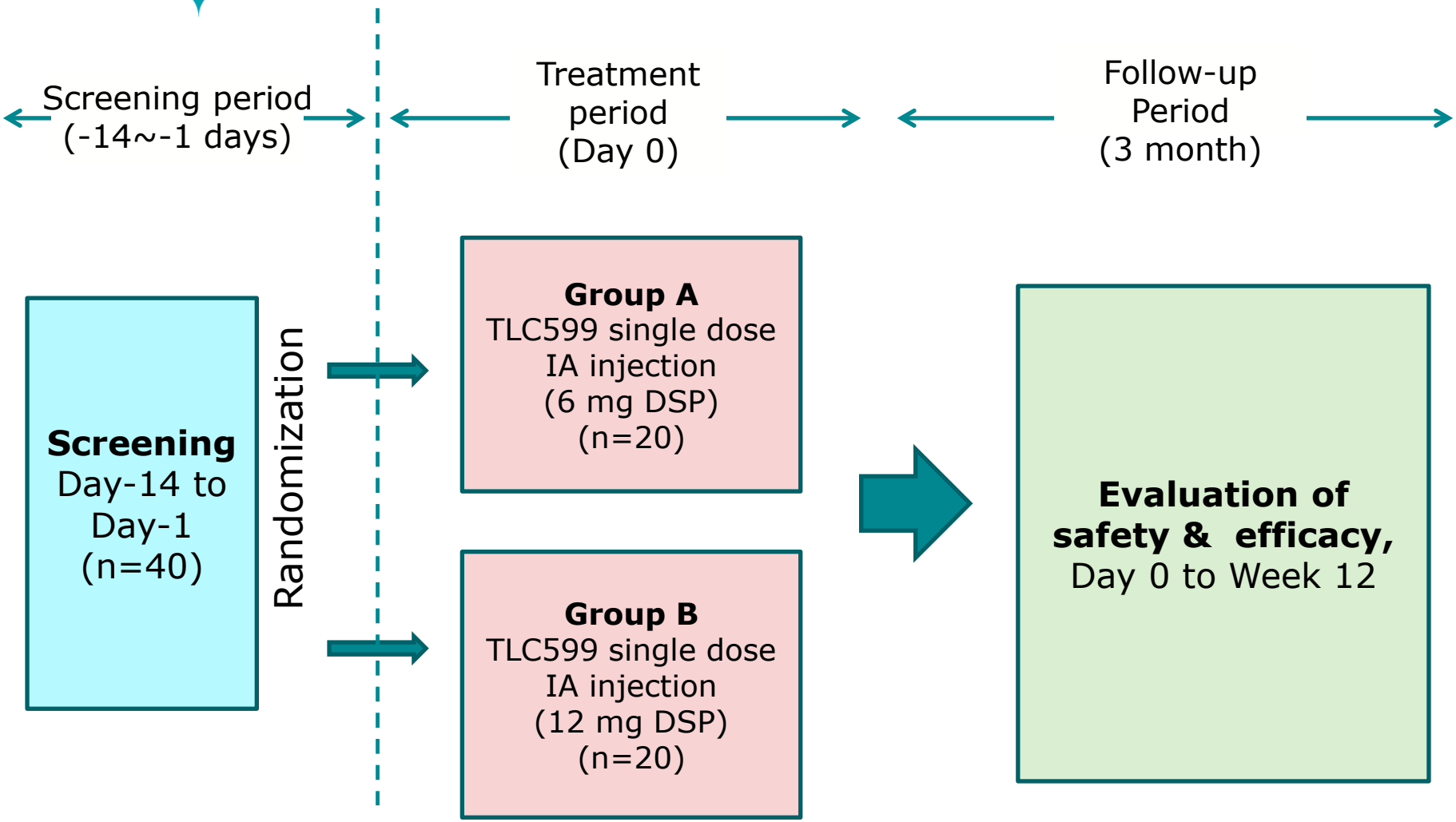
Primary objective:

- To evaluate the **safety** and **tolerability** profile of TLC599 with two dose levels of DSP lipid formulation

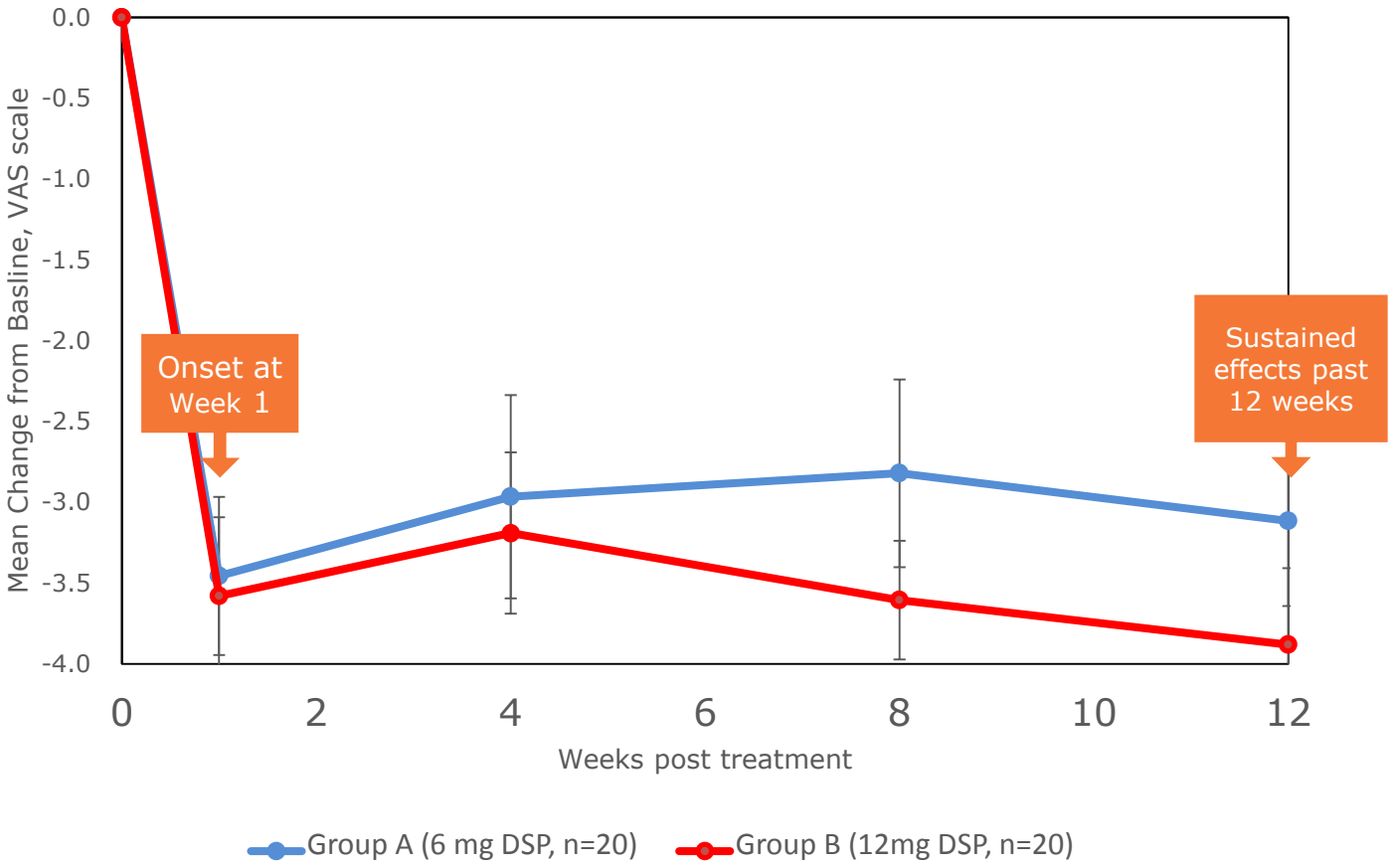
Secondary objective:

- **Efficacy** evaluation using the following:
  - **Pain score in VAS**
  - **WOMAC score**
  - IGART questionnaire
- Change from baseline, ≥30% and 50% decrease in the VAS and WOMAC
- Plasma cortisol

Study Design

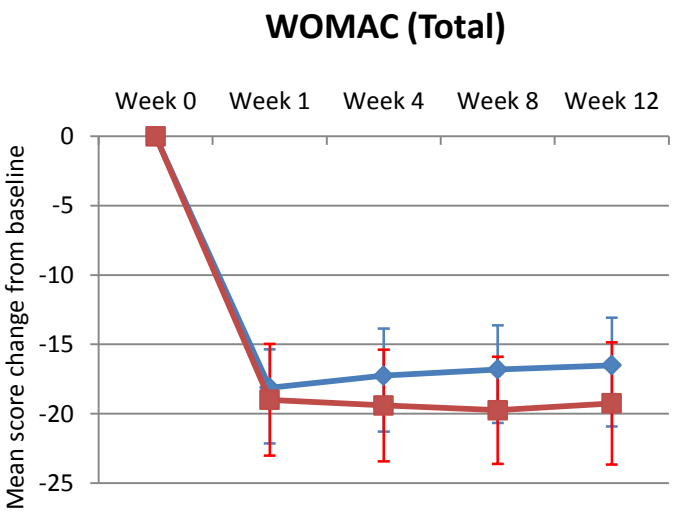


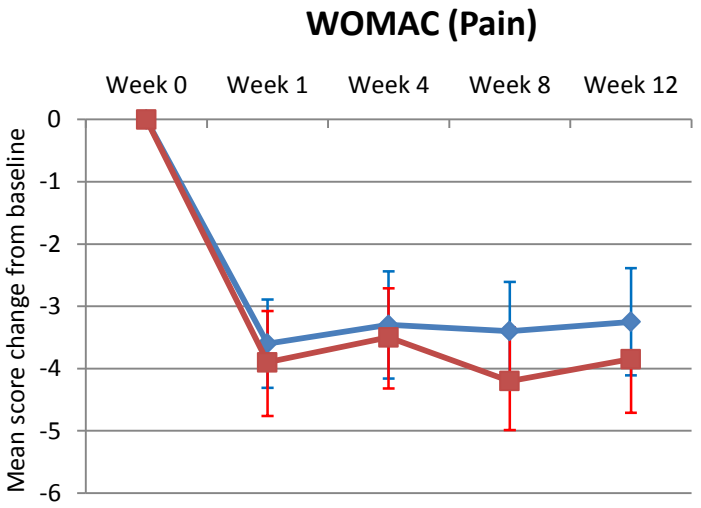
VAS Pain Score

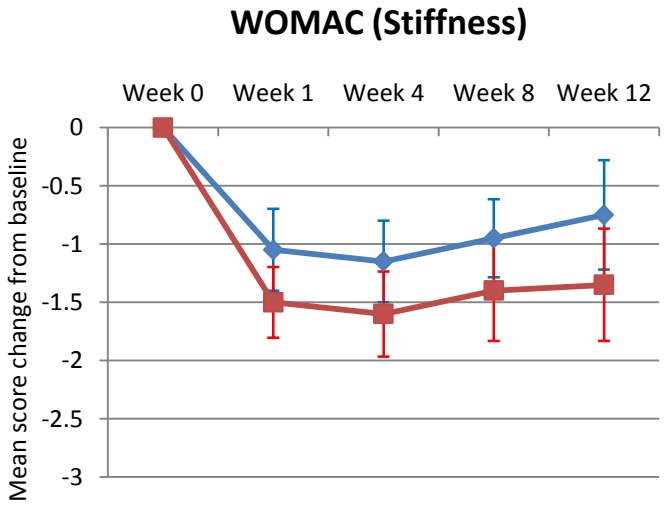


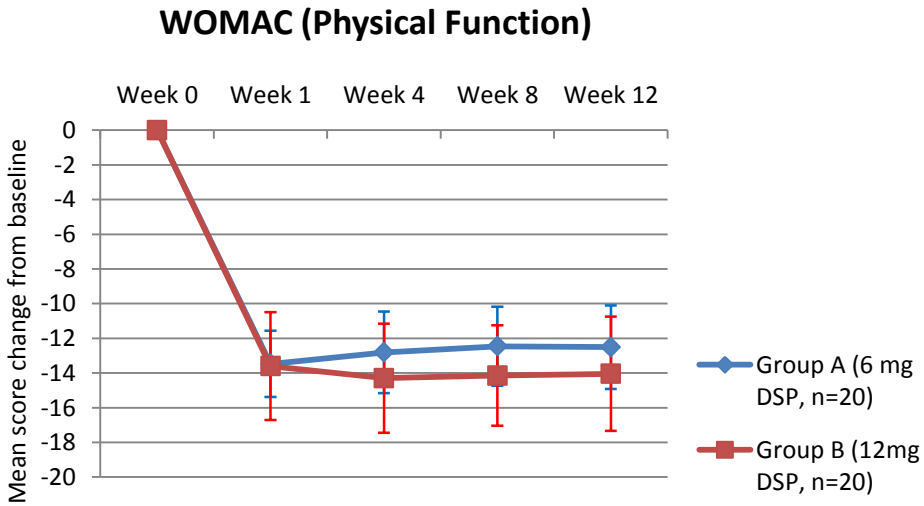
TLC599 shows faster onset and sustained release capabilities

Change in WOMAC Score from Baseline



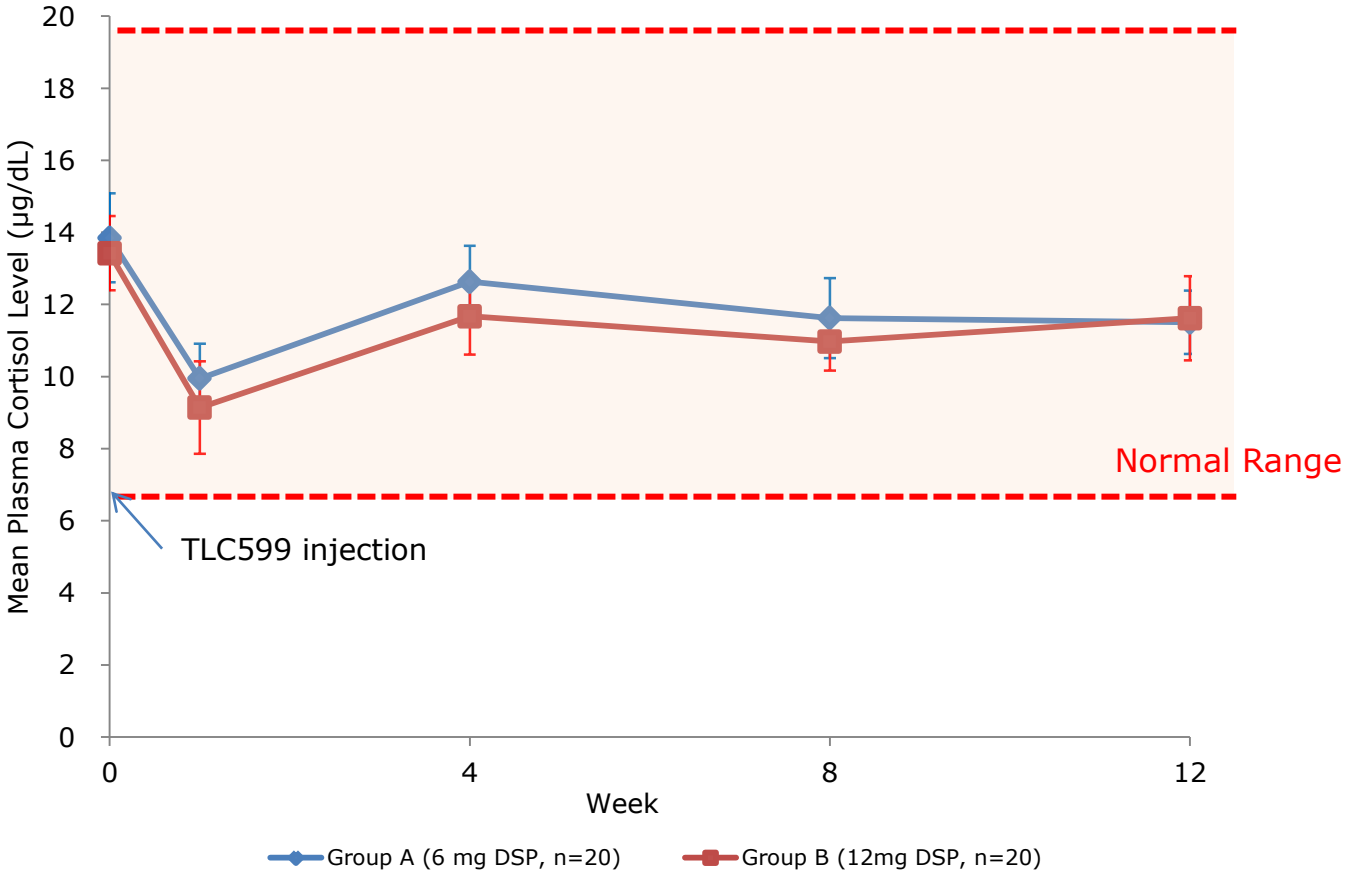






Plasma Cortisol

Cortisol is monitored due to its role in blood sugar metabolism and in the body's response to stress.

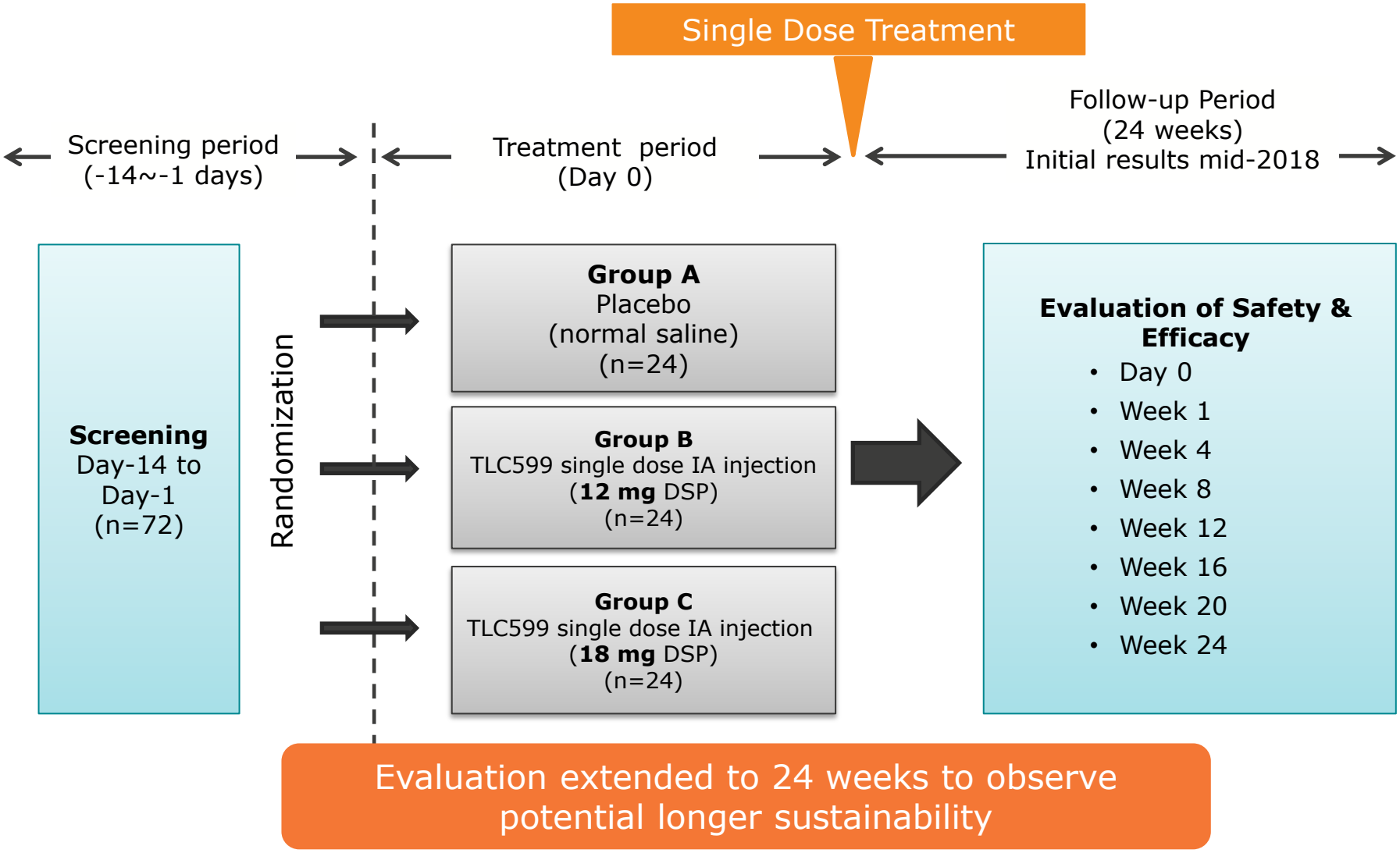


Most cortisol levels within normal range

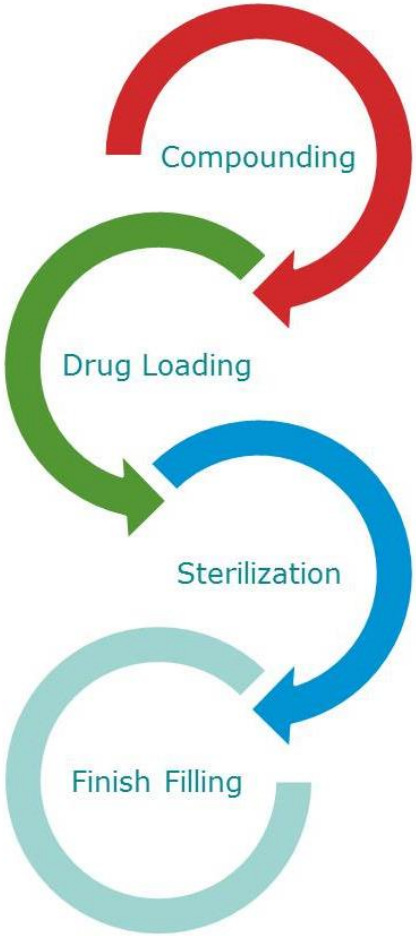
Comparison – TA & DSP

Drug	TA	ER TA	DSP	TLC599 (ER DSP)
Steroid Potency	Low	Low	**High**	**High**
Side Effect- Crystal Induced Synovitis	Yes	Yes	**No**	**No**
Chondrotoxicity	High	High	**Low**	**Low**
Onset	Slow	Slow	**Fast**	**Fast**
Sustained Release	Mid	**Yes**	No	**Yes**
Aseptic Manufacturing Process	**Sterilization**	Whole process, from raw material to final product	**Sterilization**	**Sterile filtration**
Risk of Foreign Particulate	**Low**	High	**Low**	**Low**

Ongoing TLC599 Phase II Study



TLC599 Summary



- **World's 1st multilamellar *and* multivesicular lipid formulation** of dexamethasone sodium phosphate for OA
- **Better efficacy** - showed **fast onset and sustained release capabilities** in pain relief for at least 12 weeks in Phase I/II study
- **High drug load** with high potency drug; minimize injection volume to further reduce distension pain + no synovial fluid aspiration prior to injection
- **Less local & systemic toxicity**, no cartilage damage & chondrotoxicity in **repeated-dose** animal study over 3 mo. + safe cortisol levels in clinical trial
- **Better convenience + broader usage** – flexibility in injectable **needle sizes from 21G-30G** » can treat smaller joints
- **Optimized particle size** between 0.4-0.5µm » does not escape from joint » is not phagocytosed » sterile filtration » lower contamination » **reduced costs**
- **Ongoing phase II study with 24-week evaluation period**; topline result is expected mid-2018
- **Strong IP protection + Manufacture know-how**

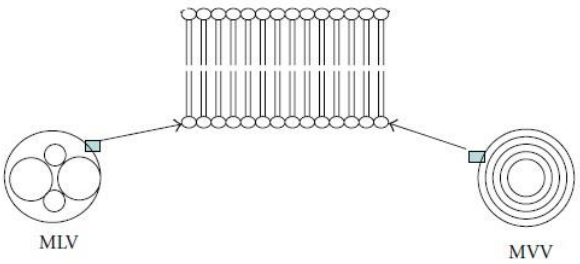
Post-Surgical Pain Program

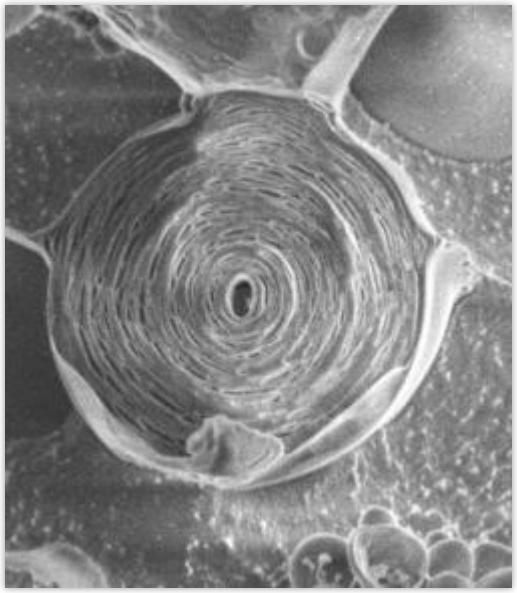
TLC590: BioSeizer™ Sustained Release Ropivacaine in Multilamellar Liposome for Infiltration Injection

TLC590 Target Product Profile

Target Product Profile	• BioSeizer™ ropivacaine in multi-lamellar liposome for infiltration injection • Just one shot provides quick and effective post-surgical pain management for **up to 3 days** after surgery
Current Treatments for Post-Surgical Pain	• Opioids • Local anesthetics – lidocaine, bupivacaine multi-vesicular liposomes • Non-opioid pain reliever • Elastomeric pump & patient controlled analgesia
TLC590 Competitive Advantages	• Safer API: **less cardiovascular and central nervous system toxicity** compared to bupivacaine • **Fast, immediate onset** with **extended pain relief** to reduce opioid usage post-surgery and avoid addiction • Lower production costs
Regulatory Pathway	• NDA - 505(b)(2)
Development Stage	• U.S. IND submission in 1Q 2018

BioSeizer™ for Post-Surgical Pain





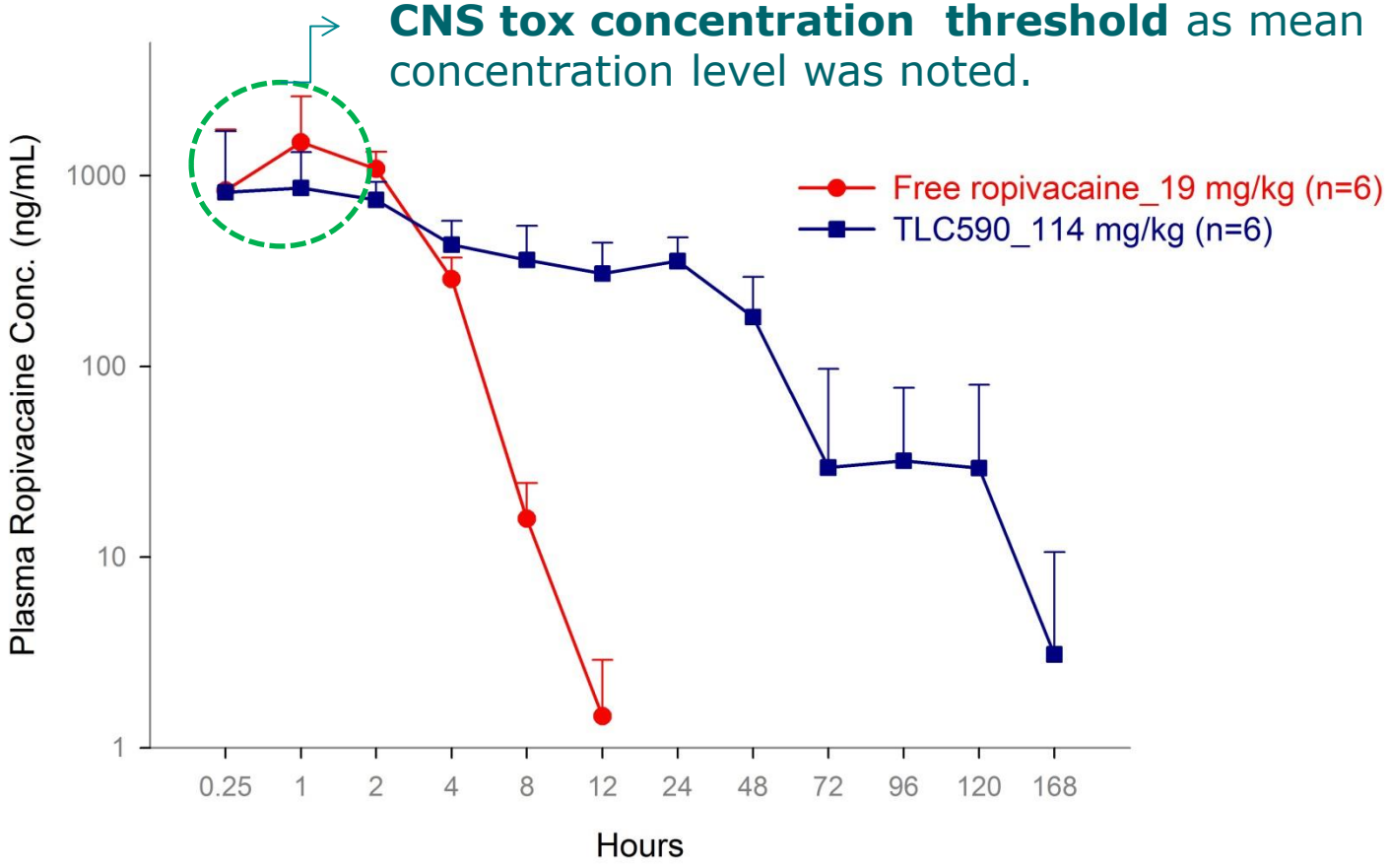
- Vesicles enclosed by **cell membrane-like bilayer**, not as rigid as polymeric particles
- MVV and dense layers capable of **high concentration drug loading** and **controlling release** of amphiphilic molecule
- Administered into local site, providing **immediate onset** and **sustained therapeutic concentration**

Bupivacaine vs. Ropivacaine

Drug	Bupivacaine	ER Bup.	Ropivacaine	TLC590 (ER Rop.)
API Potency-Sensory Block	Similar	Similar	Similar	Similar
LAST-CNS Toxicity	High	High	Low	Low
LAST-Cardiovascular Toxicity	High	High	Low	Low
Onset	Fast	Slow	Fast	Fast
Sustained Release	No	Yes	No	Yes
Aseptic Manufacturing Process	Sterilization	Whole process	Sterilization	Sterile filtration
Risk of Foreign Particulate	Low	High	Low	Low

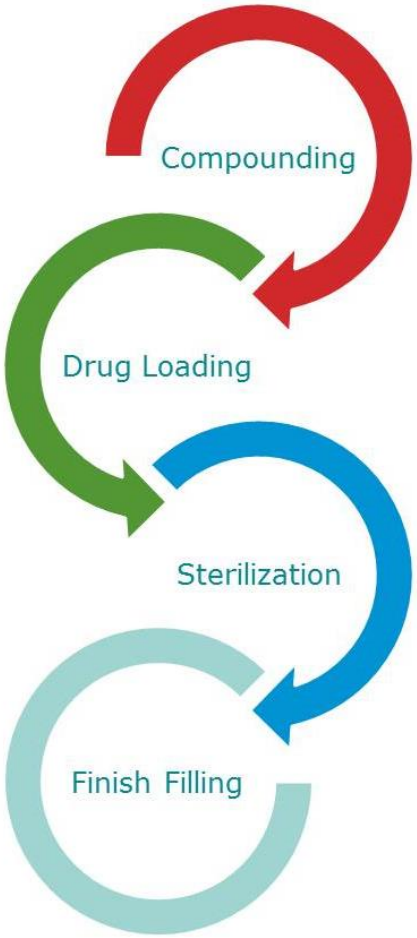
TLC590 PK Profile in Rats via SC Injection

C_{max}: FDA assessment report & approved labeling, **CNS tox concentration threshold** as mean concentration level was noted.



TLC590_114mg compared to free ropivacaine_19mg: Similar Cmax but **30 times** the half life, suggesting **>72** hours clinical effectiveness

TLC590 Summary



- TLC590 is a **multivesicular and dense layer lipid formulation** for ropivacaine drug loading
- **Less toxicity** with ropivacaine as API compared with bupivacaine
- **Scalable and reproducible** manufacturing process **bypass aseptic process**, targeting **lower COGS**.
- TLC590 has shown **extended release profile** in rat PK study with over 72hrs .
- TLC to submit **IND in 1Q 2018** based on FDA pre-IND meeting
- **Strong IP protection + Manufacture know-how**

To Sum up TLC…

Focus

- Lipid-based DDS platforms for **targeted** and **sustained release delivery**

Strategy

- Validated technology currently applied to carefully selected programs in **pain management**, **ophthalmology** and **oncology**
- Preclinical studies efficiently executed in Taiwan; IND-enabling and advancement of programs in U.S. and other high value markets
- **100+ patents worldwide**

Pipeline

- 3 products approved/marketed in Asia & partnered globally (e.g. Sandoz)
- **TLC599** in osteoarthritis in Phase II study; **topline data mid-2018**
- **TLC590** in Post-Surgical Pain Phase I/II **2Q2018**
- TLC399 in macular edema in Phase II study; topline data 4Q 2018
- TLC178 RMS Phase I/II initiation in 2Q 2018

Corporate

- Partnerships signed with Sandoz and Asian pharma companies
- ~US$47 million cash as of June 30, 2017
- **Listed on Taipei Exchange** since 2013 (4152:TWO)
- **Market cap: ~ US$170 million**

Thank You

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tlc Delivering Hope for Life