



# 10XBIO

Biotech Catalyzed

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Innovations in Body Contouring

# Overview & Company Highlights

- **Dermatology company developing a next generation adipolytic drug product (10XB101) for body contouring**
  - Superior efficacy, better tolerability, larger treatment areas than current marketed product Kybella
- **Phase 2b study demonstrates far superior efficacy and tolerability relative to Kybella indicating a paradigm shift for pharmaceutical body contouring**
  - ITT: 62% of 10XB101 patients achieve  $\geq$  grade 2 improvement on FDA primary endpoint vs. 16% for Kybella
    - Completer Population (as defined, slide 8) achieved 80% grade 2 improvement in FDA primary endpoint
  - >50% reduction in key market acceptance tolerability side effects: bruising, edema, and pain
- **Phase 3 ready sub-mental indication in 2024 with reduced development risk, time, and cost**
  - Novel formulation of polidocanol, long history safety, being developed under 505(b)2 pathway
- **Hugel, Inc., a leading aesthetic dermatology company in South Korea, licensing partner in Korea and China territories**
- **Strong intellectual property position**
  - 25 issued patents covering formulation and method of use US, EU, CA, AU, JP, KR, CN.
- **Experienced leadership by dermatology industry veterans**
  - John Dobak, MD – past CEO, DermTech, Inc. (NASDAQ: DMTK); Dan Piacquadio, MD – CEO, Therapeutics, Inc.

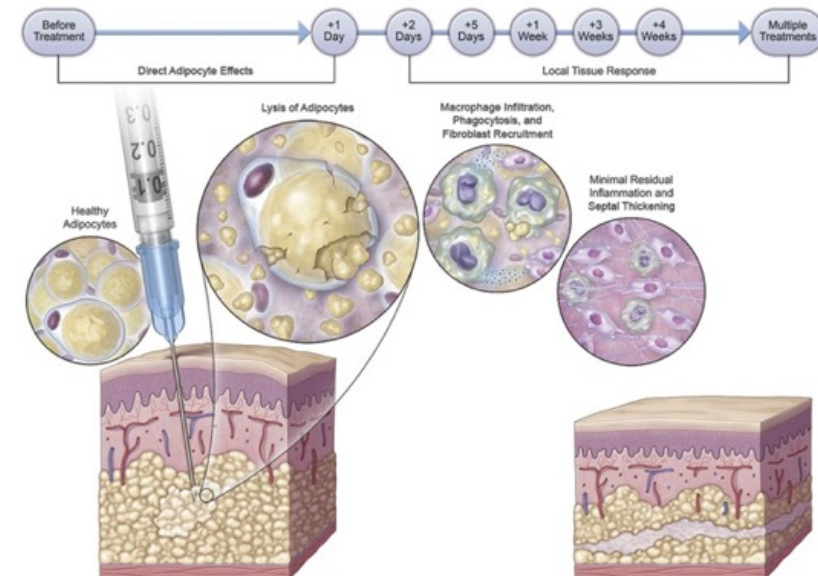
# Adipolysis Destroys Fat Tissue For Long Lasting Results

## Mechanism Of Action

- ▶ Drug volume injected based on defined pattern
- ▶ Detergent lyses cell membranes
- ▶ Destroyed fat cells absorbed by the body
- ▶ Mild fibrosis firms and tightens the submental area



Injection procedure



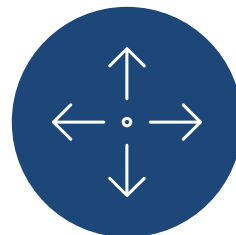
# Clinical Value Proposition of 10XB-101



Superior efficacy and tolerability  
relative to Kybella

*Demonstrates much higher 2  
grade or more improvement in  
appearance desired by patients.*

*Demonstrates reduced edema,  
bruising, pain, etc. Does not  
require local anesthetic, ice  
packs, nor chin straps*



Expands treatment areas to other  
body sites that require larger  
injection volumes to treat larger  
fat volumes

*Up to 20 CC of high concentration  
drug product injected into  
abdominal fat without significant  
tolerability or adverse events.*



May shorten treatment interval and  
time to desired aesthetic effect

*Due to injection site reactions,  
real-world treatment interval for  
Kybella is 2-3 months with up to  
12-months to complete a full  
treatment course*

# Body Contouring Opportunities (Patients per Body Region)



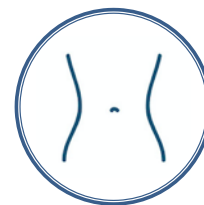
**Submentum**  
*3.0MM*



**Arms**  
*4.0MM*



**Inner Thighs**  
*5.0MM*



**Abdomen/Flanks**  
*12.0MM*



**Outer Thighs**  
*4.0MM*



**Gynecomastia**  
*0.5MM*



**Buttocks**  
*4.0MM*

**Total U.S. Potential  
Patients**  
**32.5MM**



# Submental Fat Market Opportunity (SMF)

## SMF Frequent Cosmetic Concern of High Importance

- ▶ Significant concern for 68% of patients
- ▶ Treatment improves self-confidence, patient feel younger and less self-conscious
- ▶ U.S. dermatologists and plastics surgeons see 10-11 patient/mo. for SMF concerns

Percentage of Population Somewhat to Extremely Bothered by . . .

**89%** Excess Weight on Any Part of the Body

**71%** Lines and Wrinkles Around the Eyes

**75%** Skin Texture and/or Discoloration

**68%** Excess Fat Under the Chin

**65%** Lines, Wrinkles and/or Folds in the Mid-Face Around the Cheeks and Mouth

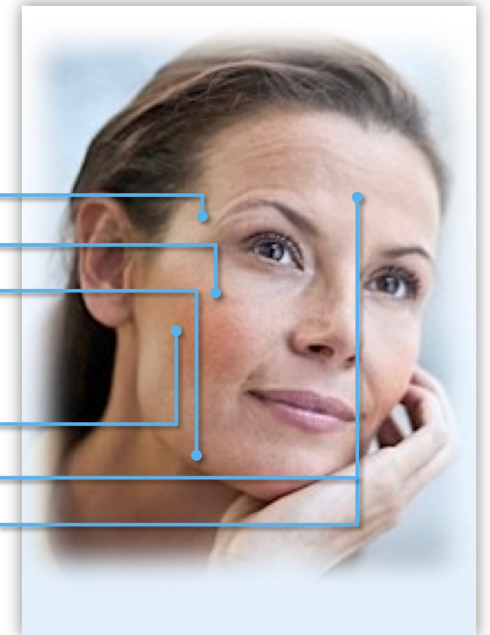
**63%** Sagging Facial Skin

**56%** Lines and Wrinkles in the Forehead Area

**55%** Lines and Wrinkles Between My Eyebrows

**41%** Hair Loss

**26%** Acne Scars



Source: 2014 American Society for Dermatologic Surgery (ASDS) Consumer Survey on Cosmetic Dermatologic Procedures.



**Submentum**  
*3.0MM Patients in U.S.*

# Product-Market Fit

## Current Treatments Do Not Address Unmet Needs for Submental Fat Treatment

- ▶ Poor efficacy
- ▶ Unpredictable results
- ▶ Prolonged treatment time
- ▶ Prolonged recovery and adverse side effects
- ▶ Poor provider economics
- ▶ High-cost relative to benefit

## Ideal Product Profile

- ▶ High efficacy- grade 2 or greater SMF improvement
- ▶ Minimal down time and adverse events
  - Patients to resume normal activities within 1-3 days
- ▶ Results achieved in 3-5 months
- ▶ Multiple treatments preferred by physicians
  - Ability to better tailor results
  - Better economics
  - Inability to correct undesirable result if therapy too aggressive
- ▶ Patients prefer fewest treatments possible
  - Okay with multiple treatments if downtime and adverse effects are limited

# Kybella Adoption Hampered by Product Profile

## Low Efficacy

- Only 16% patients on average achieve 2-grade improvement

## Poor Tolerability

- Significant swelling that can last 30 days
- Bruising
- Injection pain likened to bee sting

## Local Anesthesia Injection Pre-treatment

- Added procedure time and additional patient injections

## Extended Treatment Period

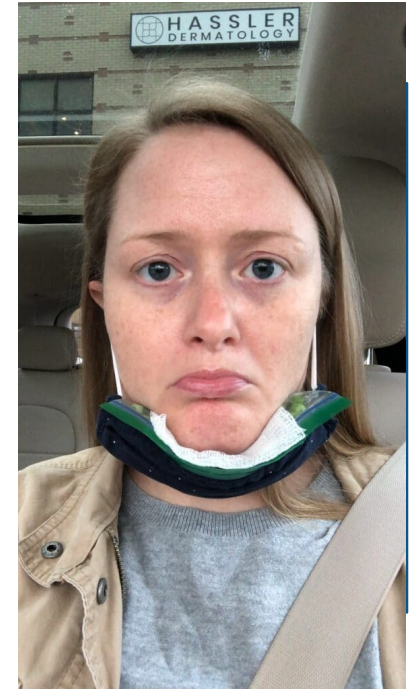
- Can take 1-year to achieved desired results

## Limited Injection Volume

- 10 ml total injection volume and side-effects limits use in other body area indications, larger volumes cause more side effects

## High-cost relative to benefit

- Estimated cost \$3,000 - \$6,000, with inferior results





# 10XB101 Phase 2b Repeat Treatment Study

- **Treatment Regimen**

- Single treatment, up to 50 injections, 0.2 ml/injection
- 4 dose cohorts, n=13/cohort, 3 active/1 placebo, (1:1:1:1)
- Treatment: up to a maximum of 6 treatments 4 weeks apart at Visit 2, 3, 4, 5, 6 and 7

- **Endpoints**

- Clinician and patient submental fat grading
  - **CSFS** (Clinician Submental Fat Score) & **PSFS** (Patient Submental Fat Score): 0-4 point scale
  - FDA Composite Endpoint: **CSFS & PSFS both  $\geq 2$**
- Local skin reactions (0 (none), 1 (mild), 2 (moderate), 3 (severe))
  - Erythema, edema, tenderness on palpation, bruising, pain, burning/stinging
- Safety labs, ECG

- **Analysis Populations**

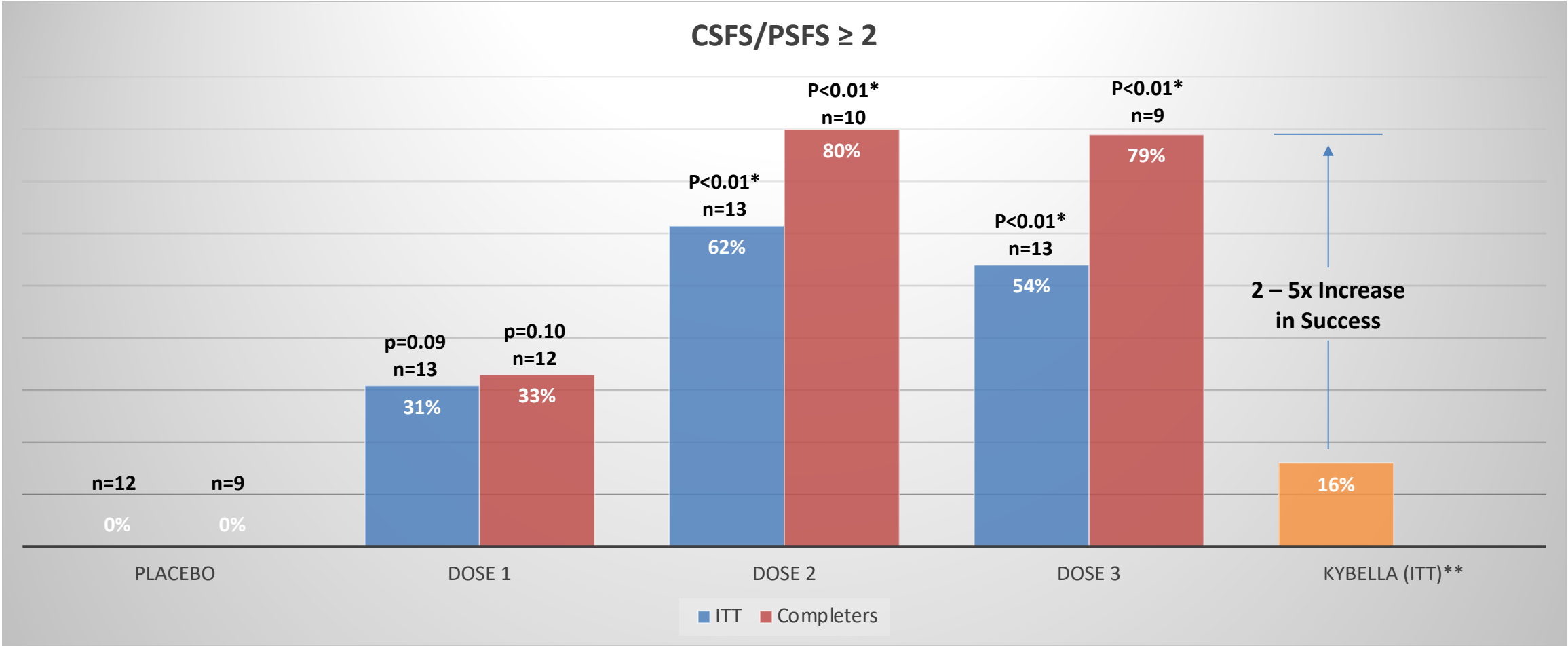
- Intent-to-Treat (ITT)
  - Includes all enrolled subjects who received any injections of test article
- Completer Population
  - Includes a subset of the ITT Population who meet the following criteria:
    - Had at least 4 treatments or completed treatments per protocol (i.e., treatments did not continue once CSFS=0)
    - Completed the 12 weeks after final treatment assessments
    - Did not have any significant protocol deviations that would impact the evaluation of efficacy

# 10xB101 Phase 2b Data Highlights

- 10XB101 ITT analysis best dose shows ~4-fold increase in  $\geq 2$ -grade improvement in composite FDA endpoint relative to Kybella (62% vs. 16%)
- 80% of Completer Population achieved a 2-grade improvement in composite endpoint
  - A meaningful proportion of completers achieve 3-grade improvement (10%-33%)
- More rapid onset of efficacy than Kybella
  - On average patients achieve 1-grade improvement after 2 treatments
  - ~50% of patients can achieve a 2-grade improvement after 3-4 treatments
- >50% reduction in key tolerability side effects that impact product adoption: bruising, edema, pain, induration, nodules, numbness
  - Superior tolerability may allow for shorter treatment intervals

# 10XB101 FDA Defined Post-Treatment Success Markedly Exceeds Kybella

(ITT Population, Composite CSFS & PSFS  $\geq 2$ , Visit 8, 4 weeks after Final Treatment)



\*\*average Refine 1 & 2 trials

# 10XB101 Patient and Clinician Submental Grading $\geq 2$ Change from Baseline Tops Kybella

(ITT Population, Best Dose, PSFS & CSFS, Visit 8, 4 weeks after Final Treatment)

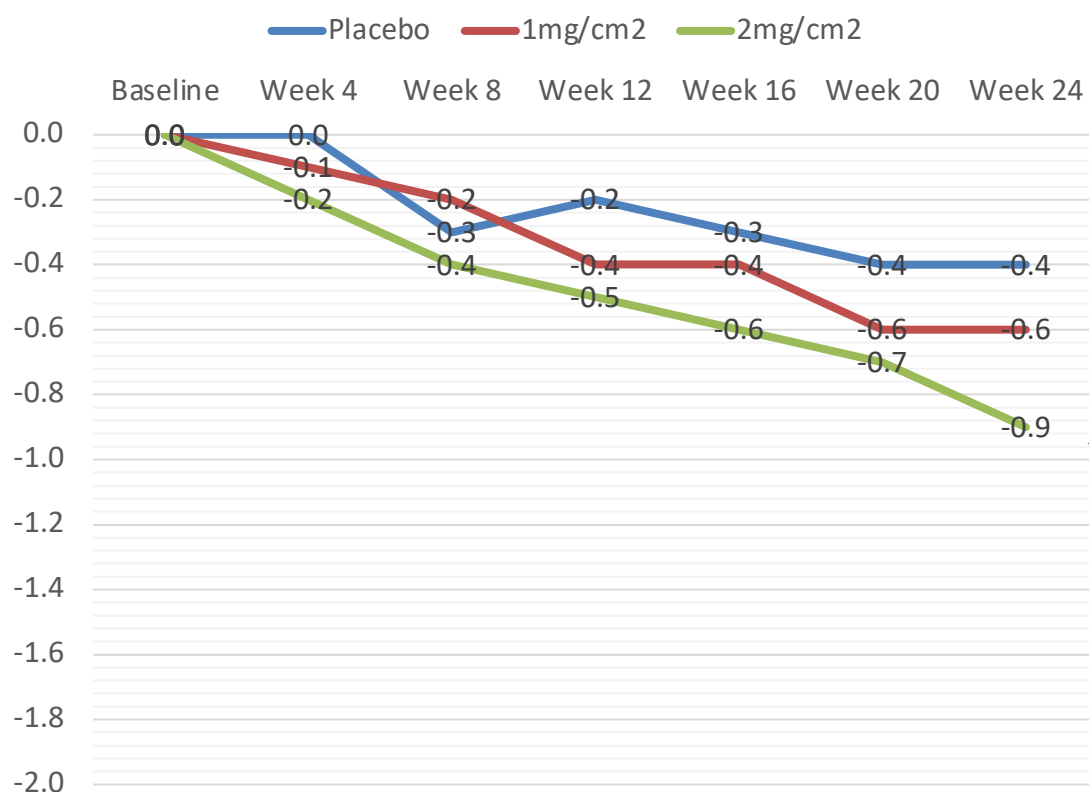
**Meaningfully higher rates of Patient Reported (PR) and Clinician Reported (CR)  
Submental Fat Assessment Change from Baseline of  $\geq 2$**

	10XB101	Kybella*
PR $\geq 1$	85%	80%
CR $\geq 1$	77%	80%
PR $\geq 2$	77%	18%
CR $\geq 2$	62%	22%

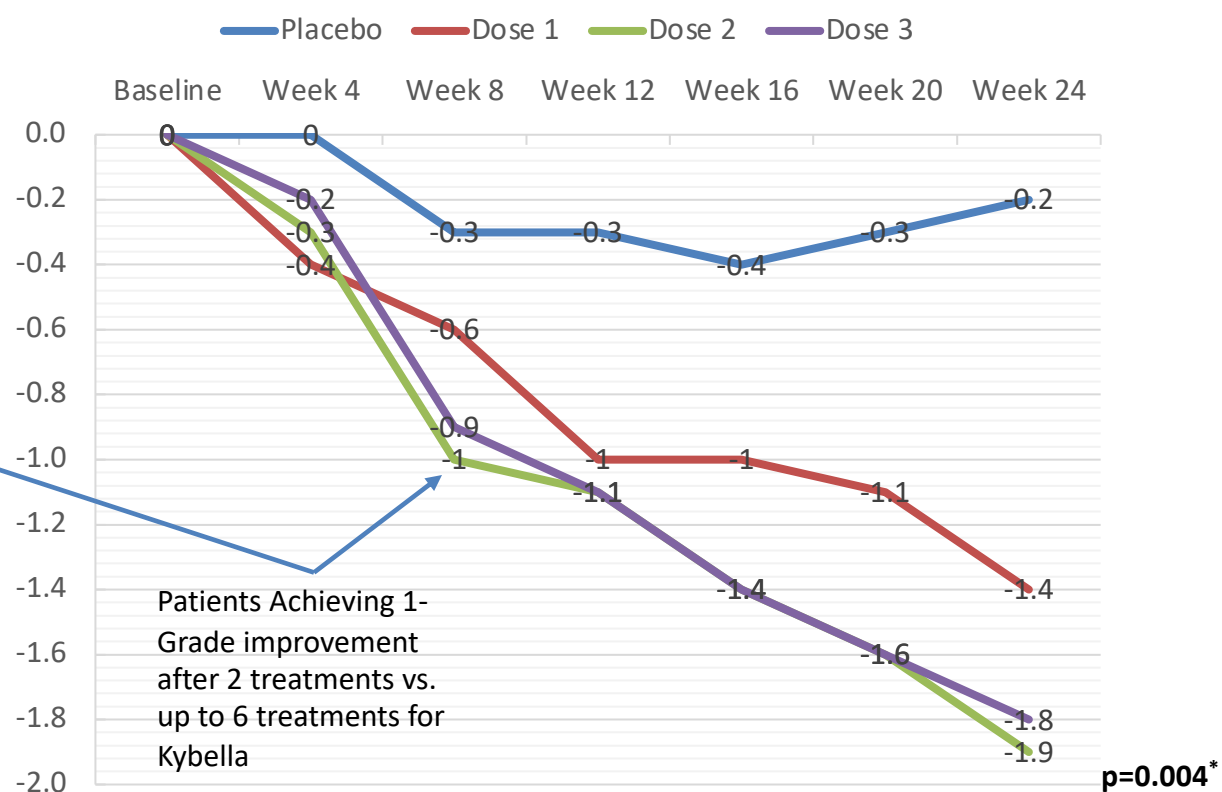
.... 10XB101 Demonstrates ~4x ....  
Greater Improvement

# 10XB101 Shows >2-Fold Increase in Mean CSFS Change at Same Time Point Versus Kybella (ITT Analysis)

## Kybella Phase 2b Data\*



## 10XB101 Phase 2b Data



## Phase 2b: Tolerability Outcomes

Blinded data reflects outcomes in aggregate for all treatment cohorts (3 active/1 placebo, 1:1:1:1)

10XB101 has meaningfully lower Injection Site Reaction Adverse Events compared to Kybella, including: edema, pain, bruising, induration, anesthesia, nodules.

98<sup>+</sup>% of all LSRs assessed per protocol are Grade 0 (none) or Grade 1 (mild),  
with the vast majority being Grade 0



# Subject #04-017: Photograph Data

**Baseline**



CSFS=3  
PSFS=3

**12 Weeks Post Treatment**



CSFS=0  
PSFS=0

# 10xBio IP Summary

## 704 Family: Polidocanol for Adipolysis

US, EP, CA, CN: Methods of reducing adipose tissue with 0.5% W/V to about 2.0% W/V polidocanol	US, AU, CA: Methods of reducing adipose tissue with 14+ day treatments w/o co-solvent	Pending
US, AU: Pharmaceutical formulation comprising up to about 5% W/V polidocanol	CA: Injectable polidocanol pharmaceutical formulation up to 5% polidocanol	CN, CA: Injectable polidocanol pharmaceutical formulation with 2%-5% polidocanol & use thereof
US, CN, CA, AU: Methods of reducing adipose tissue w/ 14+ day trmts. w/ polidocanol w/ solvent	CN: Polidocanol pharmaceutical formulation with 6%-10% polidocanol	
US, EP, CA: Pharmaceutical formulation comprising 0.5%-2% W/V polidocanol	Pending	
KR: Pharmaceutical formulation comprising 0.1%-2% W/V polidocanol	Pending	
JP: Pharmaceutical formulation comprising 0.5%-5% W/V polidocanol	EP: Use of formulation comprising up to 5% W/V polidocanol in 14+ day treatments w/o cosolvent	
JP, CA: Pharmaceutical formulation comprising 6%-10% W/V polidocanol	Pending	TBD

# Summary

- **Best-in-class pharmaceutical body contouring product**
  - Superior efficacy and tolerability relative to current products
  - Areas of treatment expanded beyond submental contouring
- **Reduced development risk, time, and cost**
  - Novel formulation of polidocanol; long history safety; being developed under 505(b)2 pathway
- **Phase 3 ready in 2024**
- **Strong partner in select Asian countries**
- **Strong intellectual property position**
  - 12 issued patents covering formulation and method of use US, EU, CA, AU, JP, KR, CN.
- **Experienced leadership by dermatology industry veterans**
  - John Dobak, MD – past CEO, DermTech, Inc. (NASDAQ: DMTK); Dan Piacquadio, MD – CEO, Therapeutics, Inc.



An aerial photograph of the San Francisco-Oakland Bay Bridge, a large cable-stayed bridge with a blue-painted steel deck and white concrete piers. The bridge spans a wide body of water, with the San Francisco skyline visible in the background under a dramatic, colorful sunset sky. The text "Thank You" is overlaid in the center of the image.

Thank You