



**Dextenza<sup>TM</sup>**  
(dexamethasone insert)  
For Intracanalicular Use

## Phase 3c Topline Results

Any statements in this presentation about future expectations, plans and prospects for the Company including the development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA, and the resubmission of the NDA and a potential NDA supplement, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder, the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this presentation represent the Company's views as of the date of this presentation. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

- **DEXTENZA met the criteria for superiority to placebo for both primary efficacy endpoint analyses of inflammation and pain**
  - Inflammation: Absence (Score of 0) of anterior chamber cells at Day 14
  - Pain: Absence (Score of 0) of ocular pain at Day 8
- **Superiority of DEXTENZA over placebo was observed as early as Day 2 for absence of ocular pain and Day 4 for absence of ocular inflammation**
- **DEXTENZA efficacy results were consistent across multiple statistical analyses**
  - There was a high rate of insert retention, as seen in prior studies
- **DEXTENZA safety profile was good, and consistent with prior studies**
- **No treatment-related serious adverse events (SAEs)**

# Phase 3c Trial Design

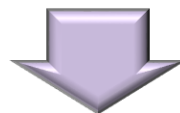
Patients undergoing cataract extraction with intraocular lens implantation; Score of 0 for preoperative pain and inflammation  
**n = 438 subjects randomized at 21 US sites**

## **DEXTENZA™**

0.4 mg dexamethasone insert  
n = 216



**Patients  
randomized  
1:1**



## **Placebo**

Hydrogel vehicle insert  
n = 222

## **Primary Endpoints**

- **Absence of cells** (score of 0) in the anterior chamber of the study eye at Day 14
- **Absence of pain** (score of 0) in the study eye at Day 8
- Ocular safety during a 45-day treatment and follow-up period

# Baseline Demographics - ITT

	DEXTENZA n = 216	Placebo n = 222
<b>Age, years</b>		
Mean (SD)	67.3 (9.09)	68.6 (8.37)
Range	35, 86	46, 91
<b>Gender, n (%)</b>		
Male	96 (44.4%)	92 (41.4%)
Female	120 (55.6%)	130 (58.6%)
<b>Ethnicity, n (%)</b>		
Hispanic or Latino	37 (17.1%)	37 (16.7%)
Not Hispanic or Latino	179 (82.9%)	185 (83.3%)
<b>Race, n (%)</b>		
American Indian or Alaskan Native	2 (0.9%)	2 (0.9%)
Asian	8 (3.7%)	1 (0.5%)
Black or African American	28 (13.0%)	25 (11.3%)
Native Hawaiian or Pacific Islander	1 (0.5%)	1 (0.5%)
White	174 (80.6%)	189 (85.1%)
Other	3 (1.4%)	4 (1.8%)
<b>Study Eye Iris Color, n (%)</b>		
Black	0	2 (0.9%)
Blue	61 (28.2%)	64 (28.8%)
Brown	106 (49.1%)	101 (45.5%)
Hazel	32 (14.8%)	37 (16.7%)
Green	15 (6.9%)	18 (8.1%)
Gray	2 (0.9%)	0

	<b>DEXTENZA n = 216</b>	<b>Placebo n = 222</b>
<b>Randomized (ITT population)</b>	216	222
<b>Per Protocol Population (PP)</b>	193	207
<b>Withdrawn from the study</b>		
Lost to Follow-Up	1	0
Consent Withdrawn	0	1
Other (Randomized but not treated)	1	0
<b>Safety Population</b>	216	221

## Proportion of Patients Achieving Primary Efficacy Endpoint

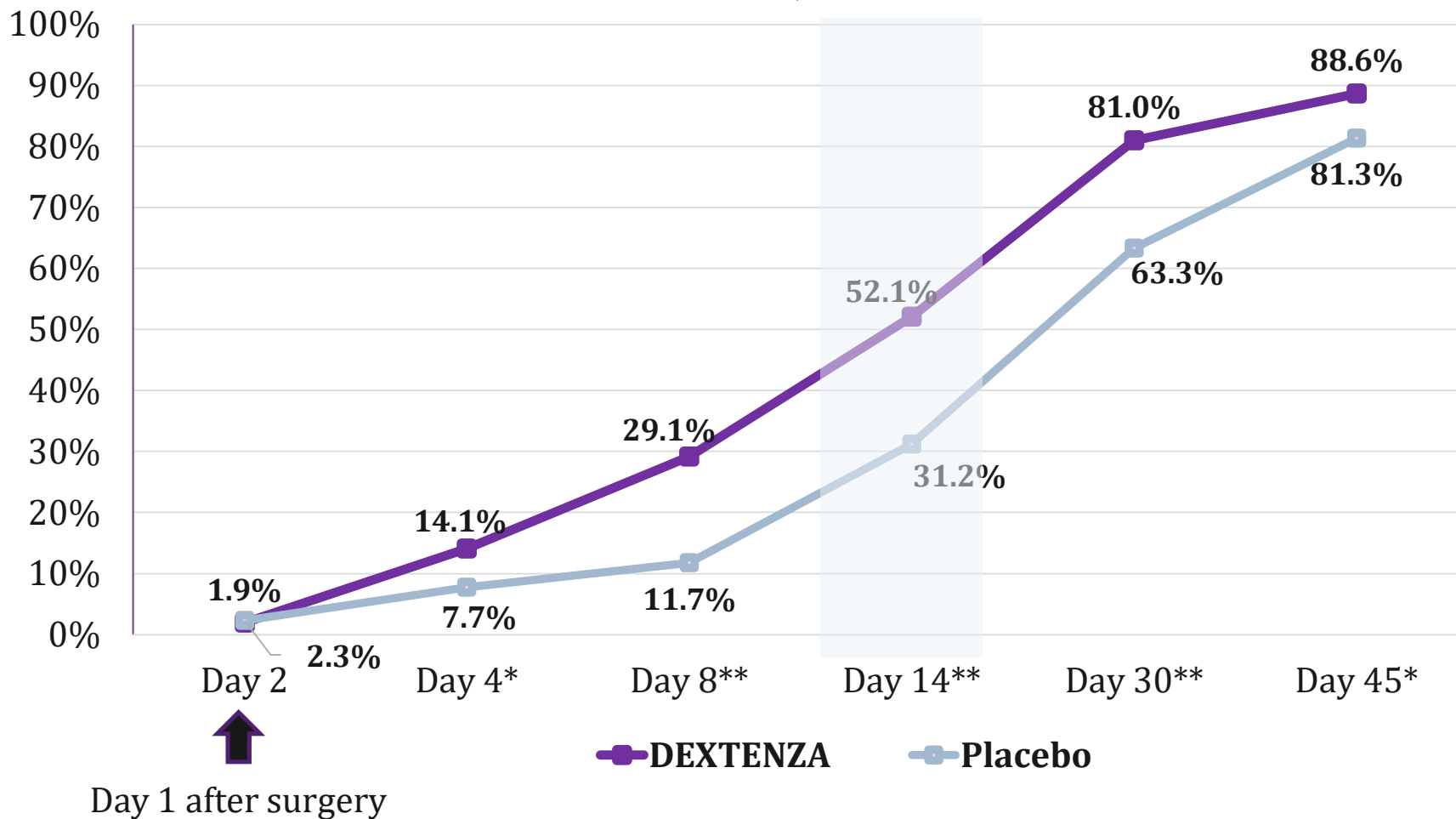
	DEXTENZA	Placebo	p value
<b>Absence of AC Cells (Day 14)</b>	52.3%	31.1%	< 0.0001
<b>Absence of Ocular Pain (Day 8)</b>	79.6%	61.3%	< 0.0001

**DEXTENZA Achieved Statistical Significance in the Primary Efficacy Analysis - ITT**

# DEXTENZA Achieved Statistical Significance in the Secondary Efficacy Analysis - ITT

## Proportion of Patients with an Absence of AC Cells (Inflammation)

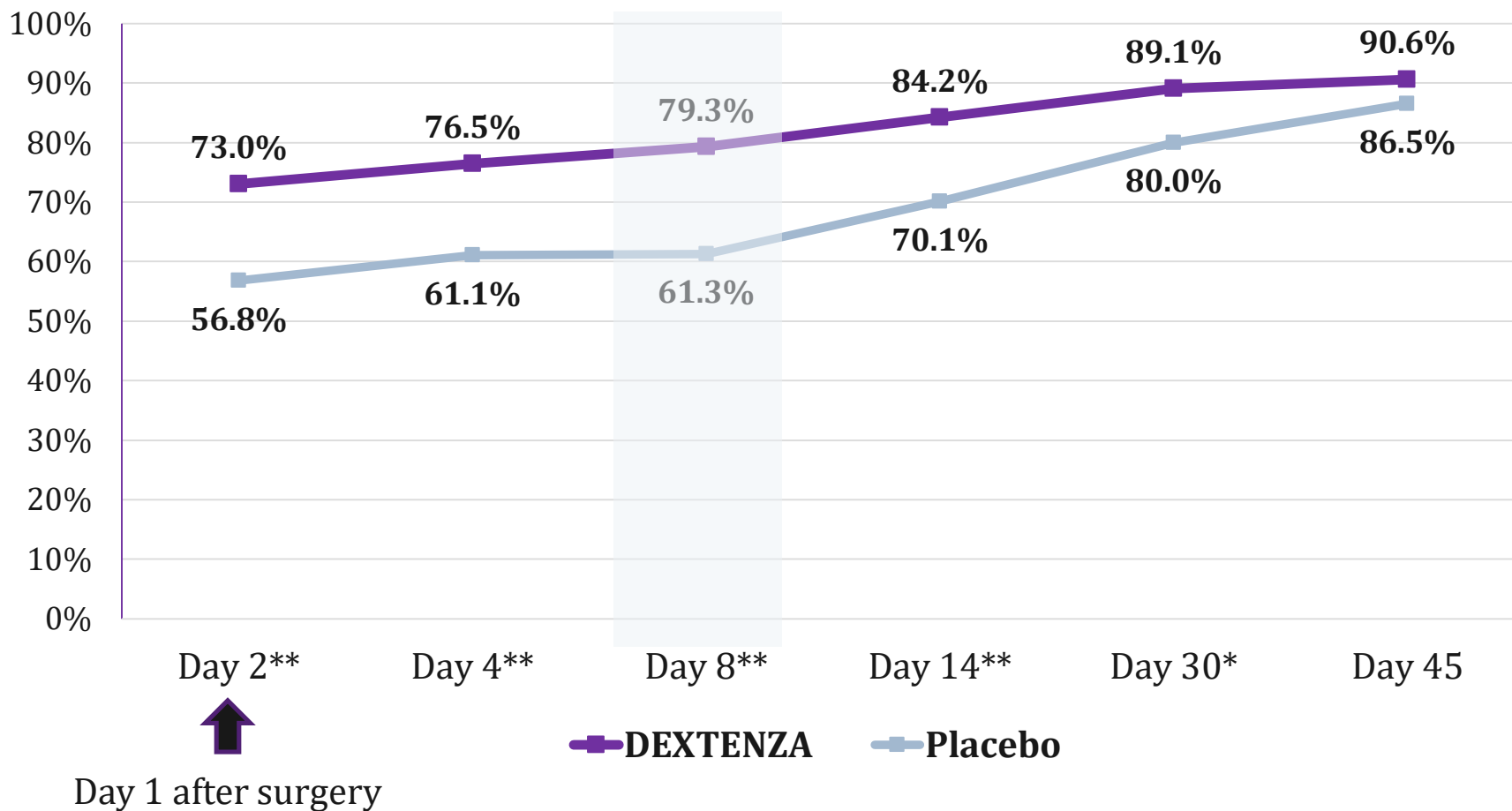
*\*P < 0.05; \*\*P < 0.0001*





## Proportion of Patients with an Absence of Ocular Pain

*\*P < 0.01; \*\*P ≤ 0.0005*



## Product Retention graded by slit lamp visualization

	DEXTENZA
Day 8 - PAIN Primary End Point	99.1%
Day 14 - INFLAMMATION Primary End Point	98.6%

	DEXTENZA n = 216	Placebo n = 221
Treatment-Emergent Adverse Events	63 (29.2%)	86 (38.9%)
Ocular TEAEs	55 (25.5%)	75 (33.9%)
Serious Adverse Events; <i>None were treatment-related</i>	3 <ul style="list-style-type: none"> <li>• Lower gastrointestinal hemorrhage</li> <li>• Retinal detachment</li> <li>• Acute cardiac failure</li> </ul>	2 <ul style="list-style-type: none"> <li>• Nephrolithiasis</li> <li>• Hypoxia</li> </ul>

- **There were no drug-related serious adverse events (SAEs)**
- **No subjects experienced a treatment-emergent adverse event (TEAE) leading to subject withdrawal**

## Most Common Ocular TEAEs (> 5%)

	DEXTENZA n = 216	Placebo n = 221
Eye Inflammation	18 (8.3%)	45 (20.4%)
Increased Intraocular Pressure ( $\geq 10$ mm vs. Baseline)	16 (7.4%) [all had onset on Day 2]	6 (2.7%)
Subjects with Increased IOP after Day 2*	2 (0.47%)*	1 (0.45%)

\*Two subjects presented with two episodes each of IOP increase  $\geq 10$  mmHg; for both subjects, the first episode was on Day 2. The second episode was on Day 4 for one subject and Day 22 for the second subject.

Extensive Clinical Testing: over 550 clinical trial participants

Primary endpoints for post-surgical ocular inflammation and pain met in two Phase 3 trials

Therapeutic levels of drug delivered for 30-days

Well-tolerated with minimal evidence of treatment-related ocular adverse events attributable to the product

Plan to submit NDA supplement for label expansion to include treatment of inflammation (subject to FDA approval of DEXTENZA NDA for pain)