Platform for new standards of care in hematologic oncology

Clinical stage biotech with continuous delivery technology

MARCH 2021 **OVERVIEW**

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“From my 31-year career in large pharma, I dealt with the risk, cost, and time associated with the development of science and new medicines. Initiatives to address these inefficiencies were met with limited success.

When I saw Starton’s technology, I recognized the opportunity to transform established medicines to address unmet needs and develop new IP quickly, with limited capital intensity.

As we executed our strategy, we have exceeded our expectations and focused the platform where the potential benefit of continuous delivery technology is maximized.

Over the next three years, we expect to advance our blockbuster development programs in hematological malignancies and bring our first commercial product to patients. We are on track to extend and improve quality of life.”

- Pedro Lichtinger, Co-Founder, Chairman, & CEO
  President & CEO, Asterias Biotherapeutics and Optimer Pharmaceuticals (2010-2016)
  President of Global Primary Care and President of Europe, Pfizer (1997-2009)

Investment Highlights

Clinical-stage biotech with low-risk, low-cost, fast-development platform technology – standard of care potential in hematology/oncology

- **Continuous delivery platform + proven safety and efficacy**
  - Platform technology lowers AUC, C_{max}, and overall drug exposure
  - Profile enables pursuit of new indications with efficient drug development process
- **Growing pipeline of differentiated products**
  - STAR-OLZ entering Phase 2/3 in CINV – targeting superiority in Nausea Control (vs NK1 standard of care)
  - STAR-LLD entering Phase 1:
    - *in CLL* – first IMiD in CLL
    - *in MM* – expanding addressable population and enhancing immunomodulatory benefit
  - Patent protection through 2040/41, includes method of use, delivery, and formulations
- **Experienced Board and management team**
  - Former Pfizer President of Global Primary Care + Celgene Global Lead, Multiple Myeloma
  - World-renowned scientific leaders in their field leading each program
  - Breadth of operational expertise in regulatory, clinical development, manufacturing, and intellectual property

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STAR-OLZ and STAR-LLD are investigational new drug products and are not approved by the FDA or any regulatory authority
AUC: area under the curve; Cmax: peak plasma concentration; CINV: chemotherapy induced nausea and vomiting; CLL: chronic lymphocytic leukemia; IMiD: immunomodulatory drug; MM: multiple myeloma

Leadership team with breadth of clinical, operational, and financial experience

Pedro Lichtinger

CEO
CO-FOUNDER

Board Chair

Pfizer
OPTIMER®

Keith Darragh

CHIEF FINANCIAL OFFICER

PHARMACOSMOS
Eleison PHARMACEUTICALS LLC
kolltan Pharmaceuticals, Inc.

Andy Rensink

CHIEF MANUFACTURING OFFICER

TAPEMARK

Cidnee Vaykovich

CHIEF OPERATING OFFICER

Board Secretary

Aequus PHARMACEUTICALS
NORTHVIEW LIFESCIENCES

Dr. Jamie Oliver

CHIEF MEDICAL OFFICER

accelovance
ACCELERATE. ADVANCE. ACHIEVE.

OCKHAM ONCOLOGY

Renowned Board of Directors

Board of Directors + Scientific Committee members:

Mohamad Hussein, MD	Chair, Scientific Committee, Board Member	Celgene; Moffitt Cancer Center; Cleveland Clinic
Kenneth Anderson, MD	Multiple Myeloma Lead, Board Member	Dana Farber Cancer Institute; Harvard Medical School
Asher Chanan-Khan, MD	CLL Lead, Board Member*	Mayo Clinic

Members contributed to REVLIMID® original approval in MM and the body of literature supporting its use in CLL

Fotios Plakogiannis, Ph.D.
Co-Founder

Managing Director, Transdermal research laboratory

TRPL Dermal Technologies

Independent Directors:

Roy F. Waldron, Ph.D.
IP Lead
Governance Committee Chair

Pfizer

Nitin Kaushal, CPA
Audit Committee Chair

pwc

Eric Baum, MBA
Comp Committee Chair

SOLIDEA

ACQUIS

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** Approved by Starton Board and shareholders, pending institution agreement*

Key accomplishments

First 18 months – *legacy programs* | **2019-2020 – *innovative***

2017: Formed platform reformulation company

- Built experienced Board
- Implemented corporate governance, financial reporting, and audit procedures
- Exclusive rights to transdermal research laboratory for formulation development
- Opened 10,000 sqft GMP development laboratory (01/ 2020)
- Completed multiple financings at increasing valuations

Advanced cancer supportive care program

- Developed IP for transdermal delivery of olanzapine (**STAR-OLZ**)
- Established proprietary blood level targets in Phase 1 disease model challenge study → *new IP*
- Completed GMP manufacturing & FDA Pre-IND
- Completed Phase 1 human bioavailability (safety & pk)

Developed proprietary algorithm

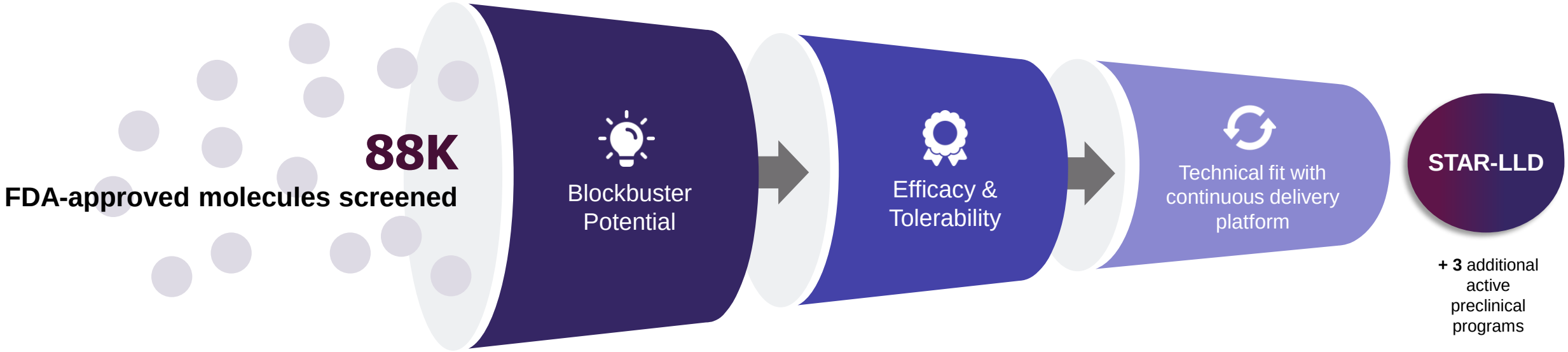
- Developed proprietary algorithm to identify optimal candidates for platform technology. Screened 88,000 potential targets
- Spun-out IP for non-core development program in $15.0mn transaction[1]
- Launched lenalidomide (**STAR-LLD**) program, focus on hematologic malignancies
- Initiated partnering STAR-OLZ process for China

Launched therapeutic hematology program

- Completed animal proof of concept study: unprecedented efficacy outcomes in myeloma animal model → *new IP*
- Attracted leading clinician-scientists to join Board of Directors and Scientific Committees
- Selected formulation for subcutaneous delivery system
- Achieved skin permeation for transdermal formulation

1. Transaction sold IP to CMIO-DRONAB and rights for formulation development partner in cannabinoids and psychedelics

Starton proprietary algorithm identified multiple candidates with potential to become multibillion-dollar products



Launched STAR-LLD program

Multiple additional candidates for continuous delivery identified

Initial focus on new indications

STAR-LLD (lenalidomide; REVLIMID)

	Indication	Status
STAR-LLD SC subcutaneous infusion	**Chronic Lymphocytic Leukemia (CLL)** (use of proceeds for current financing)	**Entering Phase 1** (Expect single Phase 1 PK study)
	Multiple myeloma	
STAR-LLD TDS transdermal delivery system	CLL	**Formulation development ongoing** Projected completion April 2021
	Multiple myeloma	
	Lymphoma + other heme malignancies	

- **New indications**
- Based on existing randomized controlled studies [1,2,3]
- **De-risked**
- **Differentiated targets** within competitive landscape

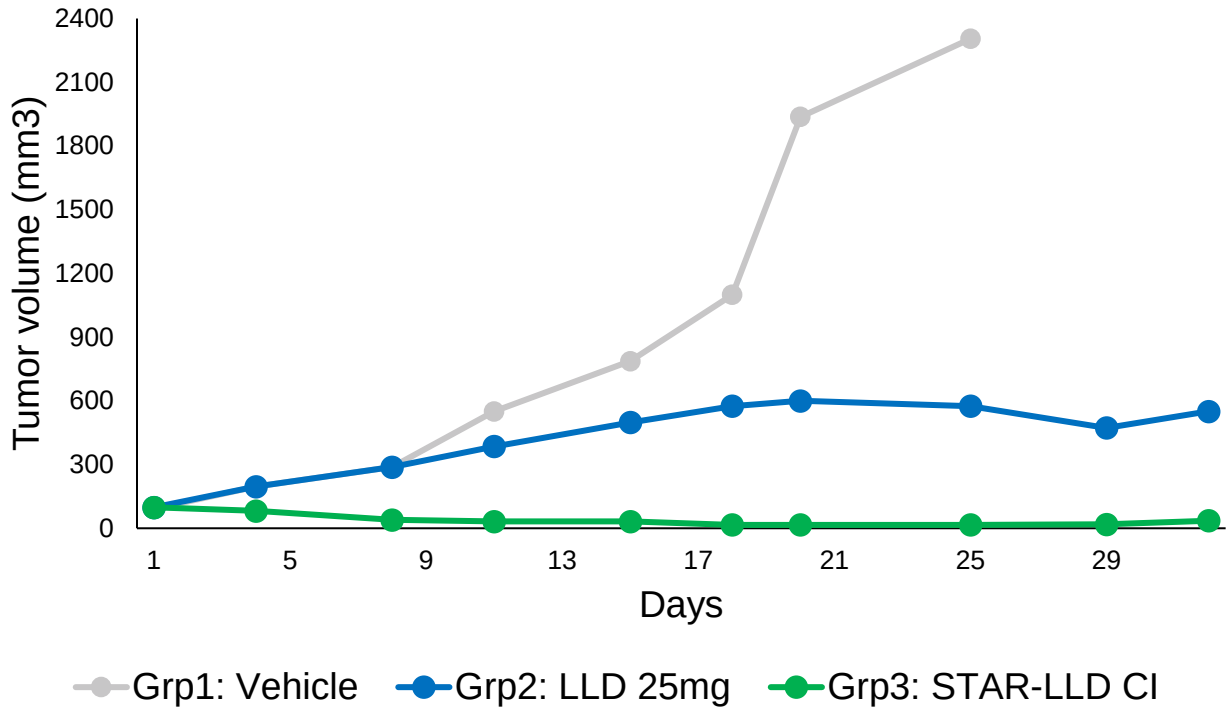
STAR-LLD unlocking the full immunomodulatory benefit of REVLIMID

Sources: 1. Chanan-Khan 2017 Lancet Hematol (CONTINUUM study) 2. Fink 2017 Lancet Hematol 3. Chanan-Khan 2017 Leukemia

STAR-LLD proof of concept study – **unprecedented** efficacy results

Tumor volume in mice
CB.17 SCID mice
H929 multiple myeloma xenograft model

Study evaluated tolerability and efficacy of lenalidomide (LLD) intraperitoneal (IP) injection (standard of care in this model) vs. LLD continuous subcutaneous delivery in SCID mice



Group	Tumor volume increase (day 29)
GRP 1 (vehicle)	+ 2518%
GRP 2 (lenalidomide IP standard of care)	+ 483%
GRP 3 (STAR-LLD SC continuous infusion)	- 81%

GRP 3 is **77%** **reduction in AUC**

Lenalidomide continuous infusion displayed superior efficacy over standard of care
CI: Continuous infusion IP: Intraperitoneal

SCID: severe combined immunodeficient

STAR-LLD in chronic lymphocytic leukemia (CLL) Overview

Strong existing data supporting lenalidomide in CLL [1,2,3]

- NCCN guidelines recommend lenalidomide for the **maintenance treatment of CLL;** but label contraindication limits use

NCCN National Comprehensive Cancer Network®

- Two Phase III trials completed by LLD oral innovator demonstrate that **progression-free survival was substantially longer** in the lenalidomide group over placebo (33.9 months vs 9.2 months)[1]

Dose escalation design resulted in tolerability issues

- No immunomodulatory drugs (IMiDs) currently approved for CLL
- Eligible for Orphan Drug Designation
- One STAR-LLD target eligible for Breakthrough Designation

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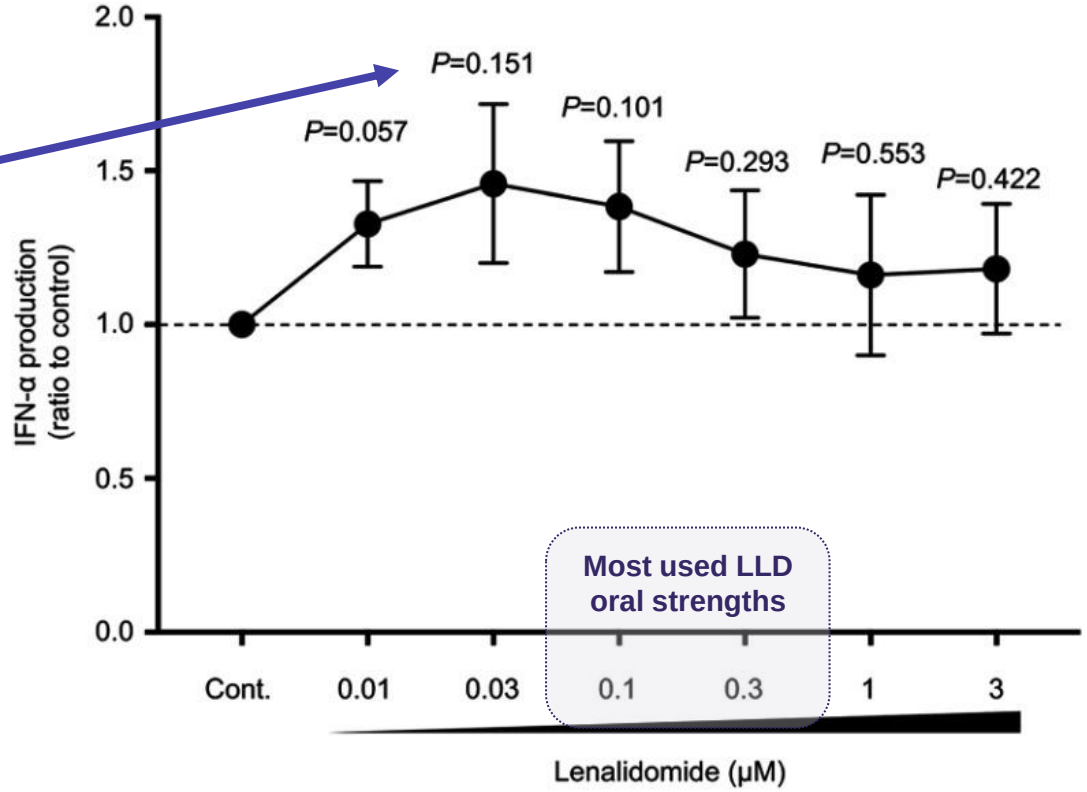
Source: 1. Chanan-Khan 2017 Lancet Hematol (CONTINUUM study) 2. Fink 2017 Lancet Hematol 3. Chanan-Khan 2017 Leukemia

STAR-LLD designed to stimulate immune function at **lower** blood concentrations

- Lenalidomide downregulates VEGF, IL-6, and TNF-α [1]
- Maximal change in IFN-α: **0.03 µM** – ***lower dose*** *than 15-25mg used in clinical practice, = STAR-LLD target blood concentration*
- LLD has meaningful immune activity in CLL [2]

STAR-LLD continuous, low-dose

Unlocking the full immunomodulatory benefit of lenalidomide



J Blood Med. 2019; 10: 217–226.

Human PBMCs incubated for 24 h with the indicated concentrations of LLD or vehicle. Data are shown as means ± SEMs of seven independent donors normalized to the value obtained for the vehicle control.

1. Mitsiades CS, Mitsiades N. *Curr Opin Investig Drugs* 2004; 2. Chanan-Khan 2006 Lancet Oncol

STAR-LLD in CLL peak revenue of $2B – $3B (US only, first indication estimate)

STAR-LLD in CLL

Target indication	Addressable patient population	STAR-LLD tx
Maintenance following BTK in MRD+ patients	6,200	2-3 years
Combination with venetoclax (VCLX)	4,300	1-2 years
Relapsed/refractory	2,000	12 months

Standard of care annual cost of therapy: **$160,000 / year**

CLL

is the MOST COMMON leukemia in adults older than 19, accounting for **37% OF CASES**[1]

21K

Americans will be diagnosed this year[1]

$6.2B

Est. US CLL market[5]

$3.4B

2020 US revenue forecast for Ibrutinib in CLL [5] – CLL standard of care; **no IMiD approved in CLL**

Sources: 1. American Society of Clinical Oncology (ASCO). 2. ASCO 3. National Institutes of Health 4. GlobalData, 2017 2020 estimate 5. DRG 2017, 2020 estimate

*Patient estimates year: 2026..Revenue estimate assumes **no price increases***

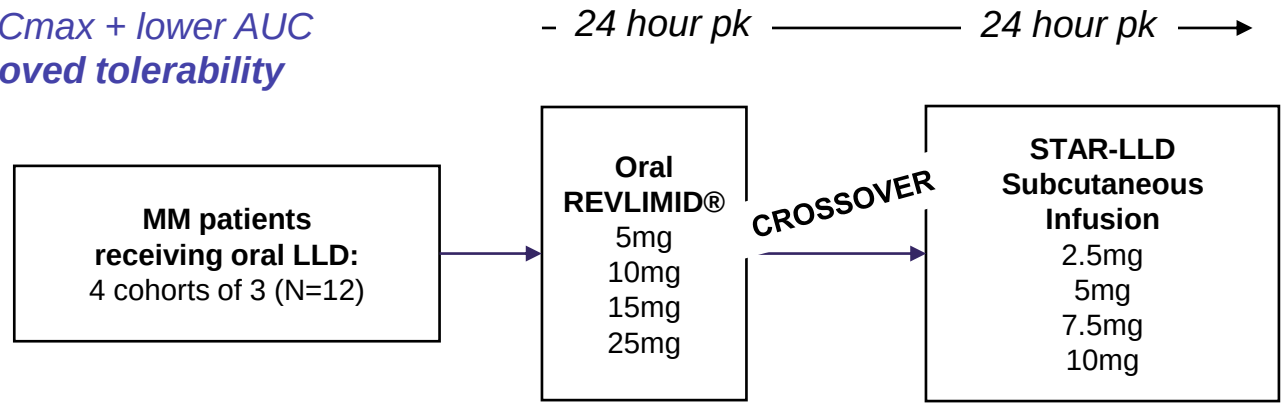
STAR-LLD Requires Only a Simple Pharmacokinetic (PK) Phase 1

Phase 1: A Comparative Bioavailability Study of a Subcutaneous Application of Lenalidomide Compared with Oral REVLIMID® in Multiple Myeloma Patients

PRIMARY OBJECTIVES:

- Establish that STAR-LLD has a **lower Cmax and AUC** than oral REVLIMID
- Measure PK of STAR-LLD SC in multiple myeloma patient population

Lower Cmax + lower AUC
*= **improved tolerability***



Study Details:

- **Low cost** ($< 2.0 mn)
- **Low risk** (delivery system known to deliver lower Cmax and AUC in all applications)
- **Fast duration** (3 months from site-open to data readout)
- Phase 1 PK supports **initiation of Phase 2's** in both CLL and MM (FDA PIND confirmed 2/19)
- *Confirms STAR-LLD reference to all REVLIMID nonclinical safety via 505(b)2*

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MM: multiple myeloma; AUC: area under the curve

STAR-OLZ (olanzapine)

505(b)2 accelerated path

	Indication	Status
STAR-OLZ transdermal delivery system	**Chemo induced nausea and vomiting (CINV)**	**Entering Phase 2/3**
	PARP inhibitor induced nausea and vomiting (PIINV)	**Phase 1 complete**

Rudolph Navari, MD

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

- Hematologist Oncologist leading majority of published research on olanzapine in CINV
- Leads Starton supportive care advisory committee

MASCC Multinational Association of Supportive Care in Cancer
Supportive Care Makes Excellent Cancer Care Possible

- Superiority in **Nausea Control** (CINV)
- Based on existing randomized controlled studies [1,2,3]
- **De-risked** and **fast to market**
- **Price benefit** within competitive landscape

STAR-OLZ validates Starton delivery system

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Sources: 1. Navari et al. 2011, 2. Navari et al. 2015 [abstract], 3. Chiu 2016

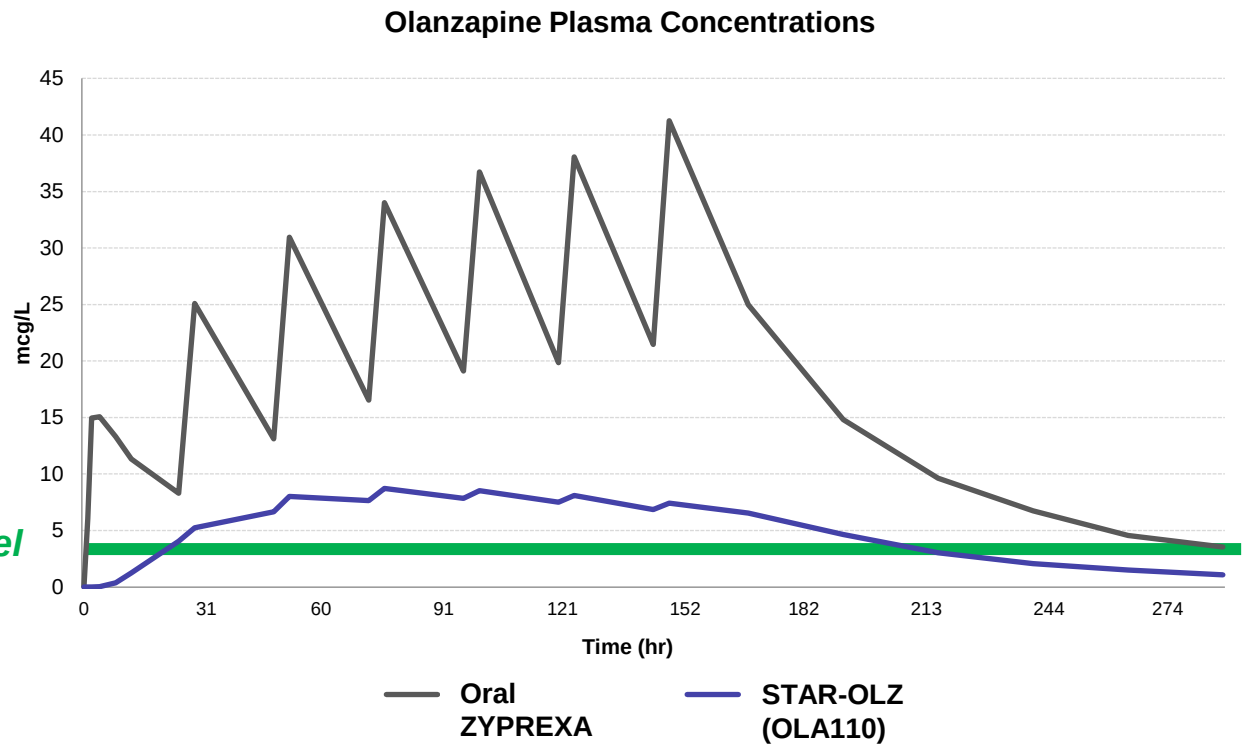
STAR-OLZ Phase 1 human BA results confirm benefit of Starton platform technology

Phase 1 human bioavailability (BA)
N=16 Healthy female volunteers

Study characterized the bioavailability and plasma PK profile of a 7-day application of OLA110 transdermal olanzapine compared to 10mg oral daily Zyprexa® for 7 consecutive days

Cohort 1 (Zyprexa)		
Parameter	**Mean**	**STD**
Total Study Dose	70,000 mcg	N/A
$AUC_{0-\infty,}$	5287 mcg/L/hr	±1599 mcg/L/hr
Cmax Day 1	15 mcg/L	±4.4 mcg/L
Tmax Day 1	4 hr	N/A
True Cmax	41.26 mcg/L	±11.4 mcg/L
Tmax	148 hr	N/A

Cohort 2 (OLA110)		
Parameter	**Mean**	**STD**
Projected Study Dose Based on Plasma Measures#	22,447 mcg	±9151 mcg
$AUC_{0-\infty,}$	1496 mcg/L/hr	±610 mcg/L/hr
Cmax Day 1	4.0 mcg/L	±2.3 mcg/L
Tmax Day 1	24 hr	N/A
Cmax	9.3 mcg/L	±3.4 mcg/L
Tmax	100 hr	N/A



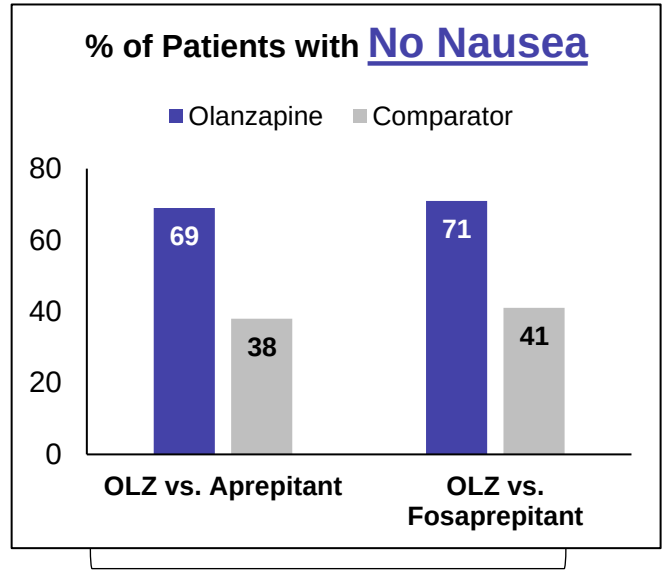
- STAR-OLZ met all endpoints in Phase 1 study
- STAR-OLZ patches exhibited acceptable skin irritation over 5 days following patch removal and reliable adhesion during the study

BA: bioavailability. Study conducted with IND waiver from FDA

STAR-OLZ in nausea and vomiting (NV) Overview

Olanzapine antiemetic efficacy is accepted and proven

- NCCN+ASCO guidelines recommend olanzapine for NV
- Multiple Phase 3 trials supporting **SUPERIORITY** of OLZ in controlling nausea [1,2,3]
- Current OLZ label has no NV indications, STAR-OLZ brings new mechanism of action to antiemetic standard of care
- STAR-OLZ in development to replace NK1 in standard of care CINV regimen



0 – 120hr CINV

CINV : Chemotherapy induced nausea and vomiting
1. Navari et al. 2011, 2. Navari et al. 2015 [abstract], 3. Chiu 2016