Platform for new standards of care in hematologic malignancies

powering continuous delivery of FDA-approved drugs

NOVEMBER 2020 **OVERVIEW**

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Executive Summary

Clinical-stage biotech platform with potential to become standard of care:

- **Continuous delivery platform, developing new indications of approved blockbuster drugs**
  - Proprietary selection for platform technology - identifies candidates for new indications where there is no standard of care or the current standard of care is not ideal
  - Platform technology allows for lower AUC, C_{max}, and drug exposure & potential for improved efficacy and tolerability
- **Multiple shots on goal, with consistent value-adding milestones**
  - Two transformational programs entering Phase 1/2 in hematologic malignancies (STAR-LLD)
  - Advanced program entering Phase 2/3 in cancer supportive care (STAR-OLZ)
- **Experienced Board and management team**
  - Former Pfizer President of Global Primary Care + Celgene Global Lead, Multiple Myeloma
  - World-renowned leaders in their field leading each program
  - Breadth of operational expertise in regulatory, clinical, in manufacturing, and in intellectual property

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

First target product: lenalidomide (REVLIMID)

- Revlimid is the standard of care in multiple myeloma (MM)
- Revlimid is the #3 highest revenue-generating drug in the world, projected $12 Bn global revenue in 2020 [1]
- It was developed and marketed by Celgene, who was acquired in 2020 by Bristol Myers Squibb for $70 Bn

STAR-LLD (LENALIDOMIDE)

subcutaneous and **transdermal** delivery systems

TO TREAT:

1. **Unique, new indications** in **Chronic lymphocytic leukemia** (CLL) – the most common leukemia in adults
2. **Significant unmet needs** and expanding Revlimid in **Multiple Myeloma** (MM) – the second most common blood cancer diagnosis

New indications

Based on existing randomized controlled studies [2,3,4]

De-risked

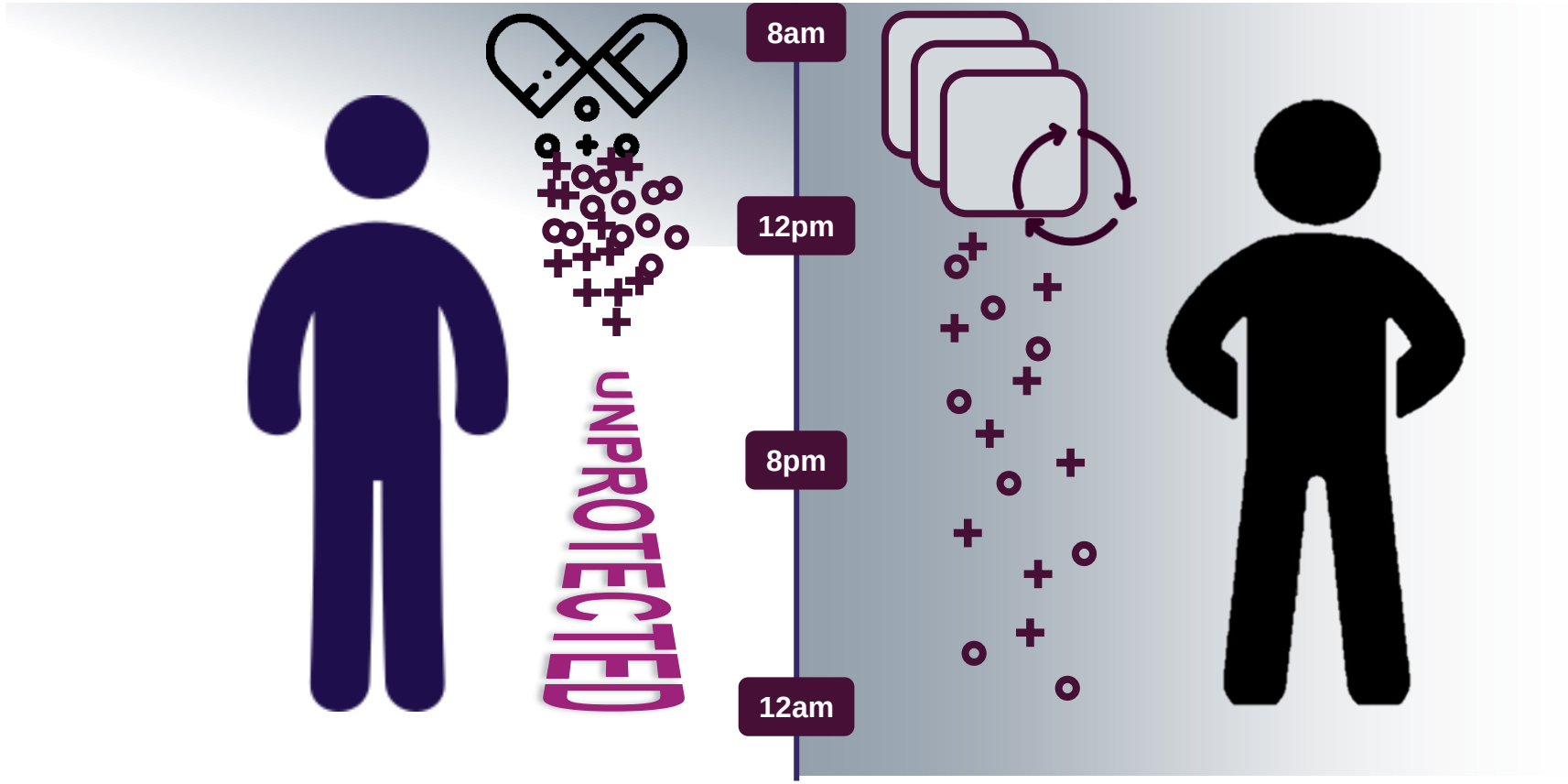
Differentiated targets within competitive landscape

STAR-LLD is a new, improved Revlimid.

Sources: 1. FierceBiotech 2. Chanan-Khan 2017 Lancet Hematol (CONTINUUM study) 3. Fink 2017 Lancet Hematol 4. Chanan-Khan 2017 Leukemia

Continuous delivery avoids periods of unprotection due to short half-life

- In oncology settings, short half-life drugs wear off quickly and leave cancer cells without contact to the drug between dosing intervals
- Oral drugs provide a high initial dose, resulting in unnecessary early high blood levels and potential for adverse reactions
- Starton uses continuous delivery systems to significantly improve **lifespan and quality of life** in hematological malignancies (blood cancers)



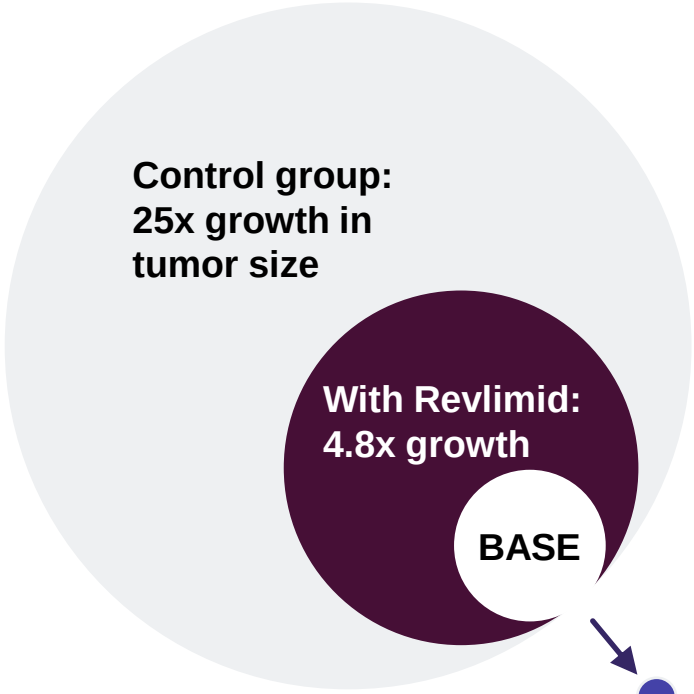
Oral delivery
Revlimid half-life: **3 hours**[1]

STARTON Transdermal + Subcutaneous
Continuous delivery systems

Sources: 1. REVLIMID Product Information

No other product has achieved STAR-LLD's response in the standard multiple myeloma (MM) animal model

STAR-LLD vs. **REVLIMID standard dose** vs. Control (placebo) in H929 **multiple myeloma xenograft model**



Illustrative representation of tumors
Not to scale

-80%
decrease in tumor size with **STAR-LLD**

- **All STAR-LLD animals alive at the end of the study.**
- Revlimid group **all died at 55 days**
- Control group **all died at 29 days**

- **80% decrease in tumor size.**
- vs **4.8x growth** with Revlimid SOC
- and **25x growth** in control groups

Animal results supported filing of **strong, broad patent family** with coverage through **2041**

Full study design and results in Appendix
SOC: Standard of Care

STAR-LLD in chronic lymphocytic leukemia (CLL): Overview

Strong existing data supporting lenalidomide in CLL

- NCCN guidelines recommend lenalidomide for the **maintenance treatment of CLL.**

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

- Multiple peer-reviewed, double-blinded academic studies in various settings supporting use of LLD in CLL [1,2,3]
- There are no immunomodulatory drugs (imids) currently approved for CLL

- Targeting three new indications in CLL →

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

STAR-LLD in multiple myeloma (MM): Overview

Oral lenalidomide (Revlimid) is standard of care for MM, but many patients do not achieve the full benefit of the drug

OVER 80%	**50%**	**UP TO 30%**
of patients dose-reduce due to toxicities [1]	of patients are Minimal Residual Disease positive (MRD+) after first line treatment [2]	of patients do not respond to therapy [3]

- STAR-LLD expected to expose the patient to 70% less drug [6]
- STAR-LLD modifies plasma pharmacokinetics which are associated with toxicity, including hematologic adverse events [4,5]
- Targeting four indications in MM →

Sources: 1. Revlimid prescribing information 2. Lahuerta et al. 2017 J Clin Oncol 3. Primary Research – Starton Scientific Advisors 4. Chen 2013, Blood 5. Brideau et al 2016 Cancer Chemother Pharmacol 6. Starton PK model and in vivo data

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**

chronic lymphocytic leukemia

MM

is the SECOND MOST COMMON blood cancer diagnosis, after non-Hodgkin lymphoma[2]

32K

Americans will be diagnosed this year[2]

$12.5B

Est. US MM market[4]

$6.5B

2020 US revenue forecast Revlimid in MM [4]
– the standard of care for MM

multiple myeloma

Multibillion-dollar opportunities for STAR-LLD in CLL and MM

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

Imid = immunomodulatory drug

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

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Kenneth Anderson, MD	Multiple Myeloma Lead, Board Member	Dana Farber Cancer Institute, Harvard Medical School
Asher Chanan-Khan, MD	CLL Lead	Mayo Clinic

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

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starton THERAPEUTICS

Starton is raising $30mm to advance the development of STAR-LLD.

This is an opportunity to invest in a

platform with successful assets

based on proven science,

with strong evidence supporting new indications

and a data-driven pipeline of additional assets

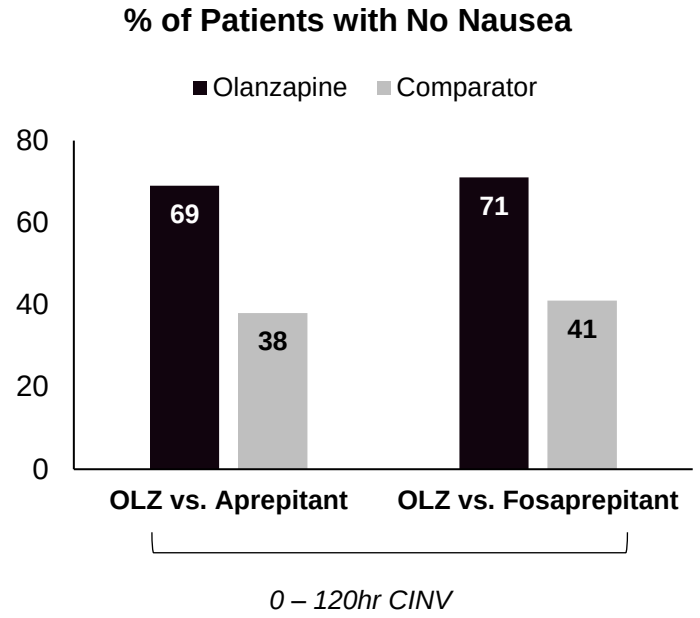
CONTACT: investors@startontx.com | +1 551 287 6456

Appendix

STAR-OLZ in nausea and vomiting: Overview

STAR-OLZ is a 7-day transdermal delivery system (TDS) of olanzapine
(reference: ZYPREXA)

- Multiple randomized controlled studies show OLZ vs standard of care is:
  - **<u>superior</u> in control of nausea**
  - **non-inferior in control of vomiting**
- NCCN guidelines recommend OLZ for CINV
- Current OLZ label has no nausea and vomiting (NV) indications
- STAR-OLZ has successfully completed its human bioavailability (BA) study and a pre-IND meeting for PIINV with FDA



Navari et al. 2011, Navari et al. 2015 [abstract]

- Targeting two indications in nausea and vomiting →

CINV : Chemotherapy induced nausea and vomiting

STAR-OLZ in nausea and vomiting: Two initial target indications

Target	Current Approach	STAR-OLZ Addressable Patient Population
1) Chemotherapy induced nausea and vomiting (CINV) Superior in Total Control vs NK1	• Triple regimen with an NK1, 5HT3, and dexamethasone	Patients per year, US only, 2026 **1.3 million** acute patients per year
2) PARP inhibitor induced nausea and vomiting (PIINV) New indication	• Nothing approved for PIINV today • Existing antiemetics have shown weak nausea control • PARP inhibitors are approved in ovarian and breast cancer and expanding in to prostate and pancreatic cancers	**82,900** chronic patients per year

NEXT STEPS

- **IND approval**
- **Initiate Phase 2/3 registration study in CINV**

starton THERAPEUTICS

Sources: Company forecast, DRG, SEER
NK1: neurokinin 1 5HT3: serotonin PARP: poly-ADP ribose

Pipeline Overview

Program	Active	Indications	Preclinical/Nonclinical	Phase 1/2	Phase 2/3
STAR-LLD SC subcutaneous infusion	Lenalidomide (REVLIMID)	Chronic Lymphocytic Leukemia (CLL)			
		Multiple Myeloma (MM)			
STAR-LLD TDS transdermal delivery system		CLL			
		Multiple Myeloma (MM)			
		Lymphoma			
STAR-OLZ TDS transdermal delivery system	Olanzapine (ZYPREXA)	Chemo-induced NV (CINV)			
		PARP-induced NV (PIINV)			
		Breakthrough CINV			
		Chronic nausea in cancer			