

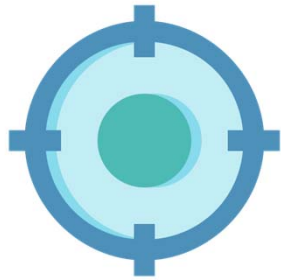


Lyndra

**What if we stop trying to change the patient,
and changed the pill instead?**



Transforming the Way We Take Medicine for a Healthier World



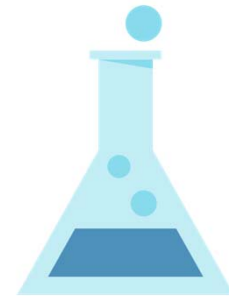
Our Vision

Ultra-long-acting oral medicines will remove the burden of daily pills and improve compliance, health, and quality of life for patients and caregivers.



Our Approach

Human nature is a hard thing to change. At Lyndra, we've turned the problem on its head. We ask, "What if we stopped trying to change the patient, and changed the pill instead?"



Our Therapies

Our ultra-long-acting oral medicines provide better health outcomes and quality of life, reduced side effects, improved drug efficacy, slowed spread of disease, and lower health costs.



Company Progression

Institutional

\$1.3 M Seed Round (2015)
\$23.5 M Series A (2017)
\$XX M Series B (2019)



Quark
venture



Grants

\$0.3 M NIH (2016)
\$6 M NIH (2017)
\$4 M BMGF (2017)
\$18 M NIH (2018)
\$XX M BMGF (2018)
\$X M DoD (2019)



National Institutes
of Health

BILL & MELINDA
GATES foundation



Access to KOLs & Resources
Complementary Initiatives

Partnerships

\$0.3 M Undisclosed (2016)
\$105 M Allergan (2017)
\$80 M Lyndra China JV (2018)



Global Development
Complementary Resources

Development

Preclinical Demonstration (2016)
Science Translational Medicine Paper (2016)
GMP Manufacturing (2017)
First in Human (2017)
Nature Communications Paper (2018)
Multiple Phase 1 Studies (2018)
US IND (2019)



Platform IP
Diverse Portfolio
Risk Reduction
Shared Investment



Experienced Team



Amy Schulman
Co-Founder
Board Member
President & CEO



Dr. Andrew Bellinger
Co-Founder
Chief Scientific Officer



Jessica Ballinger
Chief Operations Officer



Raymond Knox
Chief Engineering Officer



Jaqueline Schumacher
Vice President
Regulatory & Quality



Dr. David Altreuter
Vice President
Pharmaceutical Sciences



Dr. Susan Low
Vice President
Pharmacology &
Toxicology



Carlos Famadas
Vice President
Finance



Dr. Steve Zale
Scientific
Fellow



Dr. Tyler Grant
Associate Director
Engineering



Dr. Rose Kanasty
Associate Director
Exploratory Technologies



Board of Directors & Advisors



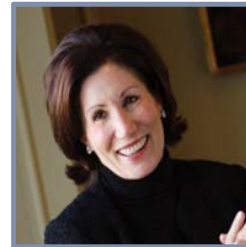
Dr. Robert Langer
Co-Founder
Board Member



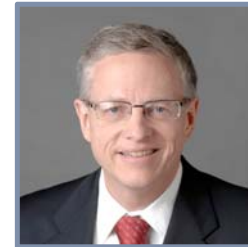
Dr. Gio Traverso
Co-Founder
Board Member



Amy Schulman
Co-Founder
Board Member
President & CEO



Catherine B Reynolds
Chairwoman
of the Board



Dr. Edmund Harrigan
Board Member



Dr. Zafrira Avnur
Board Member

Dr Colin Gardner
Co-Founder Kala Pharmaceuticals, CSO
Living Proof & TransForm
Pharmaceuticals

Dr Jim Wright
CSO Bind Therapeutics & Expert
Controlled Drug Delivery

Dr. Ian Wilding
Internationally Recognized
Pharmaceutical Sciences & Oral Delivery
Expert

Dr Lawrence J. Lesko
Professor University of Florida, College of
Pharmacy

Dr. Thomas Laughren
Director, Laughren Psychopharm
Consulting, LLC. Former FDA Division
Director of Psychiatric Products

Dr. Bruce Sands
The Dr. Burrill B. Crohn Professor of
Medicine and Chief of the Dr. Henry D.
Janowitz Division of Gastroenterology at
Icahn School of Medicine

Dr. Robert Meyer
Director, Virginia Center for Translational
and Regulatory Sciences at the University
of Virginia's School of Medicine and
Associate Professor of Public Health
Sciences

Dr. Peter Belafsky
Professor of Otolaryngology and the
Director of The Center for Voice and
Swallowing. Professor at UCD
Department of Epidemiology and School
of Veterinary Medicine



What if we stop trying to change the patient, and changed the pill instead?

Health Outcomes Depend on People Taking their Medicines as Indicated

“Drug Don’t Work in Patients Who Don’t Take Them.”
- former US Surgeon General C. Everett Koop

MEDICATION NONADHERENCE

causes at least

10% of

Hospitalizations

125,000

Deaths per Year

\$289 BN

Annual costs to US Healthcare

This **costs our health system** and **affects more people** than any actual disease

And it can be

100% preventable*

*Brody, Jane E. “The Cost of Not Taking Your Medicine.” The New York Times, The New York Times, 17 Apr. 2017, www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html.

Studies of non-adherence to medication in patients with major medical conditions

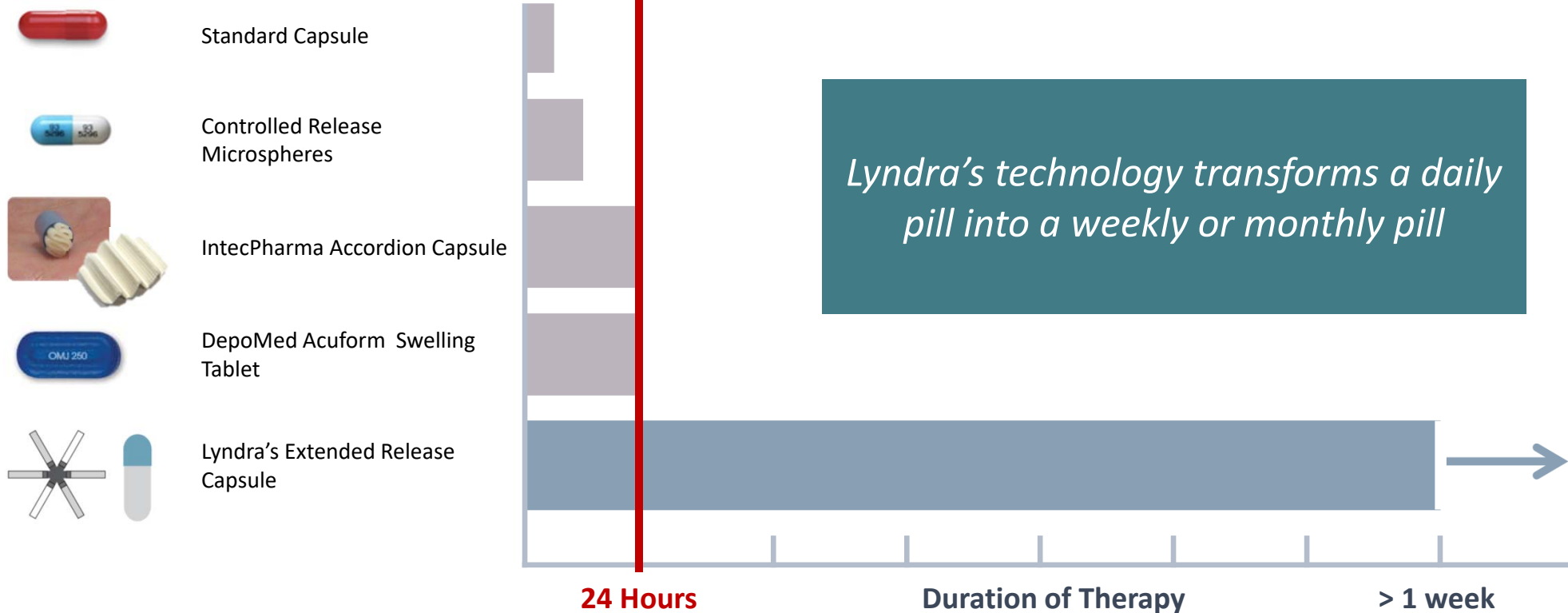
Medical condition	Number of studies	Non-/poor adherence
Diabetes mellitus	23	32.5%
Pulmonary diseases	41	31.2%
Infectious diseases	34	26.0%
End-stage renal disease	20	30.0%
Eye disorders	15	27.4%
Infectious diseases	34	26.0%
Obstetric and gynecological disorders	19	25.2%
Ear, nose, throat and mouth disorders	30	24.9%
Cardiovascular diseases	129	23.4%
Skin disorders	11	23.1%
Genitourinary and sexually transmitted diseases	17	23.0%
Cancer	65	20.9%
Gastrointestinal disorders	42	19.6%
Arthritis	22	18.8%
HIV/AIDS	8	11.7%

Kane, J. M., Kishimoto, T. and Correll, C. U. (2013), Non-adherence to medication in patients with psychotic disorders: epidemiology, contributing factors and management strategies. World Psychiatry, 12: 216-226



Lyndra has Developed the First Ultra-long Acting Oral Pill

Oral Competitive Landscape



Patient Experience with Lyndra Dosage Form

1

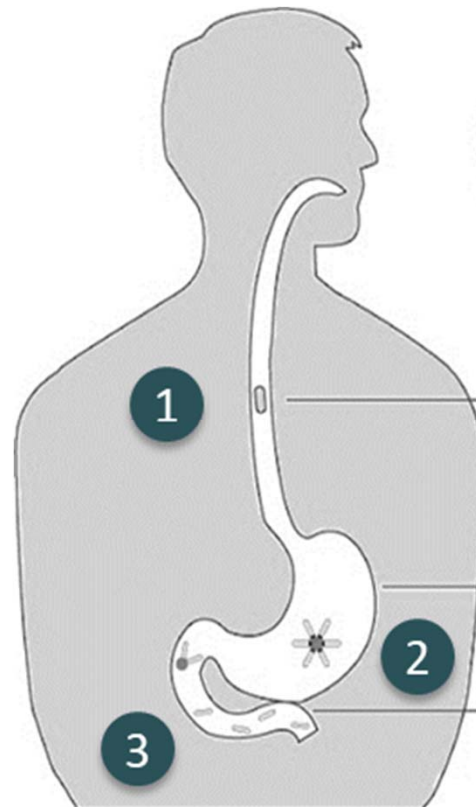
Capsule is Swallowed the Same as Other Medications

2

Medication is Released in the Stomach Over One Week

3

Capsule Exits the Stomach as Normal Food After the Week Ends



Comorbidity Considerations

- Gastroparesis (diabetes, elderly, etc.)
- Motility modulating drugs
- Constipation/intestinal motility
- Food and drug effects (alcohol, PPIs)

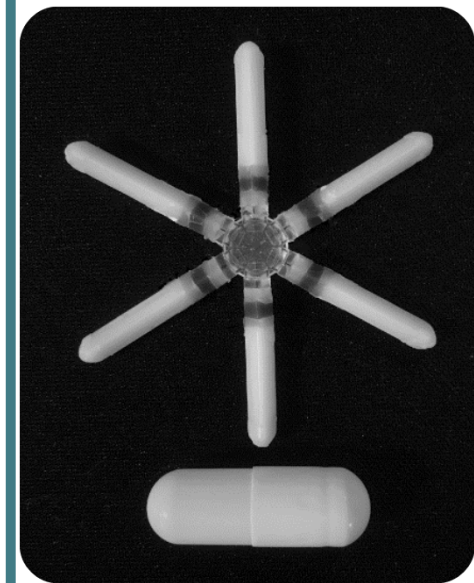
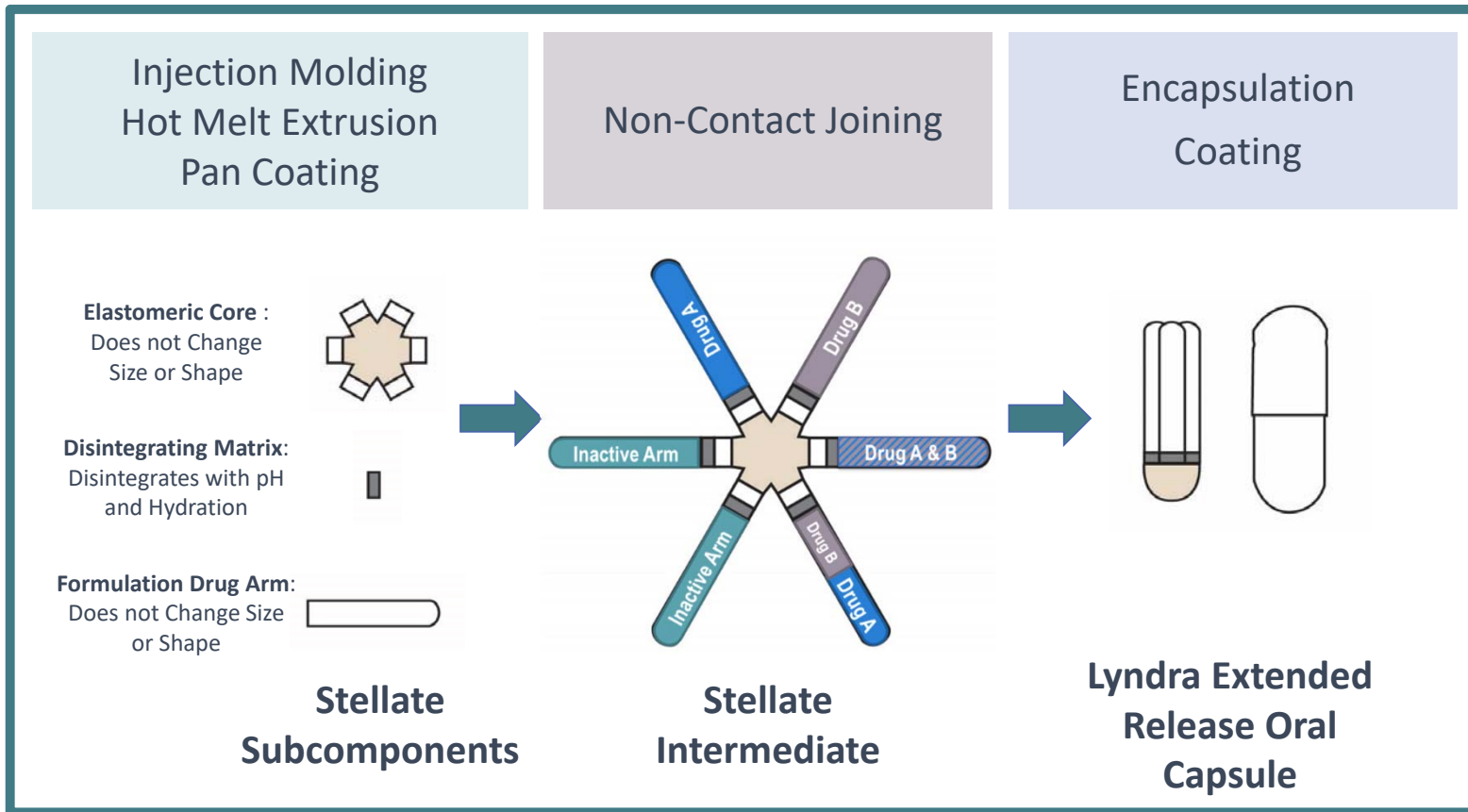
Esophageal Transit

Retention and Drug Release

Gastric Exit and Safe Passage



Lyndra's Dosage Form



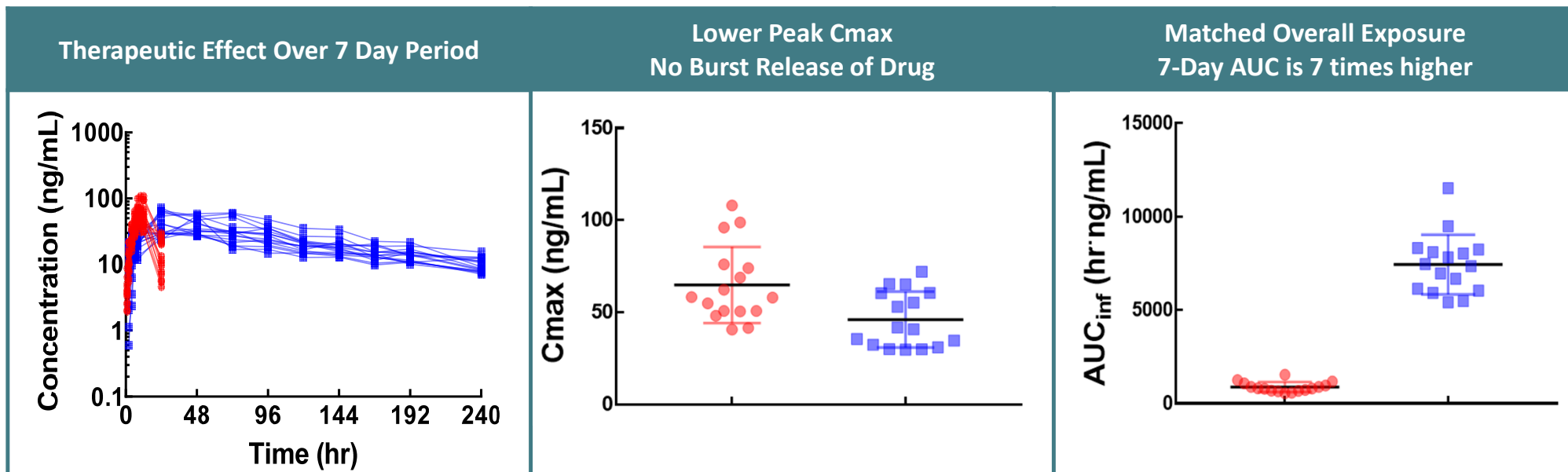
Overall Closed Length for Size 00 EL Capsule



Preclinical Pharmacokinetics Proof of Concept

Comparison of a Commercial Single Daily Dose Extended Release Product to Lyndra 7-Day Product of Single Agent:

- Achieved 7 fold higher AUC with a lower Cmax
- Potentially lower inter-subject variability



■ XR: Sustained Release Commercial Product
■ LYN Dosage Form



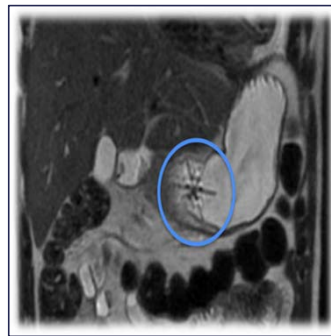
Clinical Translation

Lyndra's once-weekly product has demonstrated gastric residence is achievable with predictable pharmacokinetics in humans

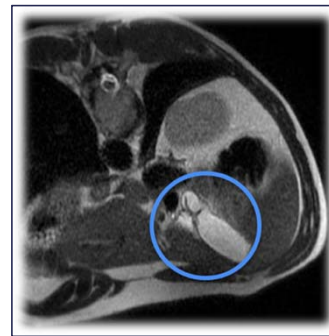
Demonstrated Gastric Residence at 7 Days by MRI



Day 2
In Stomach

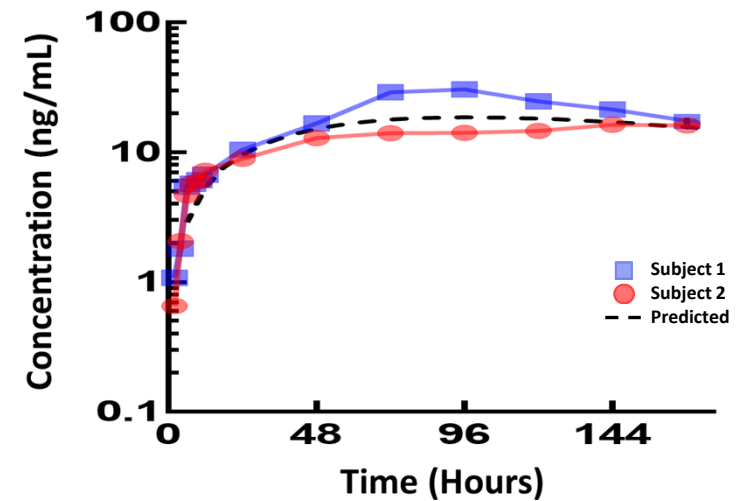


Day 4
In Stomach



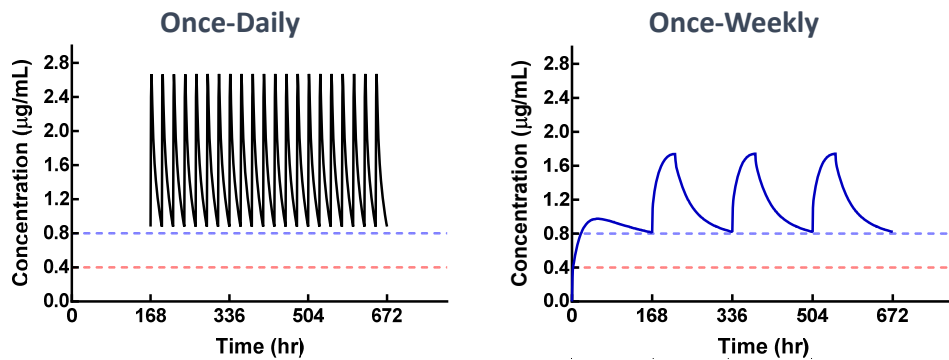
Day 7
Disintegrating
and Exiting Body

Demonstrated Initial 7-day PK : 100% Bioavailability & No Burst Release of Drug

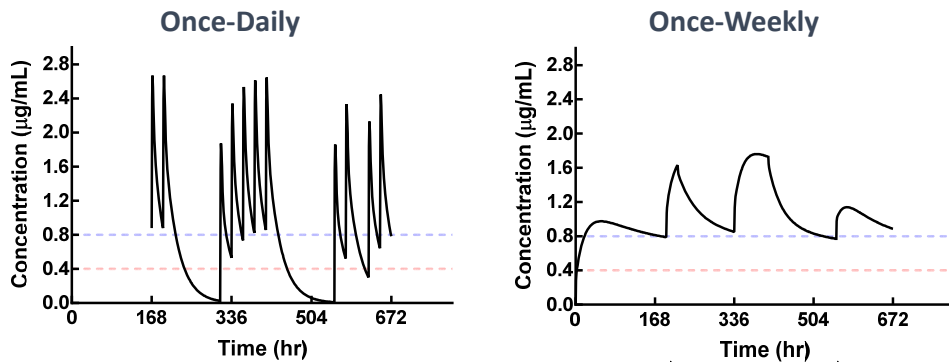


Lyndra's Dosage Form Will Provide Better Efficacy and Safety in Clinical Practice

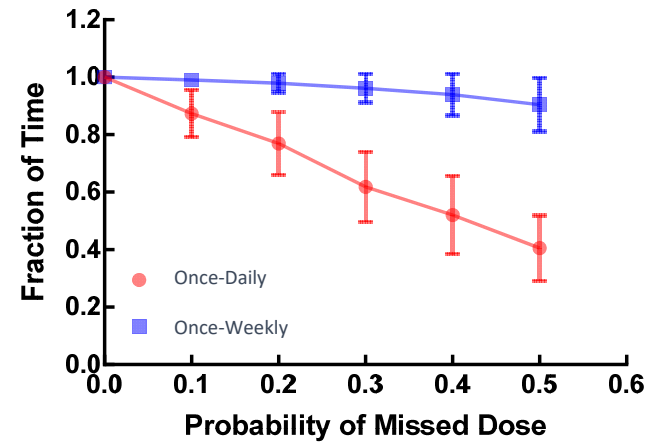
100% Adherence



50% Adherence



Once-weekly therapy maintains protective plasma levels for a considerably greater fraction of the time than once-daily therapy



Average fraction of time above 0.8 ug/mL based on 1000 Monte Carlo simulations

Monte Carlo mathematical model assessing impact of non-adherence on plasma concentration profiles by simulating PK profiles for a given probability of a missed or delayed dose

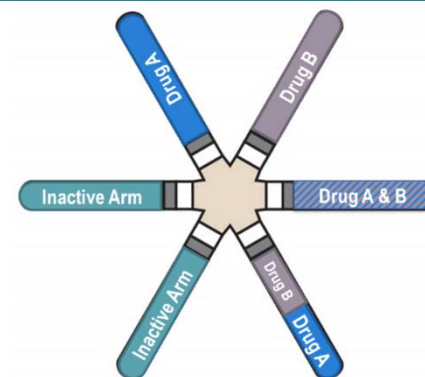


Clinical Translation and Pipeline Expansion Will be the Focus for Next 2 Years



Dosage Form Modularity Provides the Ability to Combine Execution Plans and Expand Pipeline through:

- Sharing preclinical and clinical data and experience across multiple products
- Allowing multiple drugs to be included in one capsule
- Manufacturing scale-up for commercialization with a shared platform, resulting in speed and cost efficiencies



Lyndra Will Provide Real World Value With a Combination of Improved Pharmaceutical Patient Experience and Increased Clinical Benefit

Pharmacology

- Advantages in systemic, non-systemic, and local target applications due to continuous & steady delivery
- Possibility of reducing total dose while maintaining efficacy (non-inferiority)
- Reducing Cmax could improve side effect profile
- Forgiveness if delayed administration

Therapeutic Impact

- Reduced healthcare costs through better pharmacology and measurable health outcomes
- Patient freedom from the burden of daily medications

Products

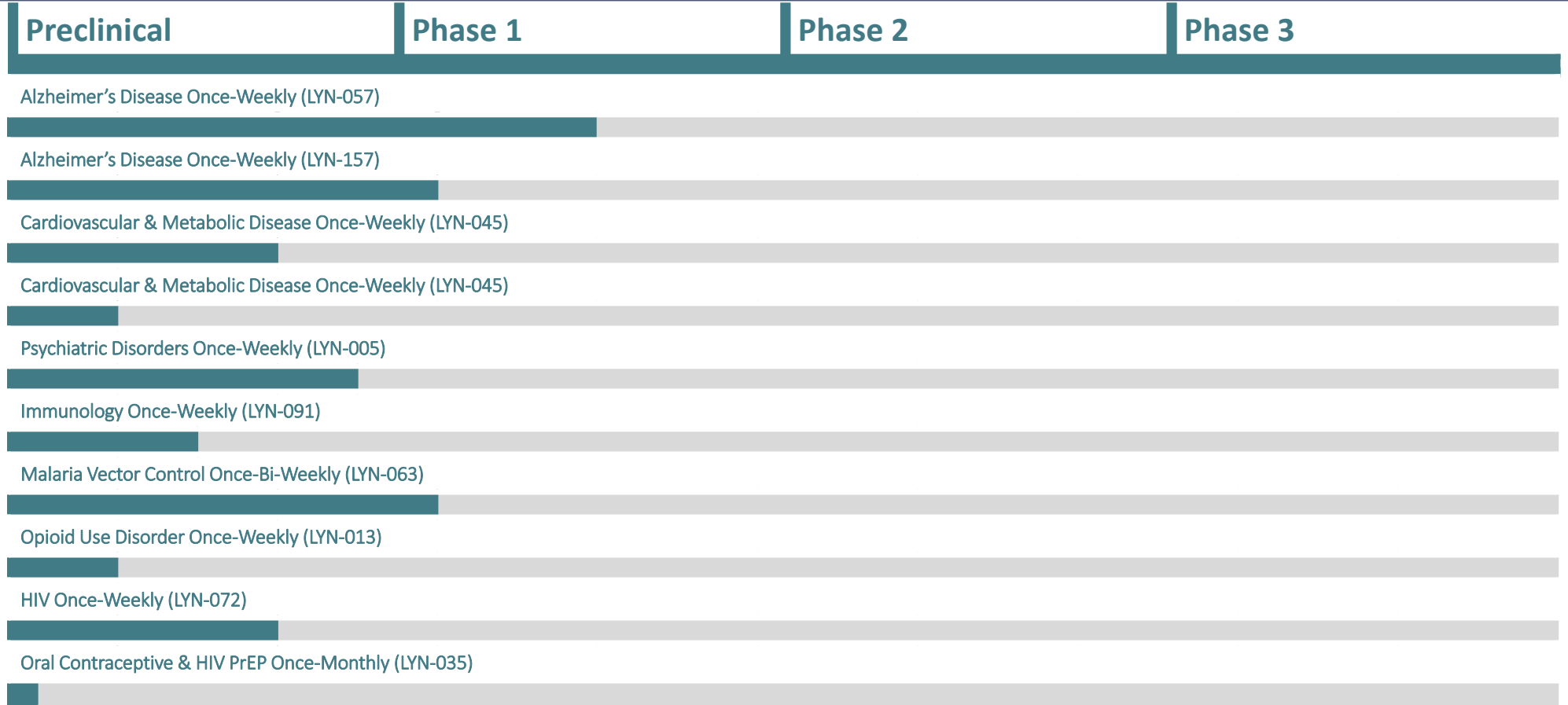
- Adaptable for wide range of single agents (small molecule / peptide) and combinations
- Discreet user controlled administration
- Reduced pill burden
- Reduced caregiver burden

Applications

- Superior Pharmacology for existing Agents
- Peri Loss of Exclusivity (LOE)
- Combination Products
- Local GI Delivery
- Non-systemic Delivery Enhanced Continuous Release
- True NCEs with established mechanisms of action



Pipeline



Lyndra Has a Robust Intellectual Property Portfolio

Title	Priority date	National Filings
Residence Structures and Related Methods	6/11/2014	AU, BR, CA, CN, EP, IL, IN, JP, KR, MX, NZ, RU, SG, US, ZA
Residence Structures and Related Methods	6/11/2014	US
Enteric Elastomers	6/11/2014	AU, CA, CN, EP, JP, US
Self-Assembled Residence Devices and Related Methods	6/11/2014	AU, CA, CN, EP, JP, US
Triggerable Shape Memory Induction Devices	5/1/2015	US
Gastric Residence Systems for Sustained Release of Therapeutic Agents*	10/23/2015	AU, CA, CN, EP, JP, US
Geometric Configurations for Gastric Residence Systems	12/8/2015	AU, BR, CA, CN, EP, HK IL, IN, JP, KR, MX, NZ, RU, SG, US, ZA
Gastric Residence Systems for Sustained Delivery of Adamantane-Class Drugs	9/30/2016	PCT
Materials Architecture for Gastric Residence Systems	5/27/2016	PCT, TW
Gastric Residence Systems with Release Rate-modulating Films	6/9/2017	PCT, TW
Encapsulation of Gastric Residence Systems	9/20/2017	Provisional
Gastric Residence Systems Using Osmotic Pumps	6/26/2018	Provisional
Systems for Enteric Delivery of Therapeutic Agents	8/15/2018	Provisional

 MIT/Partners-Licensed
  Lyndra-owned





Lyndra in the News



Lyndra
@LyndraInc

Following

What if we stopped trying to change peoples' behavior, and instead changed the pill?" –@AmyLyndra at today's #TEDMED session



1:20 PM - 2 Nov 2017

theguardian

Long-lasting pill that releases malaria drug for two weeks a 'game-changer'



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BUSINESS
INSIDER

A Gates Foundation-backed startup **wants to make daily pills a thing of the past**

BOSTON
BUSINESS JOURNAL

Watertown's Lyndra strikes Alzheimer's pact with Allergan worth up to \$105M



BBC NEWS

"Medical advances have come on leaps and bounds for HIV in the UK in recent years, however **we do know that taking a pill each day does present practical barriers** for some people living with HIV. We welcome the prospect of a treatment that removes these barriers, and presents all people living with HIV with further choice, provided that it is no less effective than current options available."

- Representative at Terrence Higgins Trust

HUFFPOST

"A **longer-acting, less invasive oral formulation** could be one important part of our future arsenal to **stop the HIV/AIDS pandemic.**"

- Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease

