



Mallinckrodt Strategic Portfolio Development

NeuroproteXeon Xenon Gas for Inhalation Licensing Agreement

October 2, 2017



Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding the proposed development and commercial licensing agreement with NeuroproteXeon, the expected timetable for completing the transaction, future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's and NeuroproteXeon's businesses and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements.

These factors include risks and uncertainties related to, among other things:

- General economic conditions and conditions affecting the industries in which Mallinckrodt and NeuroproteXeon operate;
- The commercial success of Mallinckrodt's products and of NeuroproteXeon's product;
- Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from transactions (including the NeuroproteXeon transaction);
- Conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment;
- Changes in laws and regulations;
- Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings (including with respect to the NeuroproteXeon transaction);
- Mallinckrodt's ability to successfully develop or commercialize new products;
- Mallinckrodt's ability to protect intellectual property rights;
- Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration;
- Customer concentration;
- Mallinckrodt's reliance on certain individual products that are material to its financial performance;
- Cost-containment efforts of customers, purchasing groups, third-party payers and governmental organizations;
- The reimbursement practices of a small number of public or private insurers;
- Pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs;



Forward-looking statements (continued)

- Limited clinical trial data for H.P. Acthar® Gel;
- Complex reporting and payment obligations under healthcare rebate programs;
- Mallinckrodt's ability to navigate price fluctuations;
- Future changes to U.S. and foreign tax laws;
- Mallinckrodt's ability to achieve expected benefits from restructuring activities;
- Complex manufacturing processes;
- Competition;
- Product liability losses and other litigation liability;
- Ongoing governmental investigations;
- Material health, safety and environmental liabilities;
- Retention of key personnel;
- Conducting business internationally;
- The effectiveness of information technology infrastructure; and
- Cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 30, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

Key transaction highlights – exclusive license for pharmaceutical-grade xenon gas for inhalation development product

DEAL CONSIDERATION

- License gives MNK exclusive rights to pharmaceutical-grade xenon gas for inhalation drug-device combination product in development to improve resuscitated cardiac arrest patients' survival/functional outcomes in U.S., Japan, Canada, and Australia
- Upfront payment of \$10 million; additional payments of up to \$25 million based on achievement of clinical, regulatory, and sales milestones
- MNK recognizes net sales and pays a tiered net sales-based royalty to NeuroproteXeon

FINANCIAL IMPACT

- Anticipated dilution of \$0.10 to \$0.15 to adjusted diluted earnings per share for the rest of 2017, modestly lower in 2018

TIMING

- Transaction closes concurrent with upfront payment made Oct. 2, 2017

DEVELOPMENT STATUS

- FDA¹ SPA² approved for Phase 3 clinical trial expected to begin in Q1 2018; following NDA³ submission for drug-device combination product, approval and launch anticipated in 2020
- Product granted U.S. orphan drug status with regulatory exclusivity expected through at least 2027

If approved, xenon gas for inhalation will expand Mallinckrodt's portfolio of hospital drug-device combination therapies



INOmax
(nitric oxide) FOR INHALATION



Therakos
PHOTOPHERESIS



Xenon gas for inhalation

Pharmaceutical-grade xenon gas for inhalation

- ✓ Addresses high unmet need for improving resuscitated cardiac arrest patients' survival/functional outcomes
- ✓ Reduction in brain damage demonstrated in Phase 2B study
- ✓ Established regulatory path: FDA² SPA³ and orphan designation
- ✓ Leverages proven MNK expertise with drug-device combinations and high-service model in hospitals

Cardiac arrest, even after resuscitation, can lead to coma and death; no drug therapies approved to protect against brain injury

Disease Overview

- When a patient's heart stops beating (cardiac arrest), death can occur within minutes; ~35-40% of patients are revived¹
- Despite a return of heartbeat and blood circulation (RoSC²)
 - Only 30-35% of resuscitated patients survive to hospital discharge³
 - Many survivors have significant impairment of brain function and/or coma
- Current standard of care to treat RoSC patients includes Targeted Temperature Management (TTM), or hypothermia therapy



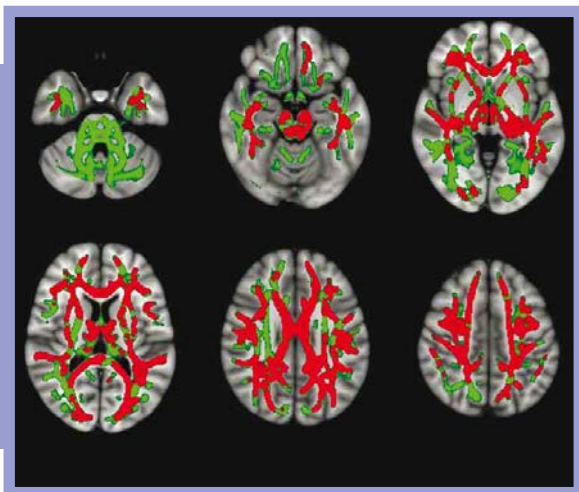
No pharmacological treatments are approved to protect against neuronal damage in RoSC patients

Average cost of care in U.S. for survivors of cardiac arrest – from the arrest through the 12 months following – is estimated at ~\$100K per patient⁴

Pharmaceutical-grade xenon gas for inhalation showed clear reduction of brain damage in Phase 2 trial published in JAMA¹

Phase 2 Results

- Xenon gas for inhalation associated with less brain damage on primary neuroimaging endpoint measured using MRI² (p=0.006)
- Reduction in mortality was not statistically significant (p=0.053) and there was no difference in neurological outcomes at 6 months in the overall population
- However, post-hoc analysis of patients resuscitated in ≤ 30 minutes³ who received xenon gas for inhalation showed improved 60-day mortality and better modified Rankin Scores* (lower mortality rates and improved cognitive and motor functions)



Patient Population: 110 comatose OHCA⁴ patients resuscitated with return of spontaneous circulation (RoSC) within 45 minutes

Treatment: Xenon + TTM⁵ vs. TTM-alone

Method: MRI used to measure biomarker – Global Fractional Anisotropy – that shows differences in the diffusion of water in white matter tracts of the brain; more diffusion = more damage

Brain damage biomarker exhibited the best independent predictive value for mortality at 6 months

Red – significantly worse damage in TTM-alone vs. xenon + TTM group

Green – no difference between groups

* See Appendix

Unique mechanism of action may contribute to lowering neuronal cell death, primary cause of disability and death in resuscitated cardiac arrest patients

Xenon¹ is a noble gas that has been used safely as an inhaled therapy in several studies to date

Cardiac arrest interrupts blood flow to the brain



Negative cascade opens calcium channels



↑ Ca²⁺ flow into cells causes neuronal cell death

Over-activation of calcium channels is known to cause neuronal damage and cell death²

Xenon binds to NMDA³ receptors through a unique glycine-binding mechanism to regulate Ca²⁺ flow through the channel

Reduced neuronal cell death expected to reduce time in coma, lower mortality rates, and improve cognitive and motor functions

Improvements in functional abilities can lower the cost of patient care

Drug Delivery System

- Pharmaceutical-grade xenon gas for inhalation delivered into breathing circuit through a proprietary delivery device
- Planned for use with TTM⁵ in hospital ER⁶ and ICU⁷

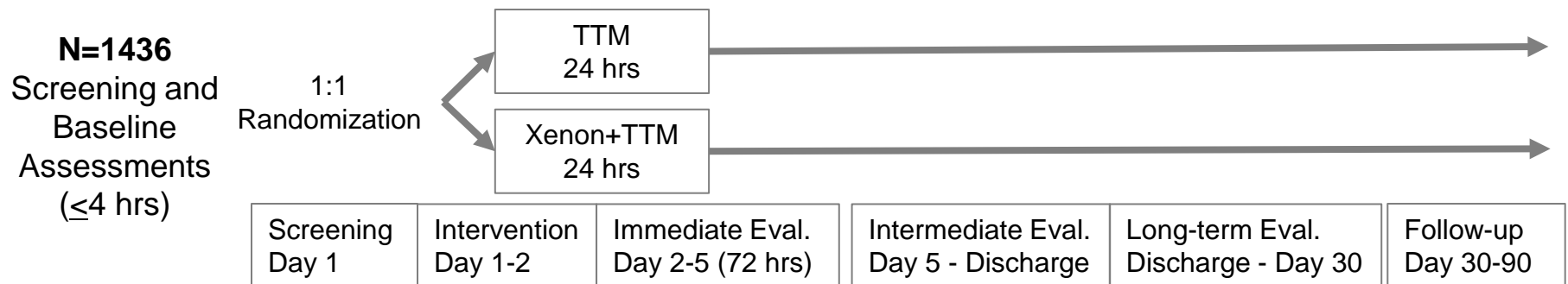
Phase 3 registration trial designed to replicate positive treatment outcomes with xenon gas for inhalation in patients resuscitated in ≤ 30 minutes

- Phase 2 patients resuscitated in ≤ 30 minutes¹ who received xenon gas for inhalation plus TTM² had improved 60-day mortality and good functional outcome

		TTM	%	Xenon+TTM	%	Relative Change
Functional Outcome	Good (mRS ³ 0-2)	32/50	64%	33/44*	75%	17.2%
	Poor (mRS 3-6)	18/50	36%	11/44*	25%	-30.6%
Mortality		17/50	34%	9/45**	20%	-41.2%

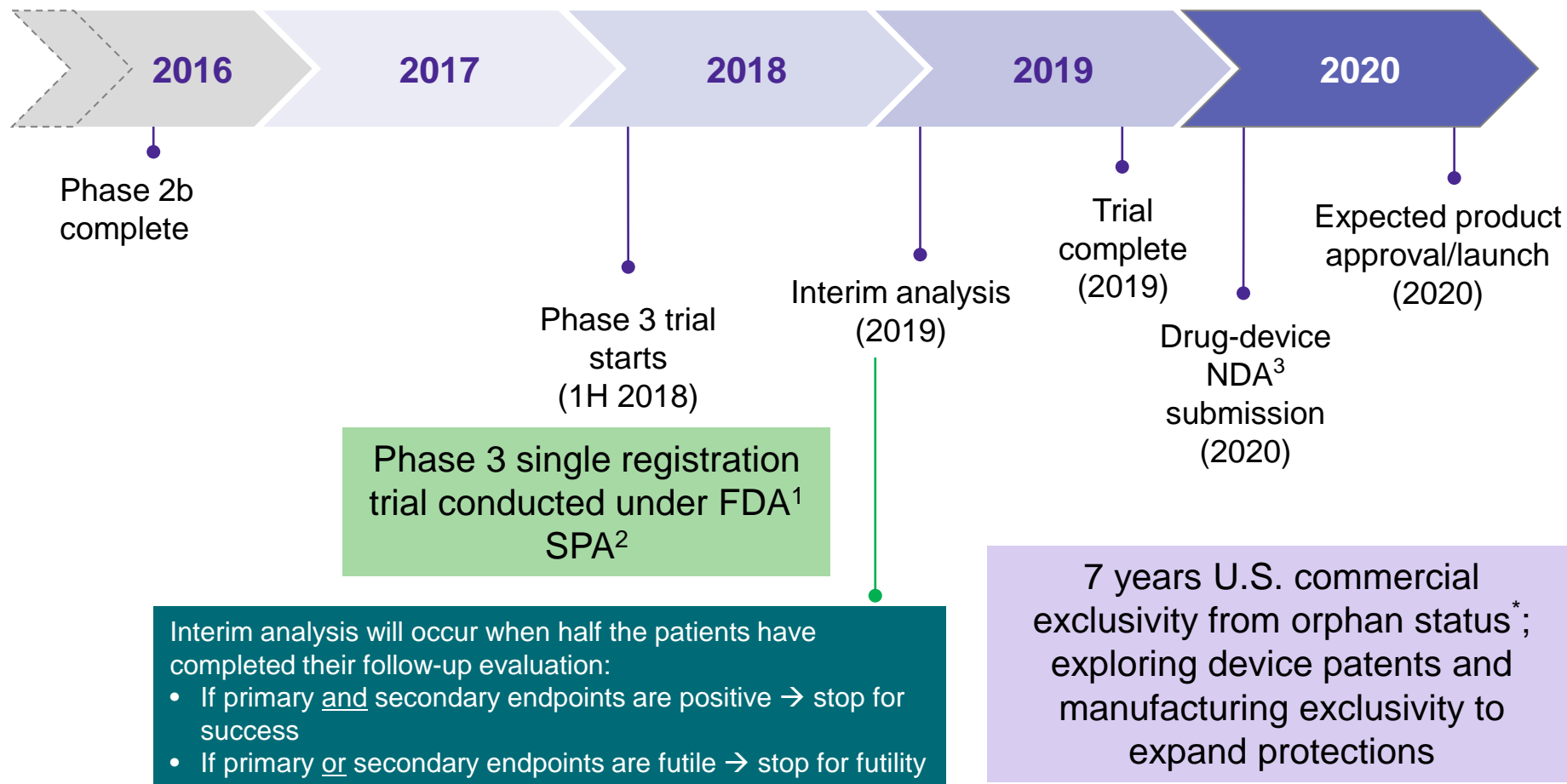
*excludes one patient with no data and one patient with mental disability who entered and exited the study with mRS³
 ** excludes one patient with no data

- Single Phase 3 registration trial – to be conducted under FDA⁴ SPA⁵
- Primary Endpoint:** % with good functional outcome (mRS ≤ 2) on Day 30
- Secondary Endpoints:** % surviving on Day 30 (plus others)



Xenon gas for inhalation granted FDA Orphan Drug Status; Phase 3 start expected 1Q 2018; U.S. launch targeted 2020

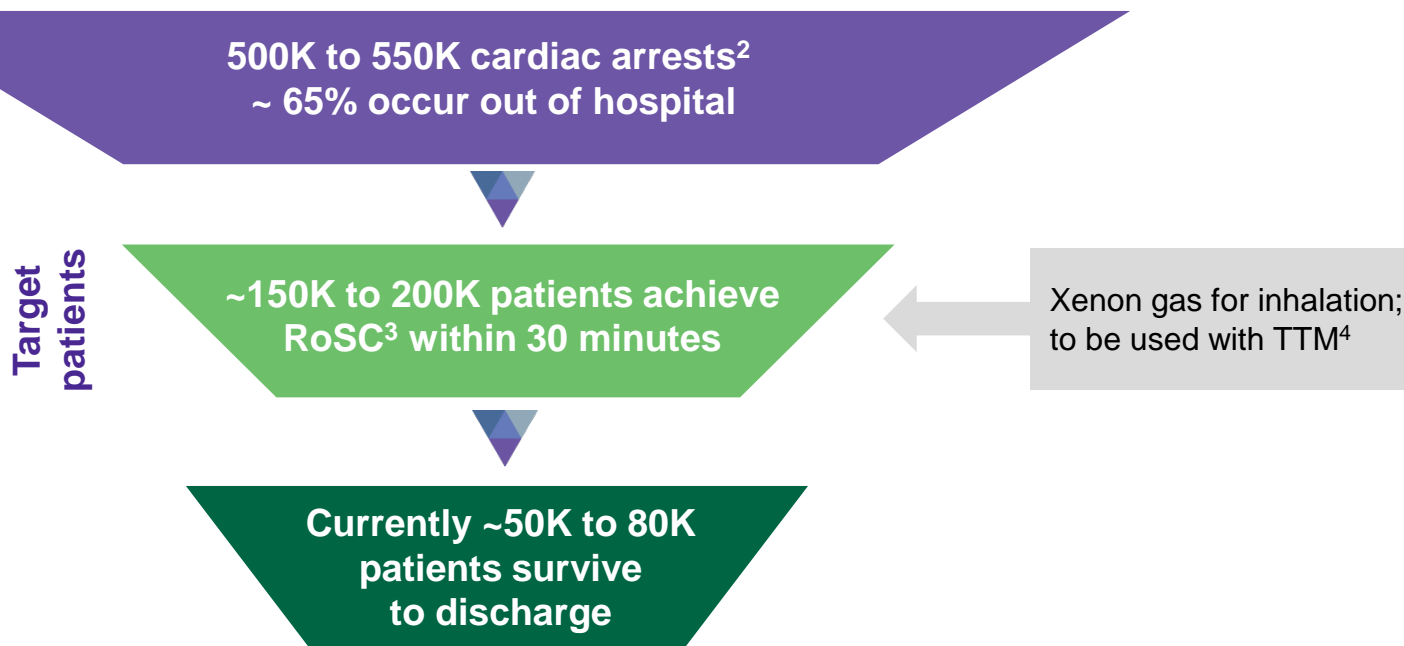
Key Milestones



* Orphan drug status granted by FDA in May 2015

Average cost of care in U.S. for survivors – from arrest through the 12 months following – is ~\$100K per patient¹

Current U.S. Demographics and Patient Flow



- AHA⁵ guidelines for post-cardiac arrest care recommend TTM
- Positive Phase 3 trial has potential to *expand* guidelines to include xenon gas for inhalation and help increase overall adoption of the guidelines
- ~55% of cardiac arrest patients are Medicare age-eligible⁶; MNK expects xenon gas for inhalation will have NTAP⁷ added to the DRG⁸ payment with added carve-out payments for commercial payers

Exclusive license to xenon gas for inhalation will allow MNK to leverage its existing commercial expertise

Penlon will manufacture devices

NeuroproteXeon will continue to be responsible for clinical development and regulatory filings

Praxair will supply the pharmaceutical-grade (cGMP¹) gas

MNK will leverage unique drug-device expertise and existing infrastructure to commercialize xenon gas for inhalation to improve resuscitated cardiac arrest patients' survival/functional outcomes



- Mallinckrodt's experience with executing the INOMAX[®] (nitric oxide) gas, for inhalation, service model provides the knowledge and ability to serve a critical population with urgent needs
- Service speed matters when patients are struggling for survival – emergency deliveries provided in less than 4 hours

Mallinckrodt continues to execute its growth strategy by pursuing development of xenon gas for inhalation

License for xenon gas for inhalation can add value to Mallinckrodt:

- If approved, broadens specialty brands hospital portfolio with a clinically differentiated asset with exclusivity through orphan drug designation and, potentially, device patents
- Addresses high unmet need in cardiac arrest
- Deepens presence in key areas of the hospital including ER¹ and ICU²; strongly aligned with existing commercial infrastructure and clinical capabilities



Mallinckrodt can add value to xenon gas for inhalation:



- Provide commercialization and launch support to optimize patient access and clinical impact
- Apply existing hospital infrastructure and expertise in commercializing drug-device combination products
- Offer expansion opportunity in select ex-U.S. markets where infrastructure already exists

If approved, xenon gas for inhalation will address critical unmet need – a natural fit with MNK's hospital portfolio

ADDRESSES HIGH UNMET NEEDS

- Expected first pharmacological treatment approved to improve survival and functional outcomes for patients resuscitated after a cardiac arrest
- Could reduce death and disability in a population with few options

CLINICALLY DIFFERENTIATED

- Unique mechanism of action targets NMDAR¹ receptors to modulate calcium channels which are directly implicated in neuronal cell death
- Inhalation delivery rapidly reaches the brain
- Reducing neuronal cell death may significantly improve patient survival and function; save costs by lowering burden of care

AREA OF HIGH ECONOMIC BURDEN

- Patients who survive to discharge today still face significant recovery costs and continue to have need for care
- Average cost of care in U.S. for survivors – from arrest through the 12 months following – is ~\$100K per patient²

WELL ALIGNED WITH HOSPITAL PORTFOLIO

- Deepens Mallinckrodt's presence in critical care and in drug-delivery combination systems
- Leverages existing commercial infrastructure and clinical capabilities



Appendix

Modified Rankin Score

Modified Rankin Scale (mRS)

- 0 No symptoms
- 1 No significant disability, despite symptoms, able to preform all usual duties and activities
- 2 Slight disability; unable to perform all previous activities but able to look after own affairs without assistance
- 3 Moderate disability; requires some help, but able to walk with-out assistance
- 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
- 5 Severe disability; bedridden, incontinent, and requires constant nursing care and attention
- 6 Death

Simplified Questionnaire (example):¹

