Pre-Approval Information Exchange (PIE) Deck: NeuroVex™

This slide provides a high-level overview of NeuroVex, a novel investigational therapy for Neurodegradative Cognitive Impairment (NCI), developed by Synexa Biopharma

Synexa Biopharma

Synexa Biopharma is a pharmaceutical company focused on developing innovative therapies for neurological disorders.

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Introduction & Disclaimer

NeuroVex is a novel investigational therapy for Neurodegradative Cognitive Impairment (NCI), developed by Synexa Biopharma. This presentation provides a high-level overview of NeuroVex for payer consideration and planning.

Unmet Need & Disease Overview

NCI Description

NCI is a progressive neurodegenerative condition characterized by gradual cognitive decline, memory loss, and impaired daily functioning. Patients experience worsening cognition that can lead to loss of independence over time.

Prevalence & Impact

NCI affects a significant patient population – an estimated 10–20% of adults over 60 experience early cognitive impairment. Prevalence is rising with the aging population, leading to growing healthcare and caregiving demands.

Risk Factors

Key risk factors for NCI include advancing age, family history of Alzheimer's or dementia, and cardiovascular comorbidities. Many patients with NCI progress to more severe neurodegenerative dementia, underscoring the need for early intervention.

Societal Burden

NCI and related dementias impose a heavy burden – high caregiving demands and healthcare costs. The economic cost of dementia in the U.S. was about $305 billion in 2020. Effective NCI treatments could delay progression, reducing long-term care costs and improving patient and caregiver quality of life.

Product Overview: NeuroVex™

NeuroVex is a first-in-class Synaptic Regeneration Modulator (SRM) that enhances synaptic regrowth and stabilizes neurotransmitter activity, aiming to slow or reverse cognitive decline in NCI. It represents a novel approach targeting the underlying synaptic loss in cognitive impairment.

Regulatory Status & Development Timeline

FDA Designations

NeuroVex has received Fast Track and Breakthrough Therapy designations from the FDA, underscoring the unmet need and promising efficacy signals

Phase 3 Trials Completed

Two pivotal Phase 3 clinical trials in NCI were successfully completed in late 2024

NDA Submission Planned

Synexa Biopharma plans to submit a New Drug Application (NDA) to the FDA in Q2 2025

FDA Review & Potential Approval

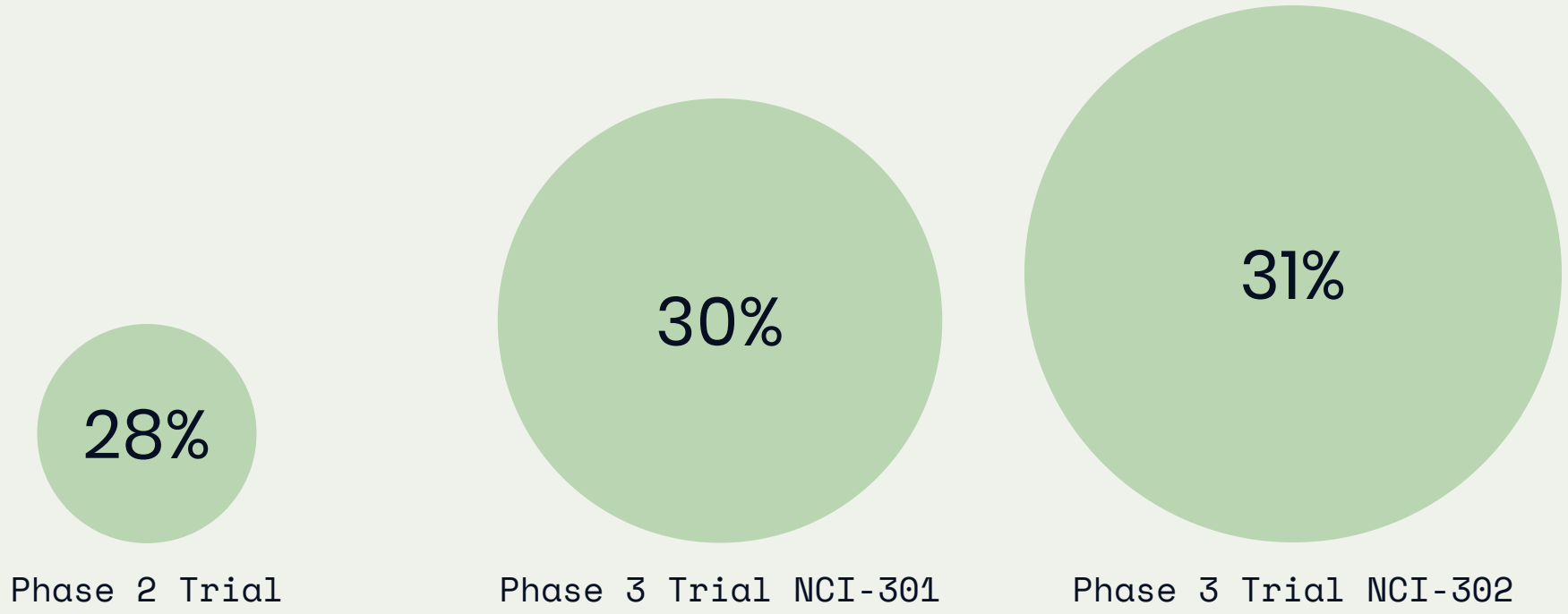
An FDA decision (approval, if granted) for NeuroVex could occur by early 2026

Anticipated U.S. Launch

Synexa projects a potential U.S. launch of NeuroVex in mid-2026, subject to FDA review outcomes

Clinical Evidence Summary

Percent improvement in cognitive test scores vs. placebo



Market Access & Pricing Strategy

Formulary Placement

NeuroVex is expected to be classified as a specialty medication on formularies (likely Tier 3 or specialty tier). Payers may implement prior authorization criteria to ensure appropriate use – for example, confirmed NCI diagnosis, disease severity documentation, and specialist prescribing. This utilization management will help target NeuroVex to patients most likely to benefit.

Pricing Estimate

Anticipated annual cost for NeuroVex is in the range of $50,000 – $99,999 per patient. Final pricing is pending, but it will be based on the value NeuroVex provides (in terms of cognitive improvement and functional preservation) and benchmarked against similar innovative neurology therapies. Synexa is mindful of affordability and will consider pricing that facilitates patient access while reflecting the drug's clinical benefits.

Value-Based Pricing

A value-based pricing strategy is under exploration to support market access. Synexa may pursue outcomes-based agreements with payers – for example, offering rebates or price adjustments if NeuroVex does not meet certain effectiveness benchmarks in real-world use. Such arrangements aim to align the cost with patient outcomes and reduce payer risk, reinforcing confidence in NeuroVex's value proposition.

Uptake Projections

Market uptake is expected to be moderate in the initial years post-launch. Synexa projects that ~20–30% of eligible NCI patients could be on NeuroVex by Year 3, assuming it is approved and added to clinical guidelines. Early uptake may be tempered by the need for physician education and diagnostic efforts to identify NCI patients. Over time, as real-world experience grows and awareness increases, uptake could expand, especially if NeuroVex demonstrates clear benefits and cost offsets in practice.

Patient Support & Distribution Plan

NeuroCare Access Program

Synexa will introduce the NeuroCare Access Program to support patients starting on NeuroVex. This program will provide financial assistance through co-pay support, help with insurance navigation, and a patient assistance program for uninsured or underinsured patients. NeuroCare will also offer patient education and counseling about NCI and NeuroVex, empowering patients and caregivers with information.

Adherence Support

A key focus of NeuroCare is adherence and persistence on therapy. Patients will have access to nurse educators or case managers who can provide training (if NeuroVex has a special administration), regular follow-up calls to check on progress, and refill reminders. This proactive support is designed to keep patients on NeuroVex as prescribed, maximizing the therapy's potential benefits in the real-world setting.

Specialty Pharmacy Distribution

NeuroVex will be distributed through a limited network of specialty pharmacies. These pharmacies are experienced in handling high-cost, specialty therapeutics and will ensure proper storage, handling, and distribution of NeuroVex. The specialty pharmacy model also enables coordinated care: pharmacists can provide personalized counseling to patients on NeuroVex, monitor for adherence, and communicate with prescribers. This distribution strategy helps maintain supply chain integrity and provides payers with assurance of appropriate utilization tracking.

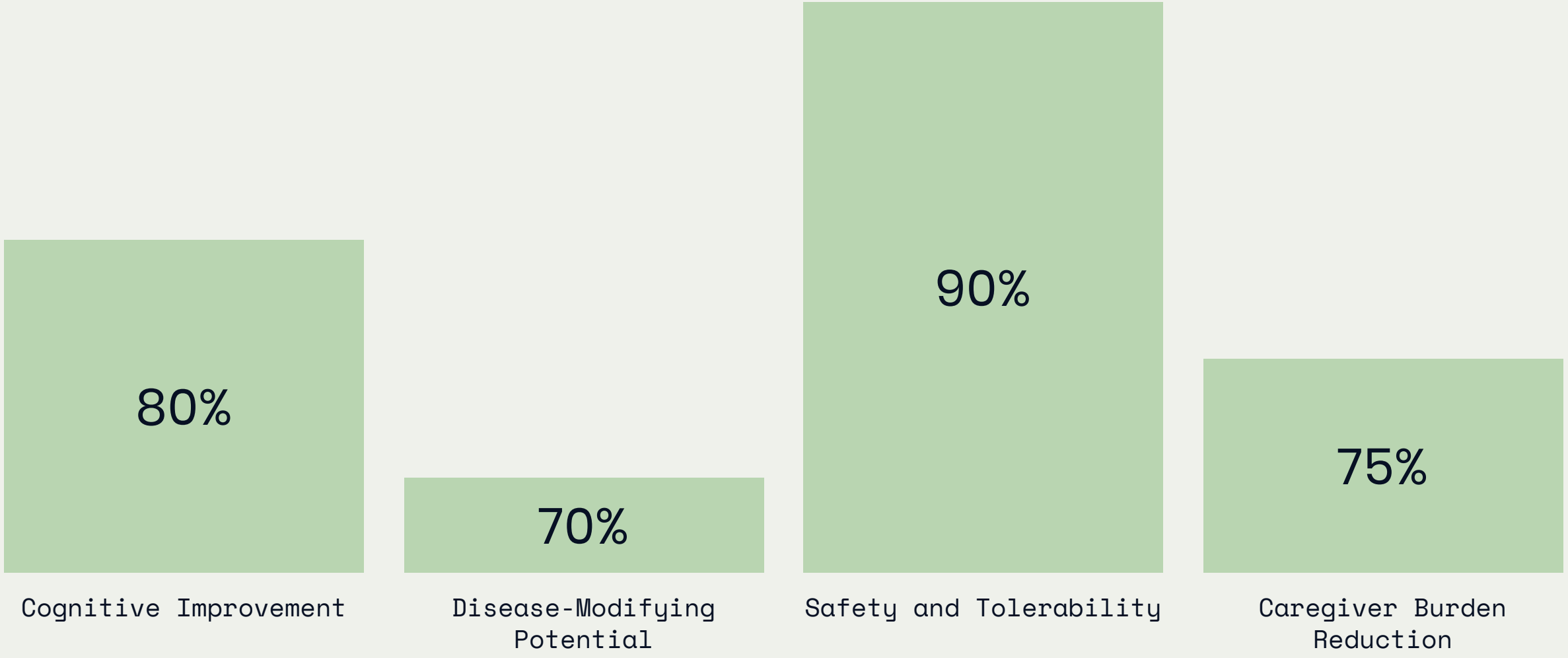
Economic & Budget Impact

- Health economic modeling suggests NeuroVex, the novel investigational therapy for Neurodegenerative Cognitive Impairment (NCI), will be cost-effective in the context of NCI. The estimated cost per quality-adjusted life year gained is approximately $150,000/QALY, which is within commonly accepted thresholds for severe diseases in the U.S.

- Additionally, by slowing the progression of NCI, NeuroVex may generate significant downstream savings by delaying the need for institutional care and reducing reliance on caregivers. The overall budget impact for payers is projected to be manageable, with an estimated gross impact of $7.5 million for a 1 million-member health plan in the first year.

Competitive Landscape

Comparison of key attributes for NCI therapies



Next Steps & Contact Information

FDA NDA Review

Phase 3 Trial Results Publication

Comprehensive AMCP Formulary Dossier

Synexa Contact Information