



# Corporate Presentation

March 2026

*Transforming public health and delivering  
shareholder value*

# Forward Looking Statements

*This presentation contains forward-looking statements, including, but not limited to, statements regarding the timing and nature of cytisinicline clinical development and regulatory review and approval; data results and commercialization strategy and activities; the potential market size for cytisinicline; the potential benefits, efficacy, safety and tolerability of cytisinicline; the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product; the development and effectiveness of new treatments; the successful commercialization of cytisinicline; and expectations regarding cash forecasts. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve Life Sciences, Inc. (“we,” “us,” “our,” or “the Company”) may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out the intentions or meet the expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that we may not be able to obtain additional financing to fund the development and commercialization of cytisinicline; the risk that cytisinicline will not receive regulatory approval in a timely manner or at all, or be successfully commercialized; the risk that new developments in the smoking and vaping cessation landscapes require changes in business strategy or clinical development plans; the risk that our intellectual property may not be adequately protected; general business and economic conditions; risks related to the impact on our business of macroeconomic and geopolitical conditions, including fluctuating inflation, interest and tariff rates, volatility in the debt and equity markets, actual or perceived instability in the global banking system, global health crises and pandemics and geopolitical conflict; and the other factors described in the risk factors set forth in the Company's filings with the Securities and Exchange Commission from time to time, including its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.*

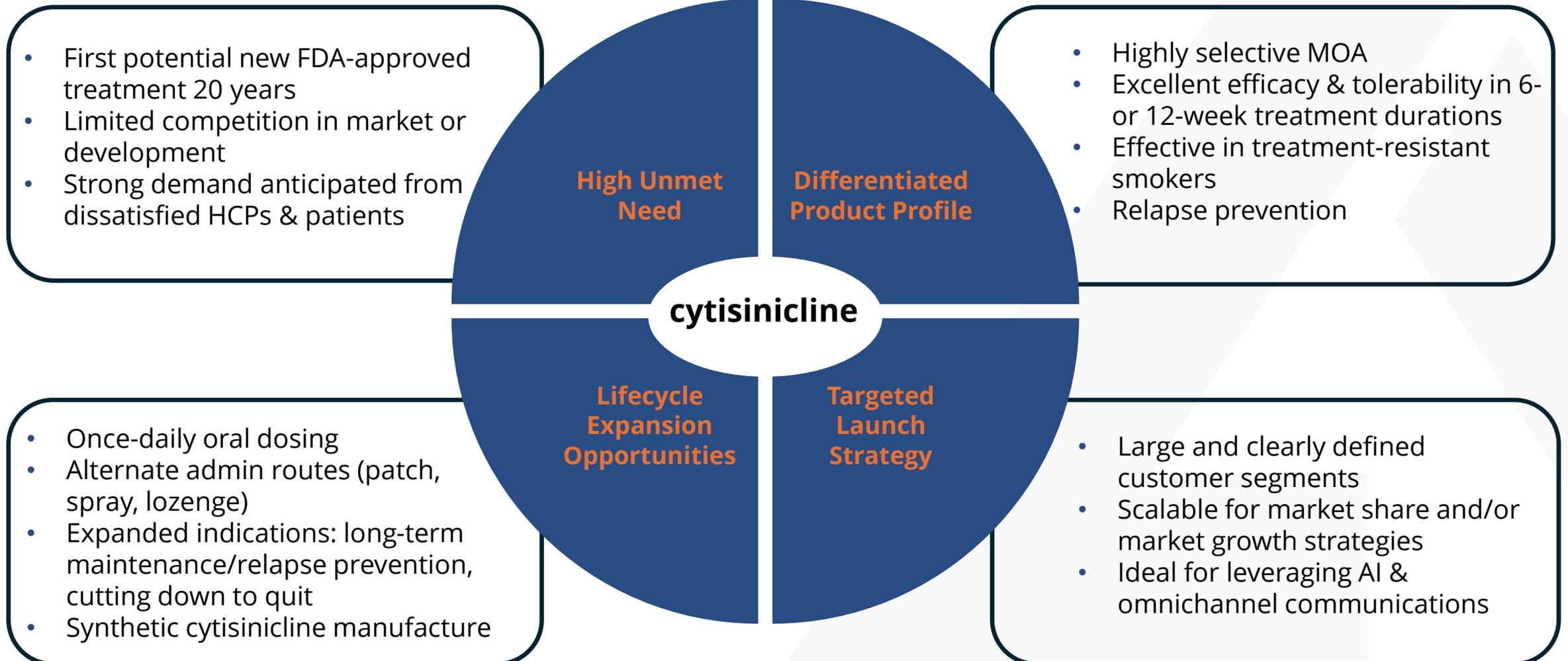
*These slides also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.*

*Certain data in this presentation are based on cross-study comparisons and are not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities and differences. The values shown in the cross-study comparisons are directional and may not be directly comparable.*

**Cytisinicline, as a first potential new nicotine dependent treatment in 20 years, gives Achieve Life Sciences a **unique opportunity** to treat an addressable market of up to 50 million Americans who use tobacco<sup>1</sup>**

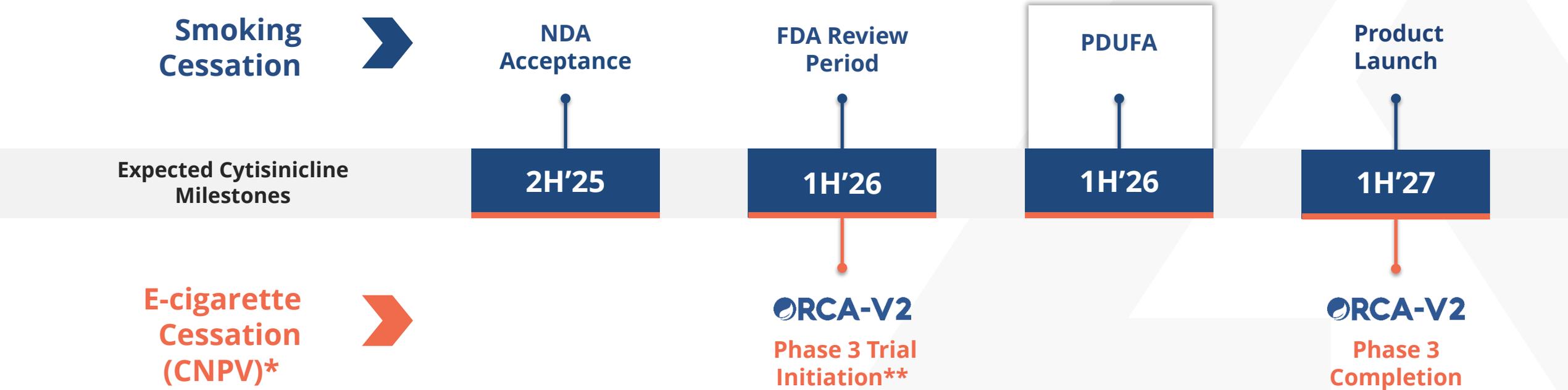
- 1 Addressing nicotine dependence, an **underserved public health crisis** costing billions of dollars and impacting lives.
- 2 Cytisinicline PDUFA for treatment of nicotine dependence for smoking cessation is June 20, 2026. **U.S. launch expected in 1H 2027.**
- 3 **Vaping cessation indication**, awarded Commissioner's National Priority Voucher (CNPV) and under FDA Breakthrough Therapy Designation.
- 4 **Competitive advantage** with a highly differentiated and well-tolerated product profile and favorable payor environment with Affordable Care Act coverage.
- 5 **Focused launch strategy** leveraging innovative, data-driven solutions to drive adoption and future growth.

# Introducing... Cytisinicline: Innovation, overdue.



# Driving toward regulatory approval and launch

Anticipated timeline and key milestones



Timeline are estimates based on management current expectations that have no guarantee and may vary.

\* Commissioner's National Priority Voucher.

\*\* E-cigarette cessation program timeline is finance dependent.

# Over \$600B in smoking-related U.S. health care costs annually<sup>1</sup>

Nicotine dependency is a medical issue, requiring a medical solution

**80%**

of deaths from lung cancer & COPD from smoking<sup>3</sup>

**2-4x**

increased risk of CVD from smoking<sup>3</sup>

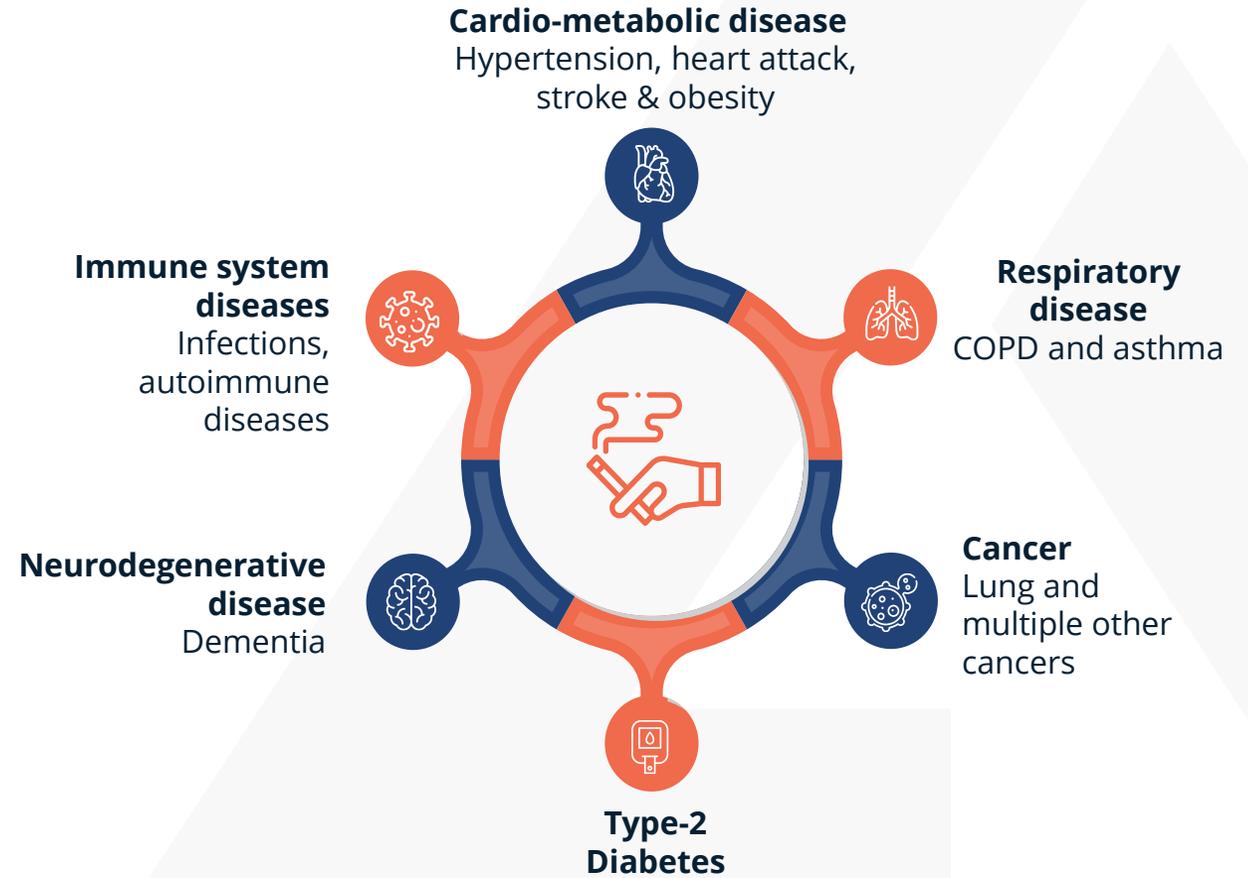
**30-40%**

increased risk of Type 2 Diabetes from smoking<sup>3</sup>

**9x**

increased risk of stroke from heavy smoking<sup>4</sup>

25M U.S. smokers with few treatment options<sup>2</sup>



**Profound co-morbidity health harms from smoking**

1. VanFrank B, Malarcher A, Cornelius ME, Schechter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641  
 2. National Center for Health Statistics. *National Health Interview Survey, 2023 and 2024*. 2026 (<https://www.cdc.gov/nchs/nhis.htm>).  
 3. USDHHS-The Health Consequences of Smoking-2014; 4. Bhat VM,-2008.

# Cytisinicline impact on cardio-metabolic disease

Smoking cessation with cytisinicline can be positioned as a high-ROI upstream cardiometabolic intervention

## STRATEGIC THESIS

Smoking cessation, when combined with cardiometabolic therapies including GLP-1 receptor agonists, SGLT2 inhibitors, and PCSK9 inhibitors, is associated with greater absolute cardiovascular risk reduction than treating individual risk factors alone.<sup>1,2</sup>

## COMMERCIAL LOGIC

Can expand the target prescriber audience by expanding outreach to include cardiology, endocrinology, and pulmonology.

## FINANCIAL LOGIC

Potential for attractive cost-effectiveness, outcomes-based contracting potential, and near-term revenue to balance long CV-outcome-trial portfolios.

## PUBLIC HEALTH PRIORITY

Directly advances prevention priorities and strengthens alignment with public health and ESG objectives.

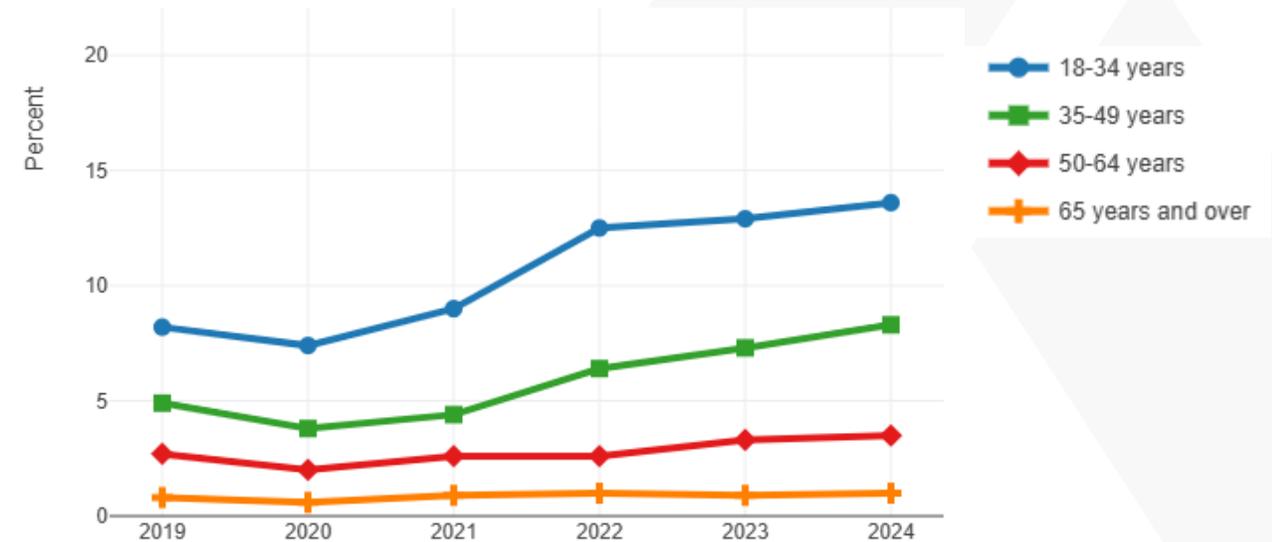
1. Cardiovascular Effects of Smoking and Smoking Cessation: A 2024 Update. <https://globalheartjournal.com/articles/10.5334/gh.1399>

2. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease. J Am Coll Cardiol. 2023;82:833-955.

# ~60% of adult e-cigarette users want to quit<sup>1</sup>

- Majority of people who **vape are 18-24** and have **never smoked**<sup>3,4</sup>
- Instead of harm reduction, this is possible **harm creation** for this group
- Many popular vapes used by young adults contain the nicotine equivalent of **13 packs of cigarettes**<sup>5</sup>
- The cumulative exposure to vape aerosols over time in these young vapers could lead to **severe nicotine dependence** and the emergence of previously unknown lung diseases

## ~18M U.S. adults reported use of e-cigarettes<sup>2</sup>



Source: National Center for Health Statistics, National Health Survey<sup>6</sup>

1. Palmer AM, Smith TT, Nahhas GJ, et al. Interest in quitting e-cigarettes among adult e-cigarette users with and without cigarette smoking history. JAMA Netw Open. 2021;4(4):e214146.  
 2. National Center for Health Statistics. National Health Interview Survey, 2023 and 2024. 2026 (<https://www.cdc.gov/nchs/nhis.htm>). Cornelius ME, Loretan CG, Jamal A, Davis Lynn BC, Mayer M, Alcantara IC, Neff L. Tobacco Product Use Among Adults - United States, 2021. MMWR Morb Mortal Wkly Rep. 2023 May 5;72(18):475-483.  
 3. Centers for Disease Control and Prevention. QuickStats: Percentage distribution of cigarette smoking status among current adult e-cigarette users, by age group—National Health Interview Survey, United States, 2021. MMWR Morb Mortal Wkly Rep. 2023;72:270.  
 4. Leigh, N. J., Page, M. K., Jamil, H., & Goniewicz, M. L. (2024). Characteristics and ingredients of disposable 'Elfbar' e-cigarettes sold in the United States and the United Kingdom. Addiction.  
 5. National Center for Health Statistics. Percentage of current electronic cigarette use for adults aged 18 and over, United States, 2019—2024. National Health Interview Survey. Generated interactively: Jul 18 2025 from [https://wwwn.cdc.gov/NHISDataQueryTool/SHS\\_adult/index.html](https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html)

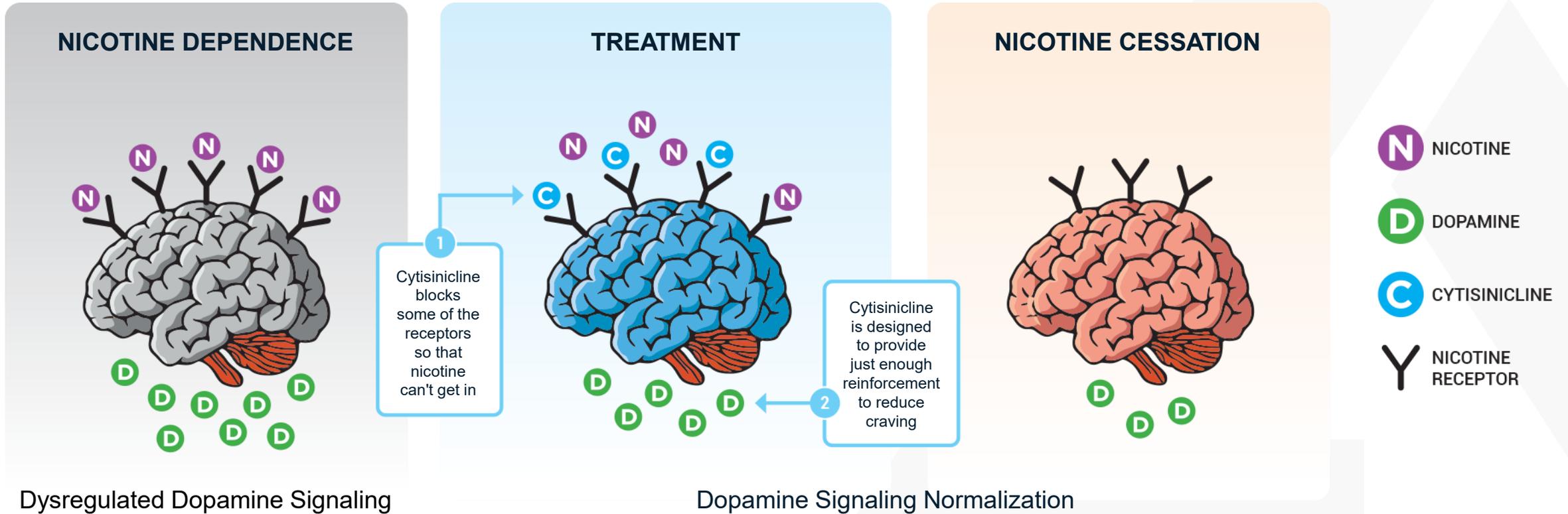


**Cytisinicline: The first new  
potential treatment option for  
nicotine dependence in 20 years**

# Nicotine dependence alters brain chemistry

Cessation helps restore it

## Dual-acting mechanism of action

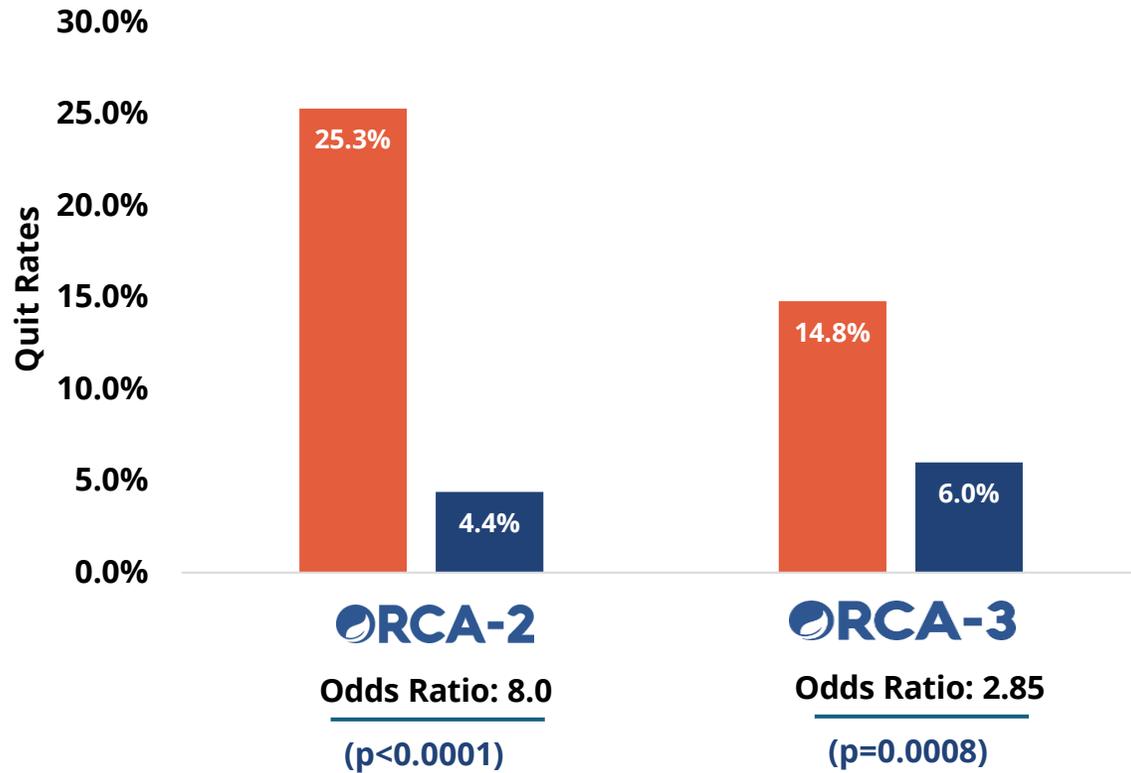


Nicotine dependence is characterized by a cycle of craving and withdrawal mediated by nicotinic receptor signaling

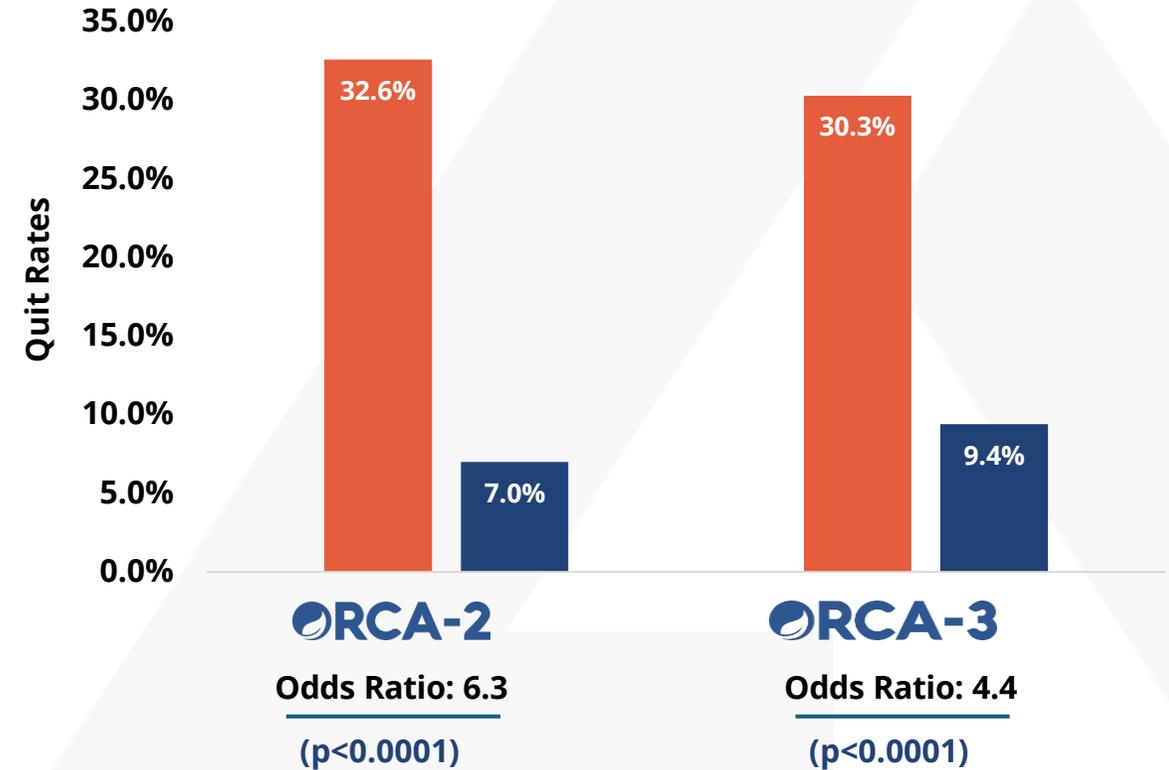
# Strong results from smoking cessation trials

ORCA-2 and ORCA-3: Efficacy, tolerability, craving reduction, broad patient response

6-week Cytisinicline Treatment  
Primary Endpoint (Weeks 3-6)



12-week Cytisinicline Treatment  
Primary Endpoint (Weeks 9-12)



■ Cytisinicline  
■ Placebo

Source: ORCA-2: Rigotti NA, Benowitz NL, Prochaska JJ, et al. Cytisinicline for Smoking Cessation: A Randomized Clinical Trial. *JAMA*. 2023;330(2):152-160. ORCA-3: Rigotti NA, Benowitz NL, Prochaska JJ, et al. Cytisinicline for Smoking Cessation: The ORCA Phase 3 Replication Randomized Clinical Trial. *JAMA Intern Med*. Published online April 21, 2025. doi:10.1001/jamainternmed.2025.0628

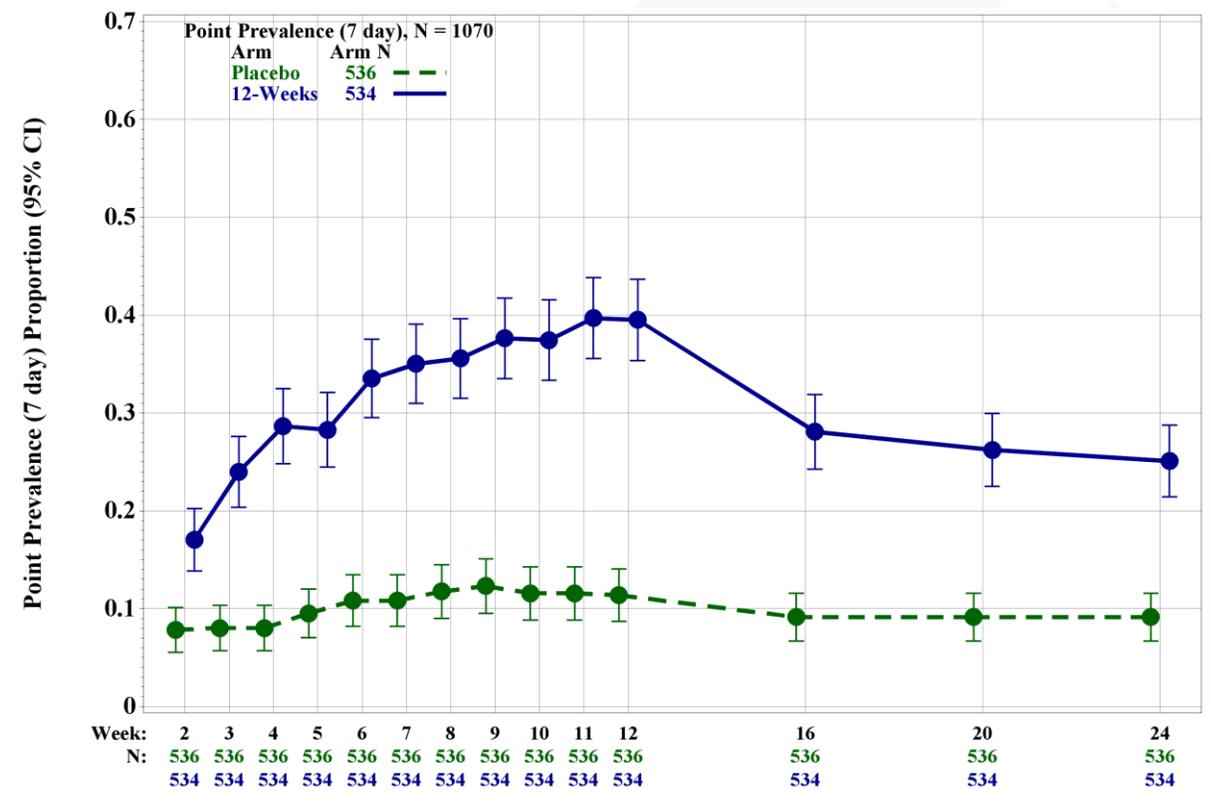
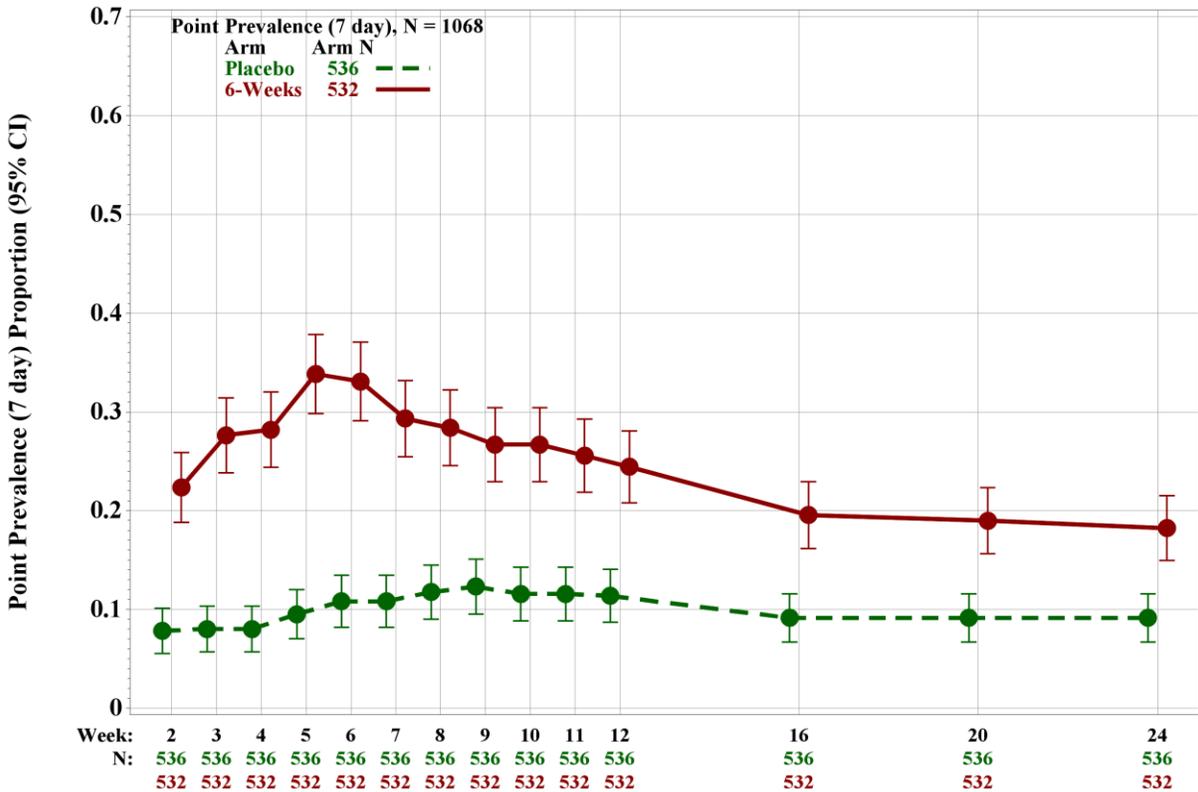
# Overall effectiveness: Pooled Phase 3 studies

Cytisinicline demonstrates higher abstinence rates vs placebo

Point prevalence abstinence rates by week for placebo vs 6-weeks or 12-weeks cytisinicline

6-week Cytisinicline Treatment

12-week Cytisinicline Treatment



Abstinence by self-report of not smoking and verified by carbon monoxide < 10ppm

# Highly selective targeting improves tolerability profile

Adverse event profile compared to Chantix®

## Comparative Analysis of Safety Events\*

Treatment Time	Cytisinicline <sup>1</sup> 12 weeks	Varenicline (Chantix®) <sup>2</sup> 12 weeks
Adverse Events		
Nausea	6.2%	30%
Insomnia	10.8%	18%
Abnormal Dreams	7.7%	13%
Headache	8.1%	15%

## Selective Receptor Targeting<sup>3</sup>



Cytisinicline is >2000 fold less potent at 5-HT<sub>3</sub> receptor<sup>4</sup>

Chantix® is a registered trademark of Pfizer, Inc.

1. Data on file; Achieve Life Sciences ORCA-2 & ORCA-3 pooled data.

2. Chantix Prescribing Information, 6/2018 Pfizer, Inc.

3. Coe J et al. J. Med. Chem. 2005, 48:3474-3477; Papke RL et al. JPET. 2011, 337:367-379; Slater YE et al. Neuropharm. 2003, 44:503-515; Lummis SCR et al. JPET. 2011, 339:125-131.

4. Lummis, SCR, Price, KL, Clarke A, SRNT-E 2020.

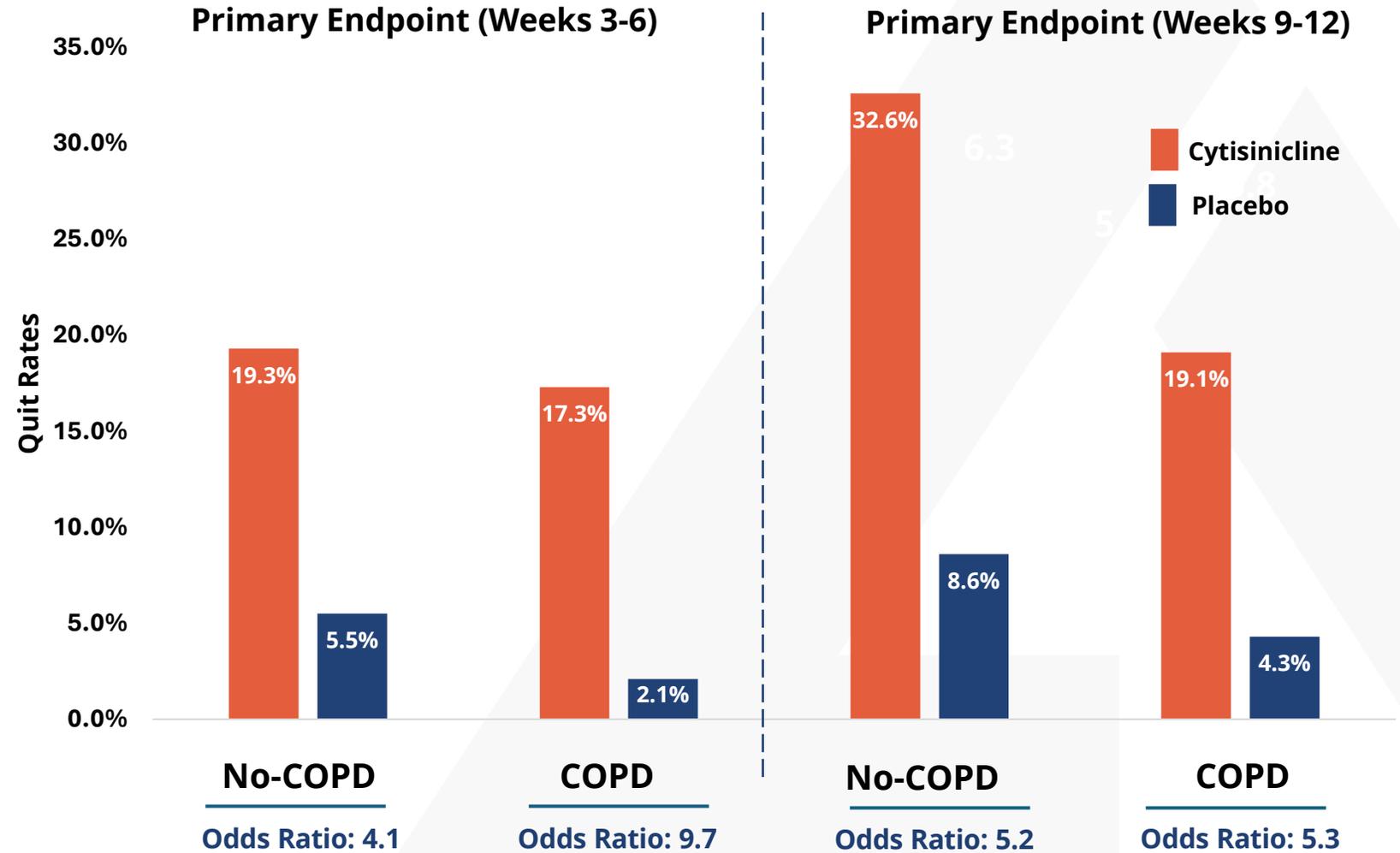
\*Not a head-to-head comparison trial evaluation.

# Comparable quit rates in COPD and non-COPD smokers

Efficacy and tolerability extend to heavier, more treatment-experienced smokers

Smoking cessation is the most impactful intervention for people living with COPD, and cytisinicline is being evaluated as a potential tool to support quitting.

Aligns with Achieve's broader strategy to expand indications to vaping cessation and beyond

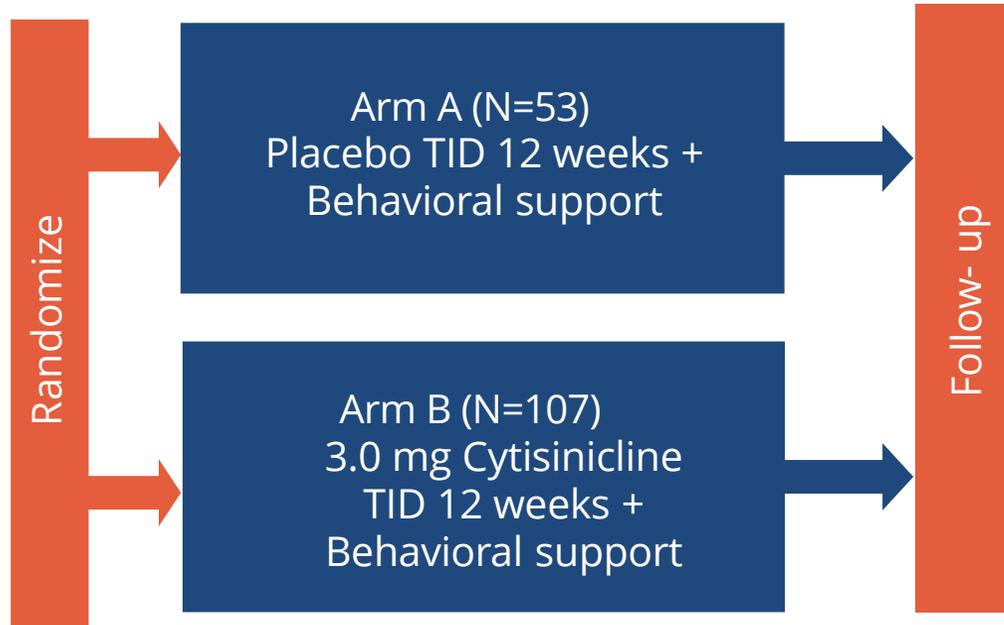


# Vaping trial expands nicotine dependence opportunity

Efficacy, tolerability, compliance, Phase 3 warranted

## Phase 2 ORCA-V1 trial design

### Nicotine E-Cigarette Cessation Trial



## Key insights from vaping cessation trial (N=160)

### Robust efficacy

Statistically significant quit rates despite small sample size showing 2.6x (p=0.035) increased likelihood of quitting

### Excellent tolerability

Favorable adverse event profile demonstrated, no serious adverse events reported

### High-level compliance

Greater compliance observed in cytisinicline-treated arm compared to placebo

### Phase 3 warranted

Strong evidence supporting use of cytisinicline for vaping cessation to be further evaluated in Phase 3 ORCA-V2 trial



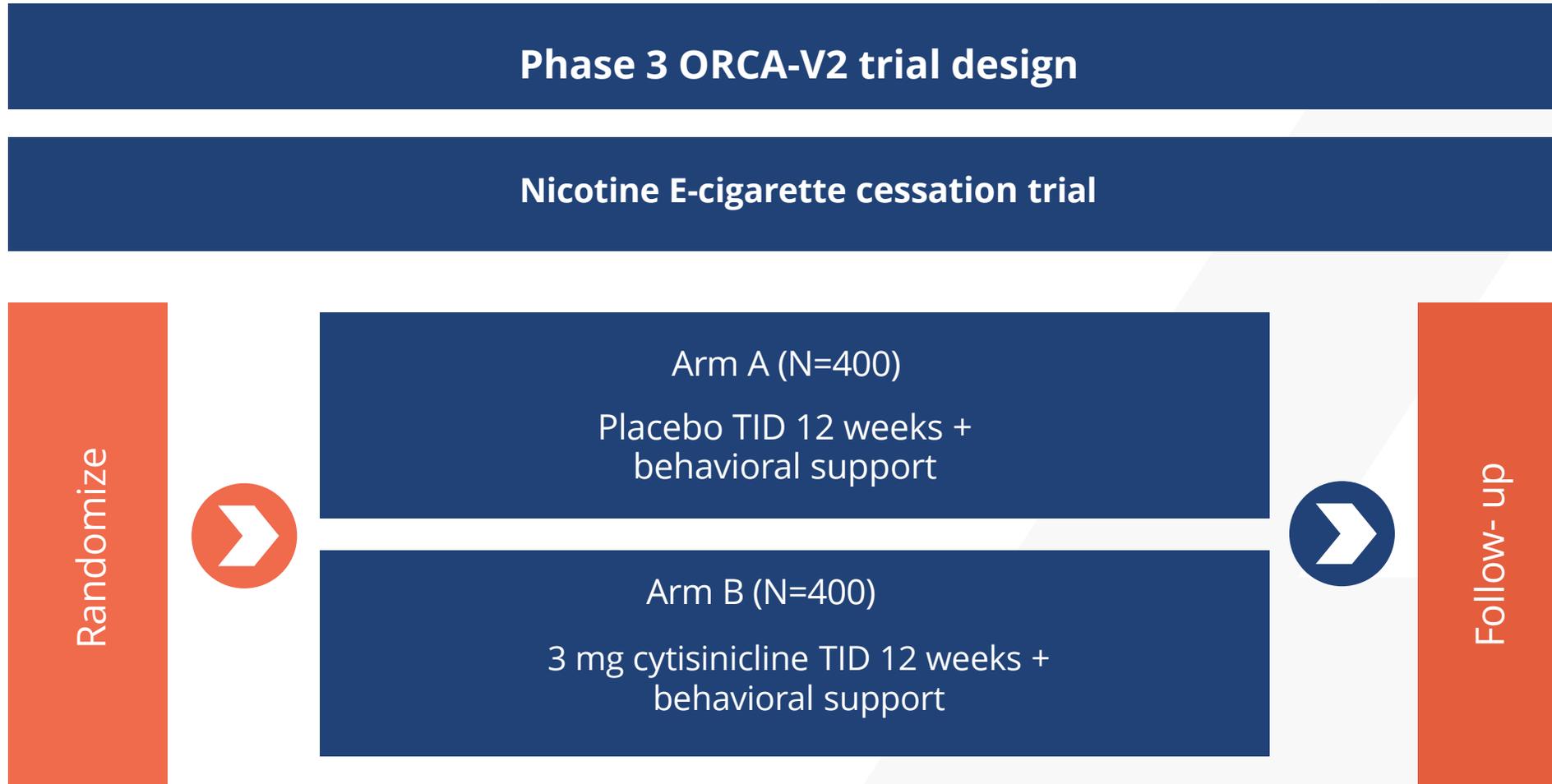
# Commissioner's National Priority Voucher for vaping

Cytisinicline one of first nine treatments awarded CNPV

- CNPV program accelerates the review of products that align with national priorities
- Selected products must address large emerging public health needs such as crises, provide innovative cures, address unmet medical needs or enhance national security through drug development and manufacturing to advance the health interests of the U.S.
- Rapid approval expected in 1-2 months compared to standard 10-12 months
- Enhanced communication with FDA reviewers to streamline development and approval processes
- Non-transferable designation

# Granted CNPV and Breakthrough Therapy designation for cytisinicline in vaping cessation

Phase 3 ORCA-V2 trial design for vaping cessation





**Innovative and Focused... a  
data-driven commercialization  
strategy for maximum impact**

# Attractive market conditions to launch the first smoking cessation treatment in 20 years

Clearly defined customer segments with high unmet need



Limited treatment options with nothing new since 2006 – most have tried and failed

Well-established therapeutic category



Harms of smoking are known – education to focus on optimal patient selection

Ease of market entry and prescribing



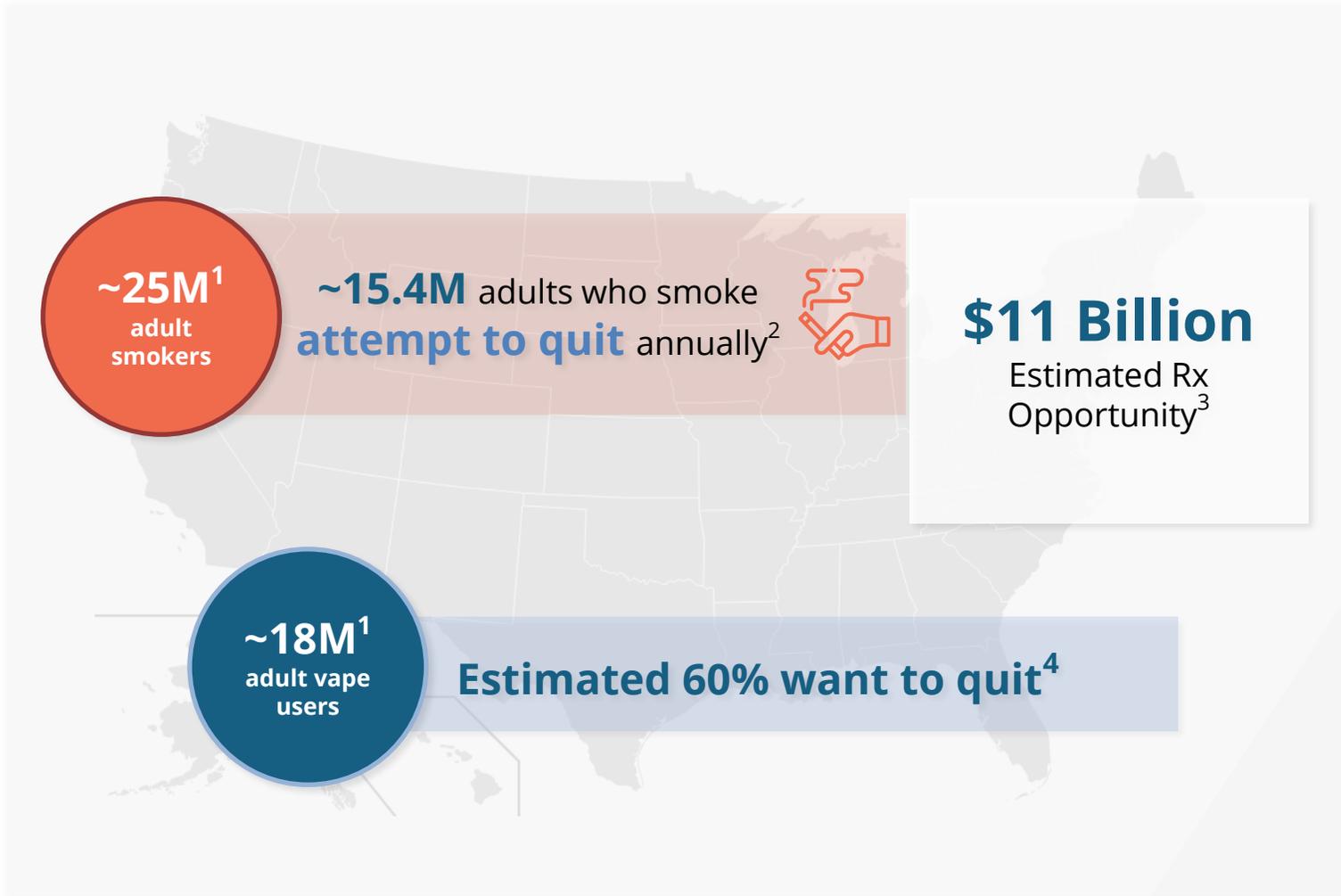
ACA coverage expected  
Favorable tolerability profile reduces HCP burden

Quiet promotional landscape



No branded products to battle for share of voice and customer headspace – nothing new on the horizon

# Unlocking value by addressing a critical unmet public health need



**Lack of options for people who want to quit & for HCPs**

~53% attempt to quit smoking annually<sup>2</sup>

~50% who saw an HCP received advice about quitting<sup>5</sup>

<10% successfully quit<sup>2</sup>

No new FDA-approved options in 20 years



**CDC estimates 36% of people who smoke utilize Rx and OTC cessation treatments annually<sup>5</sup>**

1. National Center for Health Statistics. National Health Interview Survey, 2023 and 2024. 2026 (<https://www.cdc.gov/nchs/nhis.htm>).  
 2. VanFrank B, Malarcher A, Cornelius ME, et al. Adult Smoking Cessation United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633-641  
 3. Estimate of \$500/mo. Chantix pricing - 1 mo.. Rx/patient  
 4. Palmer AM, Smith TT, Nahhas GJ, et al. Interest in quitting e-cigarettes among adult e-cigarette users with and without cigarette smoking history. JAMA Netw Open. 2021;4(4):e214146.  
 5. Centers for Disease Control Smoking Cessation Fast Facts, accessed 2/8/25.

# Precise targeting of high-volume prescribers and engaged quitters

Changing the Narrative about Nicotine Dependence  
**Medical Issue vs. Moral Issue**

Drive Awareness & Education of Cytisinicline  
**First New Treatment in 20 Years**

Focus at Launch on Audiences Most Likely to Take Action:  
**High-Volume Prescribers & Engaged Quitters**

## Cessation Rx Enthusiasts

- High prescribing volume of varenicline
- Sizeable smoking population in practice
- Actively initiates in cessation discussions and follows up
- Prefers Rx to natural treatments
- Favorable impression of cytisinicline

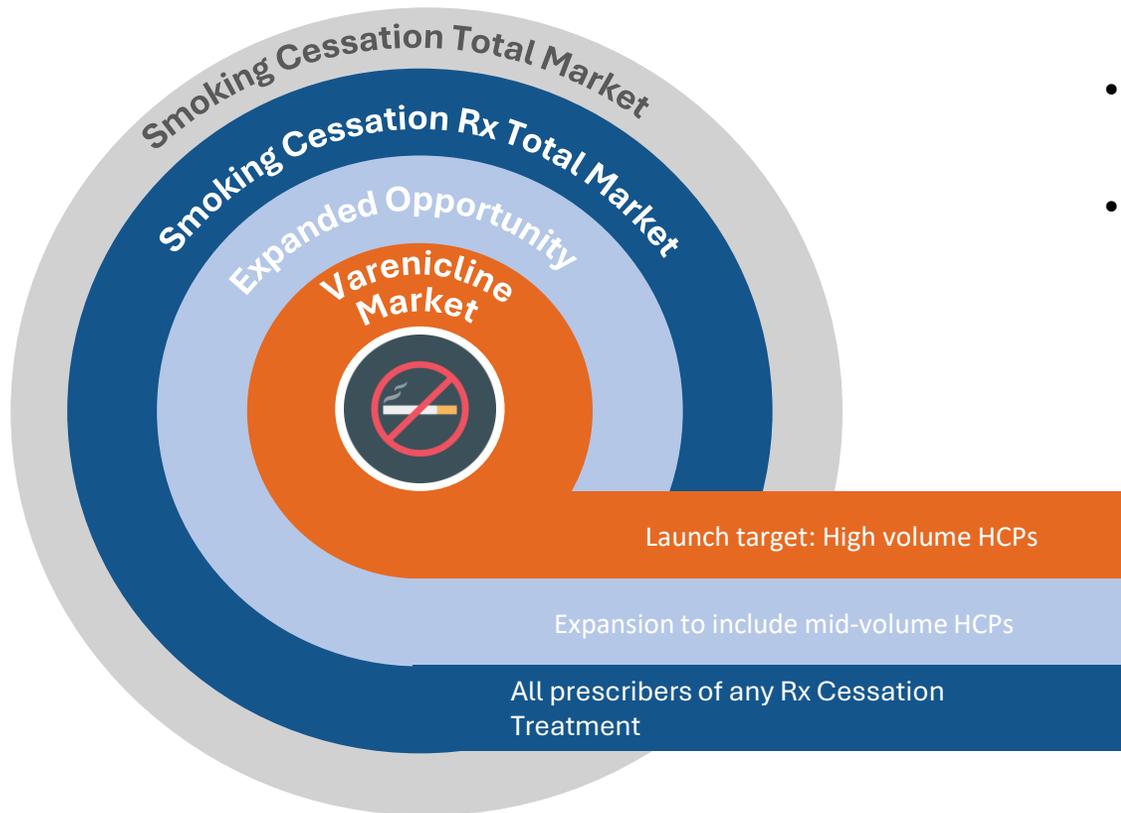
## Highly Motivated Quitters

- Heavy, long-term smoker embarrassed of habit and concerned about its health impact
- Consider quitting a top priority
- Confident in healthcare system and utilize it regularly
- Proactively pursue Rx from doctor
- Willing to take oral medication for 6-12 weeks

# Focused Health Care Provider (HCP) launch targeting

Built for growth: initial target on market share in high volume prescribers

- Chantix peaked at ~2.8M Rx (75% in U.S. market - \$800M)<sup>1,2</sup>
- Launch focus on priority, primary care HCP targets to convert market share to varenicline
- Designed to establish foothold and direct future expansion efforts on additional targets and/or market growth initiatives



- 1** — **Market share launch strategy: Phased digital + F2F/virtual promotion to high-decile prescribers**
- 2** — **2<sup>nd</sup> wave expansion option: Extend promotion efforts to additional targets (patients or HCPs)**
- 3** — **3<sup>rd</sup> wave expansion option: Further conversion and market growth**

# Embracing the evolution of pharma promotional model

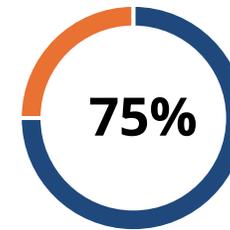
HCP access and engagement preferences have changed

## Traditional approach: Activity based & siloed

Over-indexing on F2F sales rep-to-doctor interactions and rep-provided content



## Ignores HCP reality



IM HCPs do not meet with pharma reps<sup>1</sup>



Time HCPs give rep for in-person discussion<sup>2</sup>



Average time HCP spends daily engaging with non-branded affiliated digital and social channels<sup>3</sup>

1. Veeva Pulse Field Trend Report, Jan.-Dec. 2023.

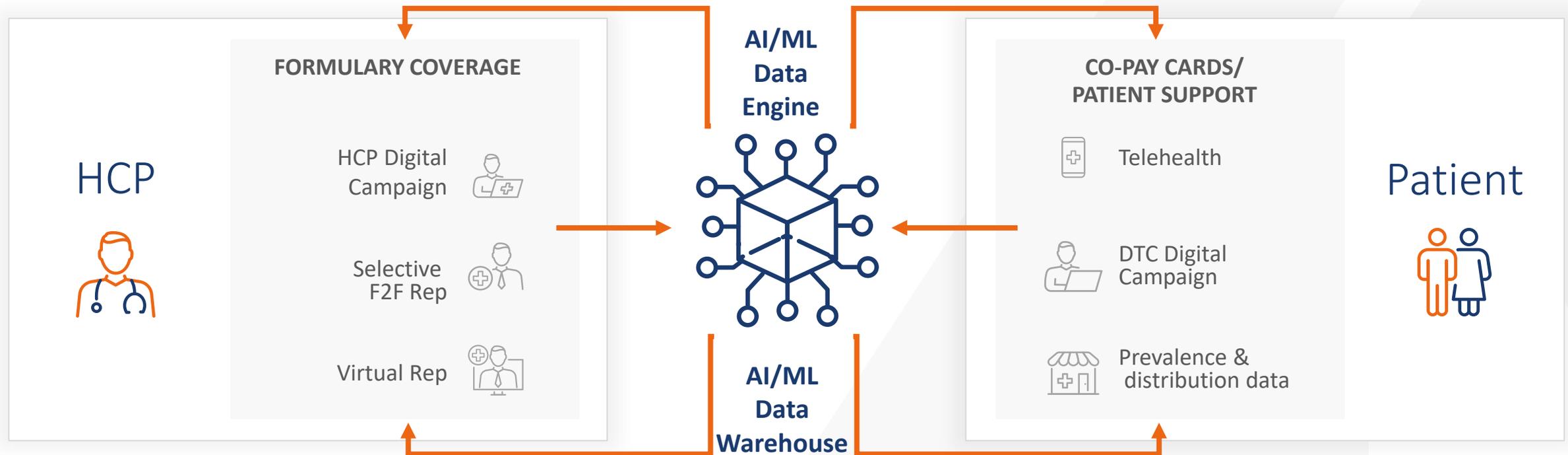
2. P360 "Maximizing Pharma Sales Call Effectiveness in Today's Industry" Dec. 2023.

3. Prescriber Point Maximizing HCP engagement with your mobile & social media channels, July 2024.

# Integrated ecosystem is required

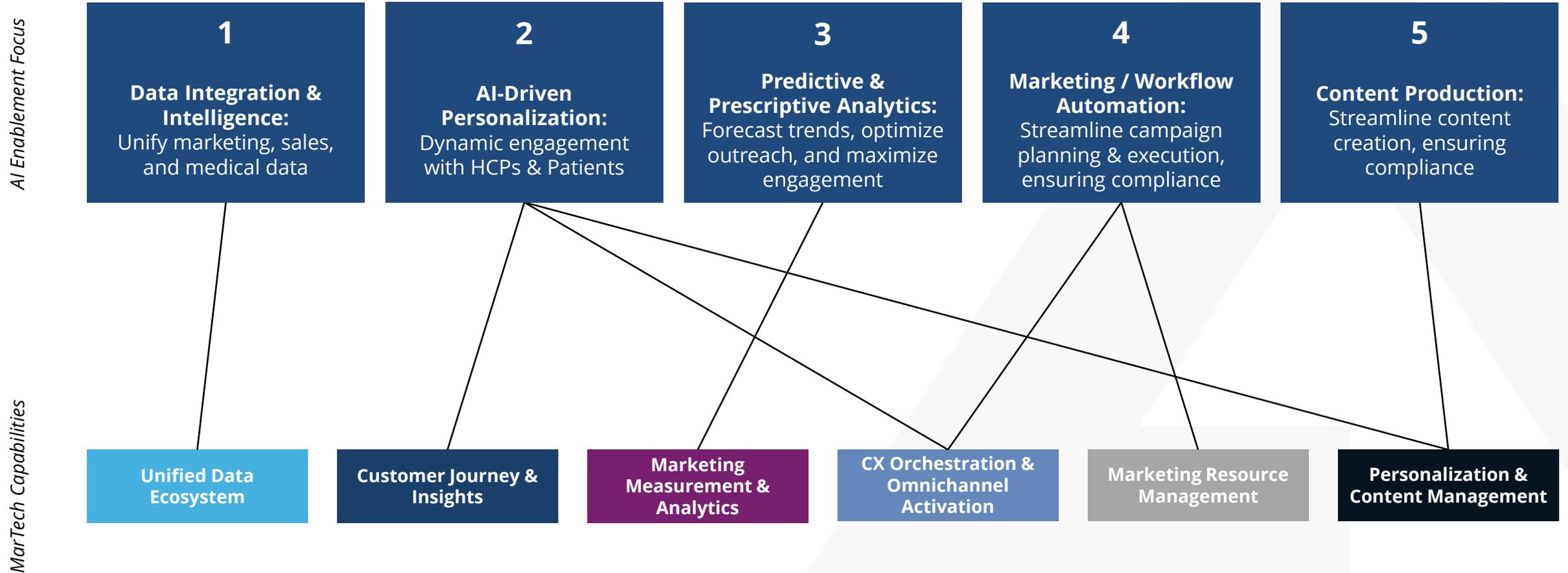
HCP access and engagement preferences have changed

Leverages AI and ML to orchestrate fully integrated services with more agility and efficiency



# AI as a strategic enabler

AI is a critical enabler in our marketing evolution: enhancing data-driven decision-making, customer engagement, automation, and predictive insights



# Role of data in Achieve's marketing strategy

Achieve's data requirements are anchored in strategic marketing imperatives

## DATA NEEDS

### Patient

Designed Enriched behavioral and demographic data (e.g., search behavior, smoking cessation intent)

### HCP

Decile-based prescribing behavior and openness to prescribing

### Channel

Performance metrics across digital, social, and offline channels

### Public Health & Regulatory

Market and competitor trends, legislation and insurance changes, and research outcomes

INGEST INTO AND ACTIVATE FROM A UNIFIED DATA ECOSYSTEM

## DATA GOALS

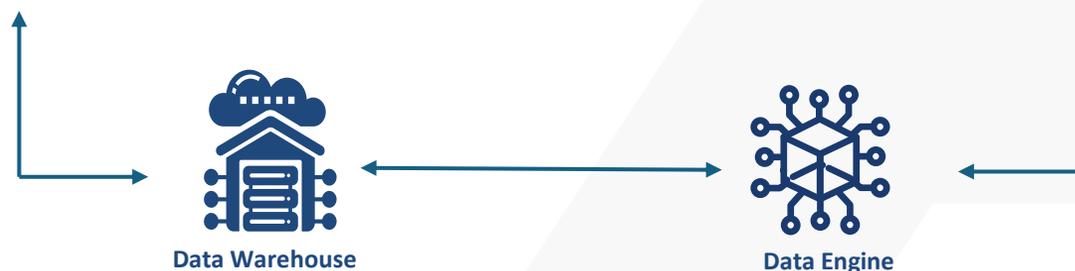
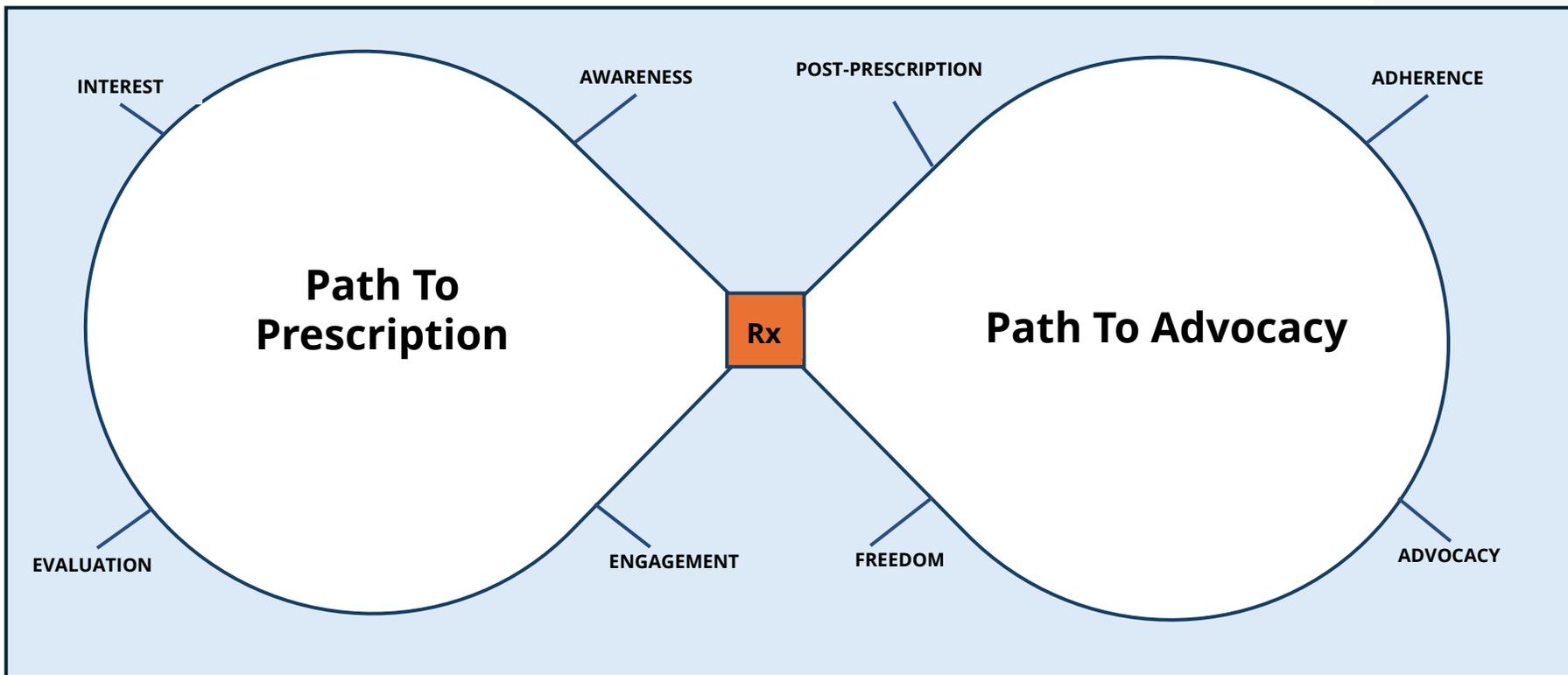
Enable targeting precision through enriched profiles

Drive activation success with actionable insights

Ensure compliance with data privacy standards

# Launch focus on data-driven omnichannel approach

Right message, right time, right channel - to optimize reach and impact



HCP Toolkit  
Examples



Email



Social

SKIPTA

Medscape

sermo SRNT

Professional Networks



Virtual Sales  
Reps



F2F Reps



Patient Toolkit  
Example



KOL Content



Banner Ads



Social



Paid Search



Earned Media



**Aiming to transform public  
health while delivering  
shareholder value**

# ACHV: Poised to disrupt and drive value

## Executive summary

### Public health priority

Smoking is the leading cause of preventable death and disease.<sup>1</sup>  
Covered by the Affordable Care Act.<sup>2</sup>

### Near-term solution

With a compelling data package and differentiated product profile, we believe cytisine is well-positioned to become the new standard of care for nicotine dependence.

### Proven leadership

Executive team and board of directors with track record of successful value creation.

### Clear commercial vision

Large and underserved market opportunity and patient need for new and effective treatment for nicotine dependence.

### Strong IP position

Broad IP portfolio and patent protection to 2040.  
Synthetic cytisine IP pending.

### Liquidity

Cash position as of 12/31/25 was \$36.4 million.

1. US Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Centers for Disease Control and Prevention; 2014. <https://www.cdc.gov/tobacco/sgr/50th-anniversary/index.htm>.

2. US Department of Health and Human Services. *Patient Protection and Affordable Care Act Health-Related Portions of Health Care and Education Reconciliation Act; 2010*. <https://www.hhs.gov/healthcare/about-the-aca/index.html>.



Thank you!