



Corporate Presentation

January 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 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.

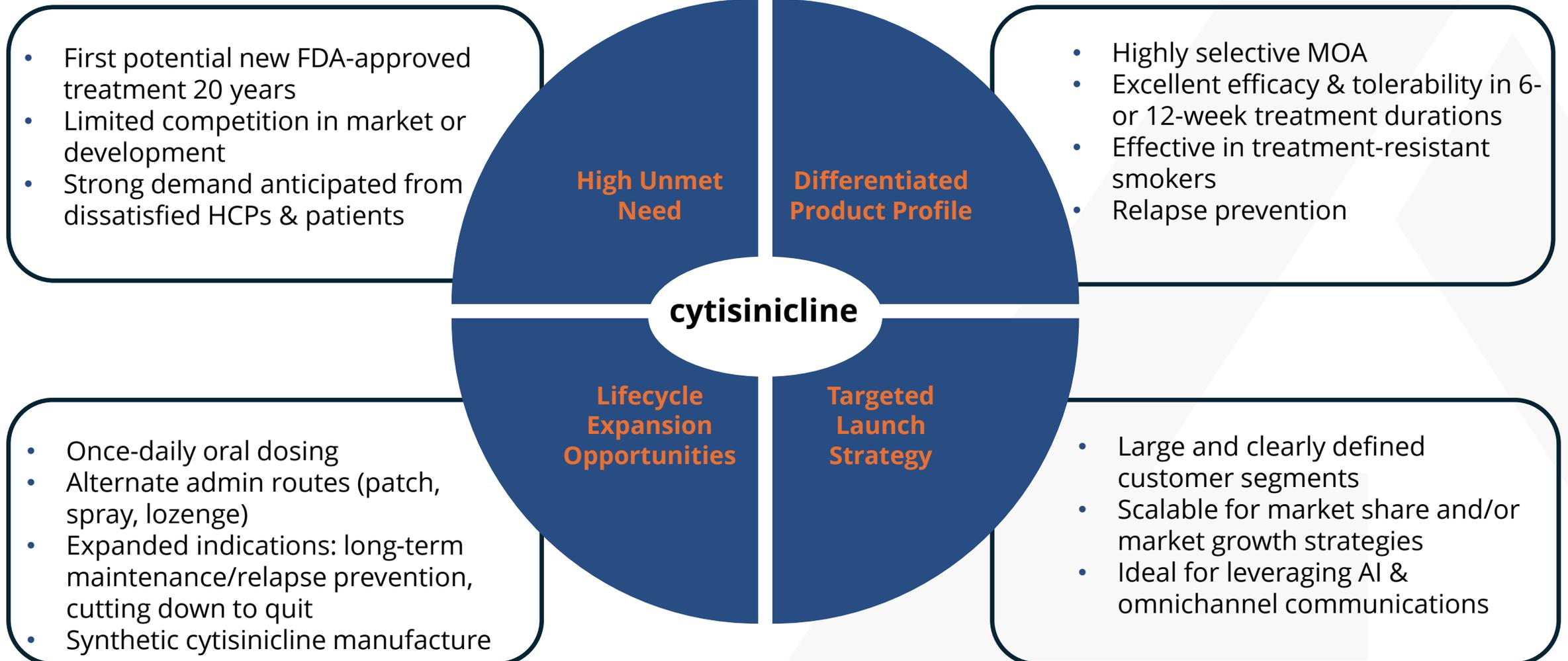
Certain data in this presentation are based on cross-study comparisons and are not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities and differences. The values shown in the cross-study comparisons are directional and may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

Cytisinicline, as a first potential new nicotine dependent treatment in nearly 20 years, gives Achieve Life Sciences a **unique opportunity to treat an addressable market of up to 50 million Americans who use tobacco¹**

- 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 expected June 20, 2026.
- 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 anticipated Affordable Care Act coverage.
- 5 **Focused launch strategy** leveraging innovative, data-driven solutions to drive adoption and future growth.

1. Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults—United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a1>.

Introducing... Cytisinicline: Innovation, overdue.



Driving toward regulatory approval and launch

Anticipated timeline and key milestones

Smoking Cessation 

NDA Acceptance

FDA Review Period

FDA Approval

Product launch

Expected Cytisinicline Milestones

2H'25

1H'26

1H'26

2H'26

1H'27

E-cigarette Cessation 

 ORCA-V2

Phase 3 Trial Initiation*

 ORCA-V2

Phase 3 Completion (CNPV)**

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

* E-cigarette cessation program timeline is finance dependent.

** Commissioner's National Priority Voucher.

Over \$600B in smoking-related U.S. health care costs annually¹

Nicotine dependency is a medical issue, requiring a medical solution

80%

of deaths from lung cancer & COPD from smoking³

2-4x

increased risk of CVD from smoking³

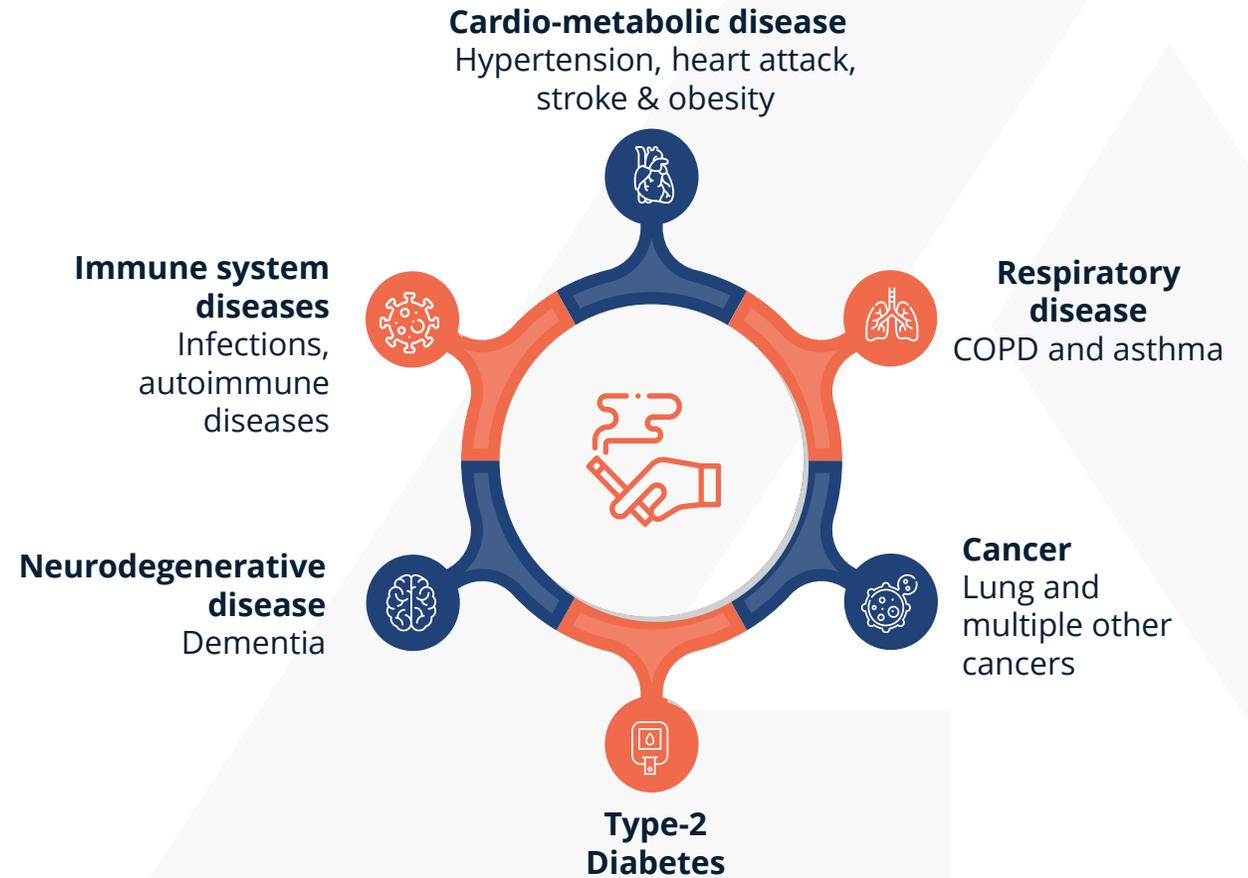
30-40%

increased risk of Type 2 Diabetes from smoking³

9x

increased risk of stroke from heavy smoking⁴

29M U.S. smokers with few treatment options²



Profound co-morbidity health harms from smoking

1. Centers for Disease Control and Prevention. (2024, September 17). Economic trends in tobacco. <https://www.cdc.gov/tobacco/php/data-statistics/economic-trends/index.html>. 2. 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; 3. USDHHS-The Health Consequences of Smoking-2014; 4. Bhat VM,-2008.

Cytisinicline impact on cardio-metabolic disease

STRATEGIC THESIS

- Smoking cessation is one of the highest-impact, most modifiable cardiometabolic risk factors. 9 million obese smokers in U.S.¹ Cessation increases absolute CV risk reduction when bundled with GLP-1/SGLT2/PCSK9/anti-thrombotics.

COMMERCIAL LOGIC

- Same prescribers (PCP/cardiologists/endocrinologists/pulmonologists), digital-first delivery, and public-health tailwinds enable efficient scale.

PAYER ENVIRONMENT

- Enables outcomes-based contracts in obesity/diabetes/ASCVD programs (continuous abstinence endpoints).

STRATEGIC POSITIONING

- Shift from treating downstream disease to removing upstream causes; credible prevention narrative with payers, employers and policymakers.

FINANCIAL LOGIC

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

PUBLIC HEALTH PRIORITY

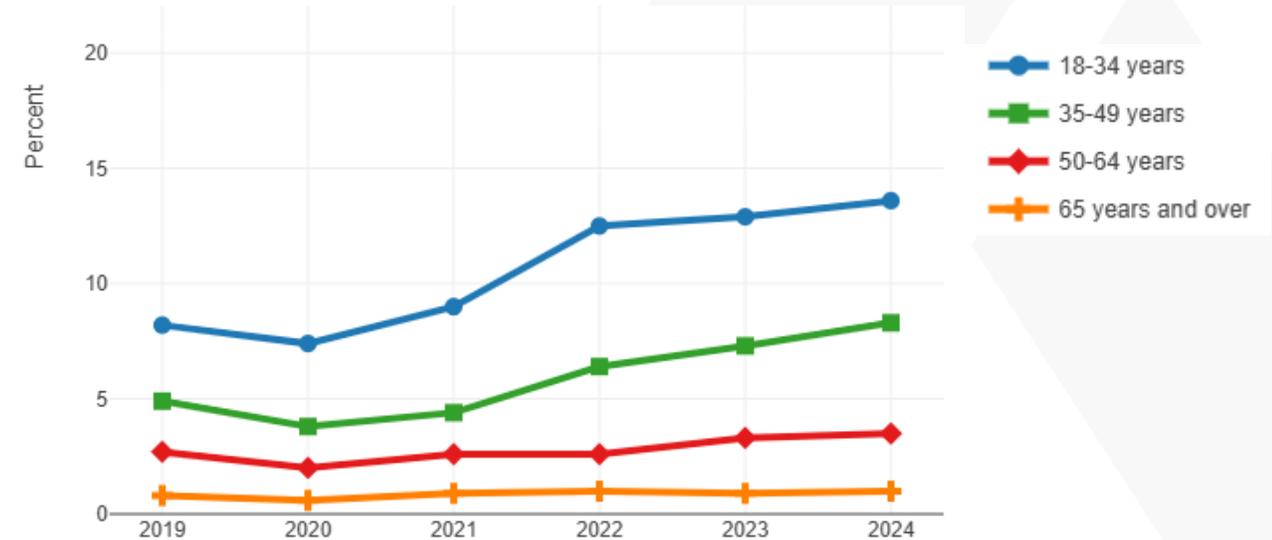
- Strengthens prevention narrative and ESG/public-health alignment.

1. NIH National Library of Medicine (2006, Jul. 1). Smoking, obesity, and their co-occurrence in the United States: cross sectional analysis. [https://pmc.ncbi.nlm.nih.gov/articles/PMC1488756/#:~:text=Nearly%2041.5%25%20of%20adults%20\(81,women%20smoke%20and%20are%20obese](https://pmc.ncbi.nlm.nih.gov/articles/PMC1488756/#:~:text=Nearly%2041.5%25%20of%20adults%20(81,women%20smoke%20and%20are%20obese)

~60% of adult e-cigarette users want to quit¹

- Majority of people who **vape are 18-24** and have **never smoked**^{3,4}
- 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**⁵
- 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

~17M U.S. adults reported use of e-cigarettes²



Source: National Center for Health Statistics, National Health Survey⁶

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. Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: <https://dx.doi.org/10.15620/cdc/174583>
 3. 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.
 4. 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.
 5. 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*.
 6. 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://www.cdc.gov/NHISDataQueryTool/SHS_adult/index.html

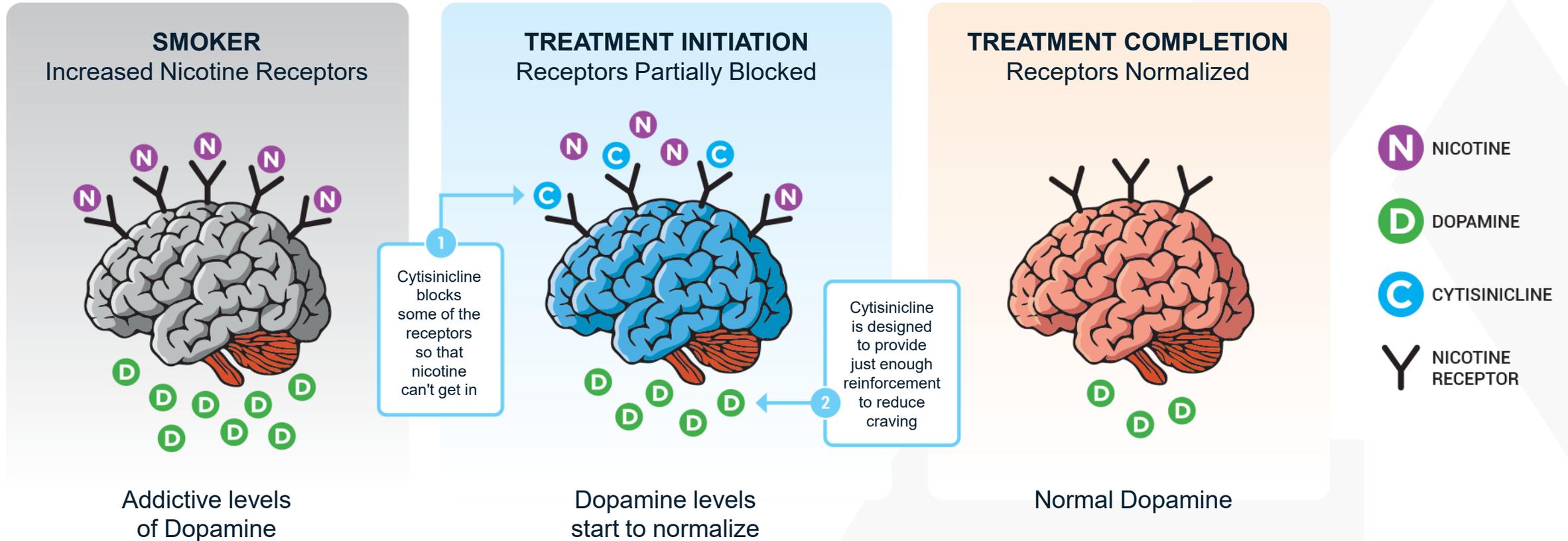


**Cytisinicline: The first new
potential treatment option for
nicotine dependence in 20 years**

Nicotine dependence alters brain chemistry

Cytisinicline helps restore it

Dual-acting mechanism of action



Nicotine Dependence is a neurobiological cycle of craving and withdrawal

Smoking cessation trials demonstrated clear benefits

Efficacy, tolerability, craving reduction, broad patient response

Key insights from smoking cessation trials (N=1602)

Robust efficacy

Odds ratios exceeding all available treatment options in both 6- and 12-week dosing options

Excellent tolerability

Nearly all single-digit rates of adverse events and excellent treatment adherence

Reduction in cravings and urges

Clear and significant reductions in overall urges and cravings occurred within 6 weeks of cytisinicline treatment

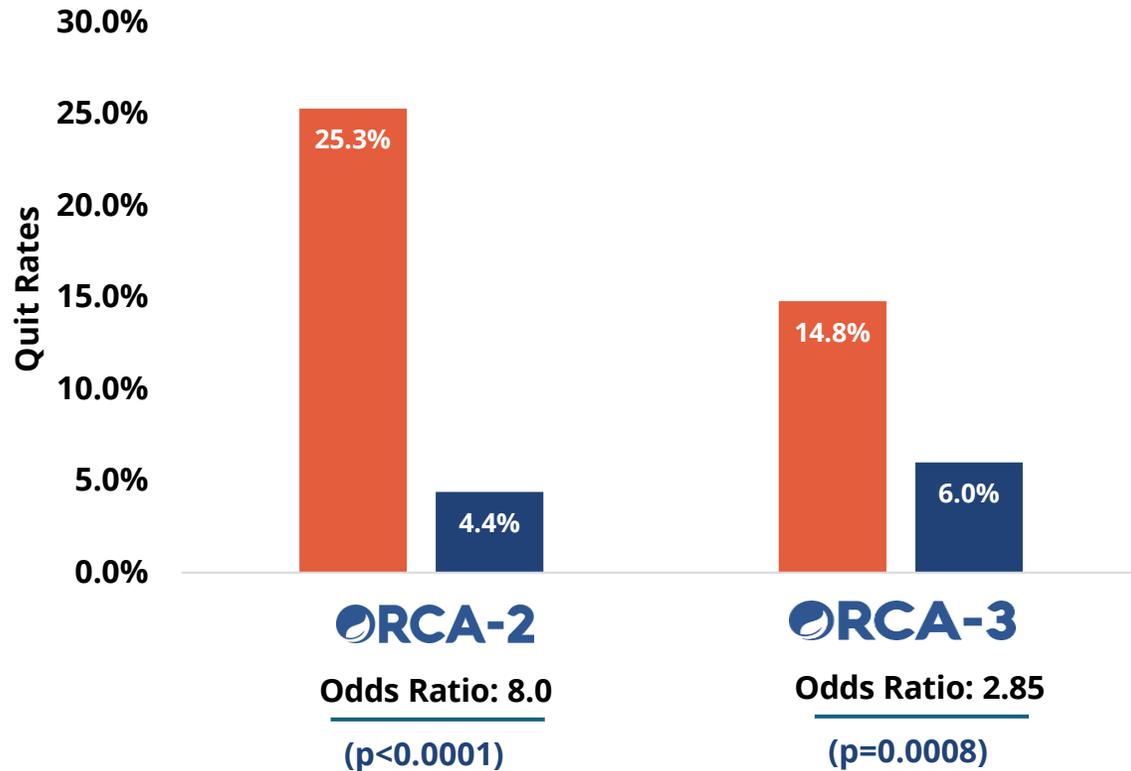
Broad patient response

Cytisinicline benefited heavily pre-treated and hardened smokers regardless of gender, age, prior quit attempts (# and methods), and other concomitant medical conditions

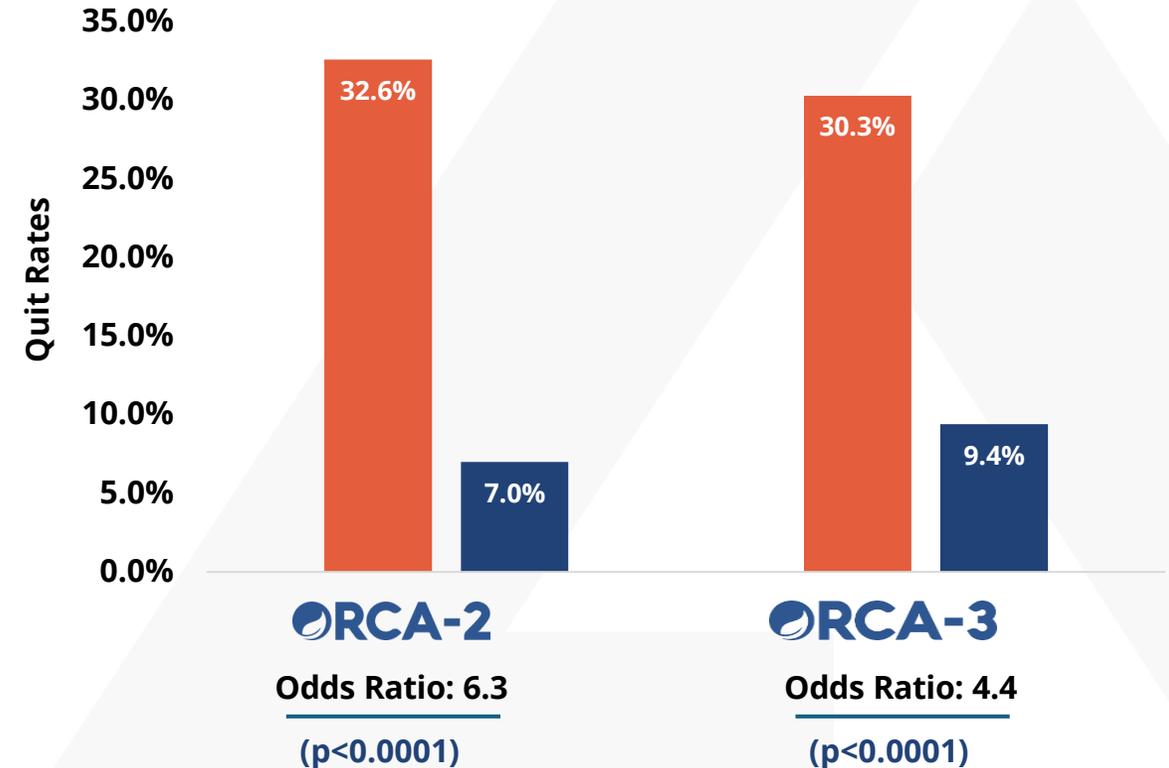
Strong results from smoking cessation trials

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

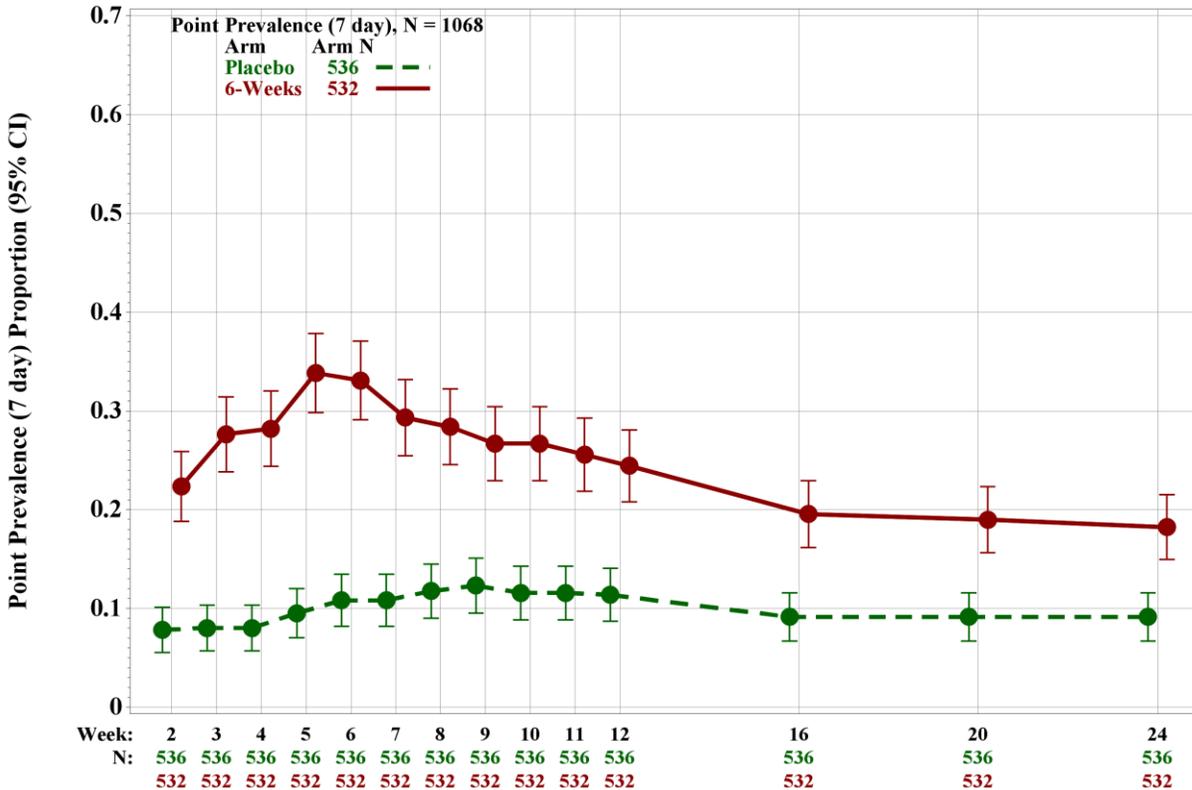
Source: ORCA-2: Rigotti NA, Benowitz NL, Prochaska JJ, et al. Cytisinicline for Smoking Cessation: A Randomized Clinical Trial. *JAMA*. 2023;330(2):152–160. ORCA-3: Rigotti NA, Benowitz NL, Prochaska JJ, et al. Cytisinicline for Smoking Cessation: The ORCA Phase 3 Replication Randomized Clinical Trial.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

Overall effectiveness: Pooled Phase 3 studies

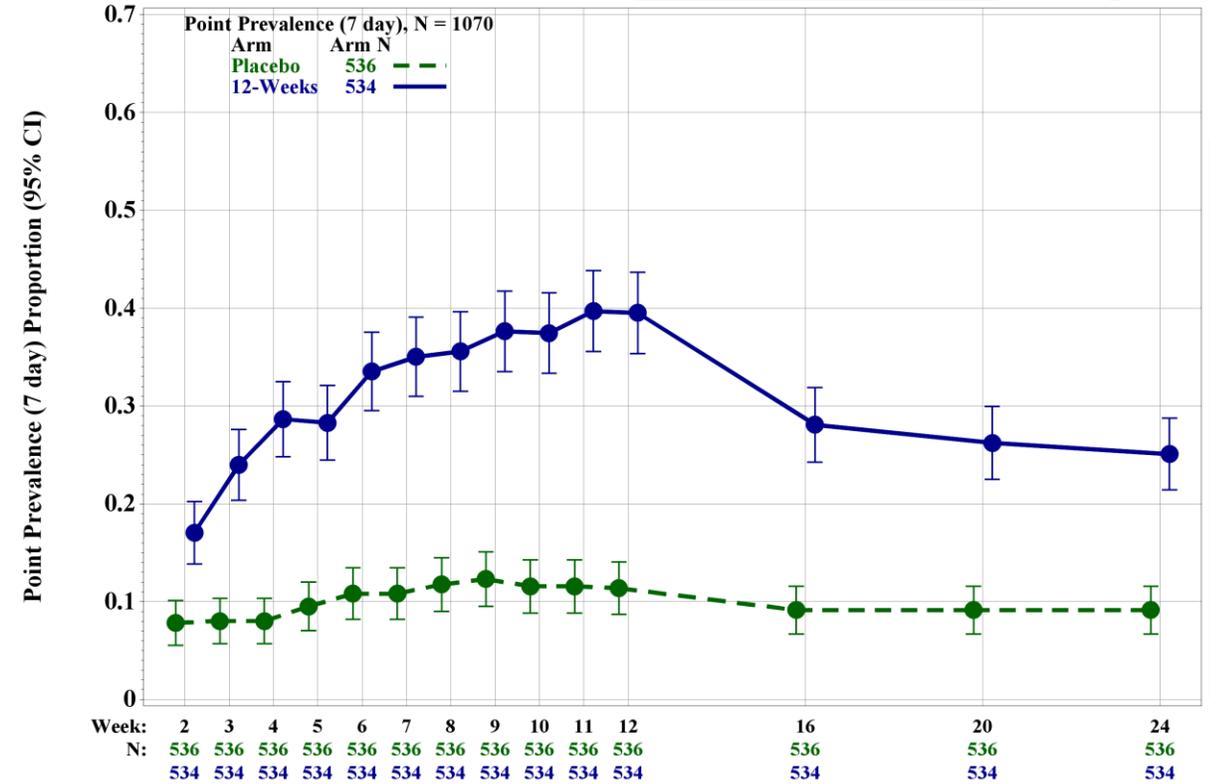
Cytisinicline demonstrates higher abstinence rates vs placebo

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

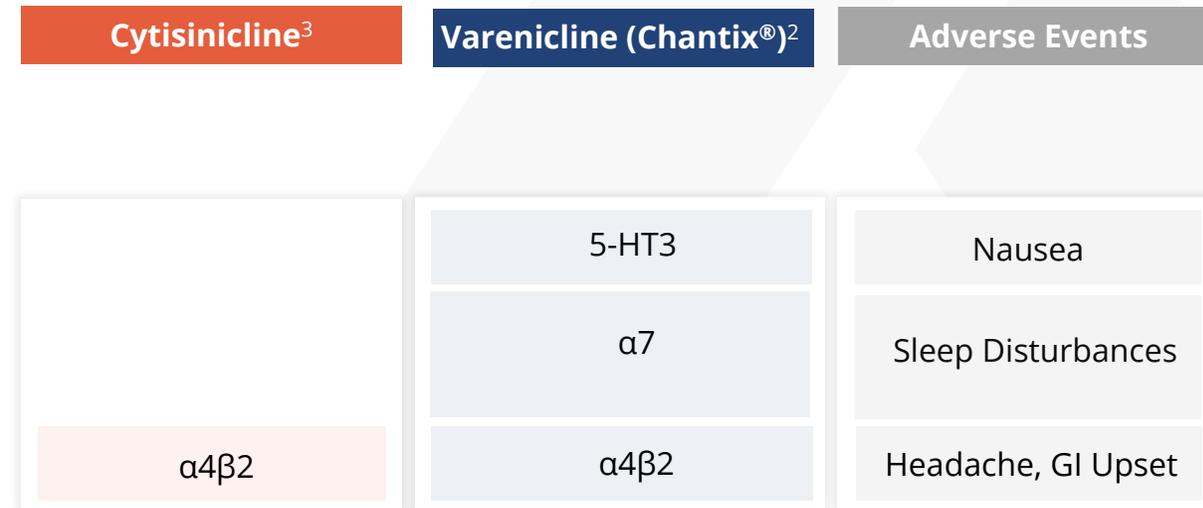
Highly selective targeting improves tolerability profile

Adverse event profile compared to Chantix®

Comparative Analysis of Safety Events*

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

Selective Receptor Targeting³



Cytisinicline is >2000 fold less potent at the human 5-HT3 receptor⁴

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.

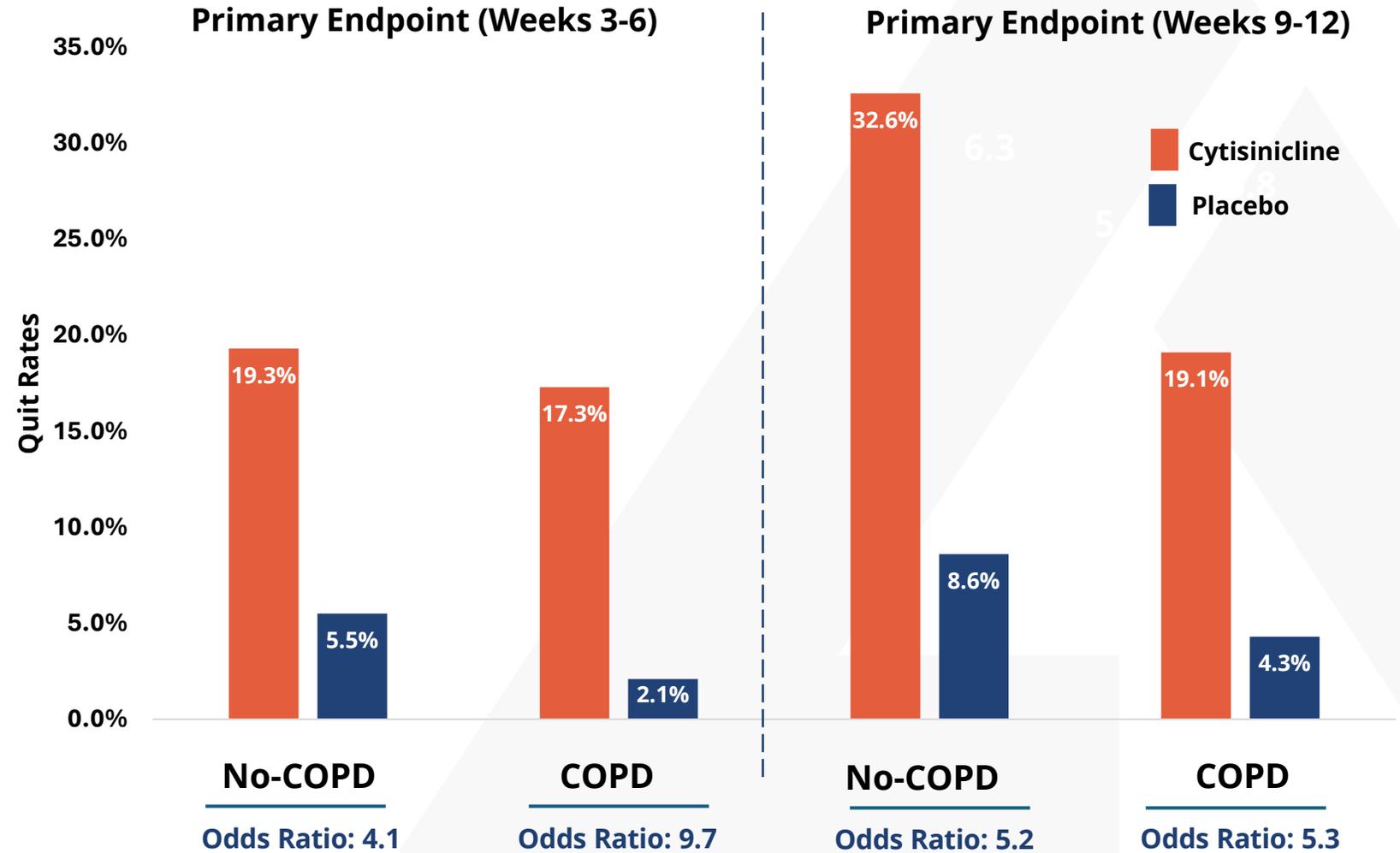
*Not a head-to-head comparison trial evaluation.

Comparable quit rates in COPD and non-COPD smokers

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

Quitting smoking remains the most impactful intervention for COPD, and cytisinicline is being explored as a potential therapy to help address this critical need.

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



Commissioner's National Priority Voucher for vaping

Cytisinicline one of nine treatments awarded CNPV

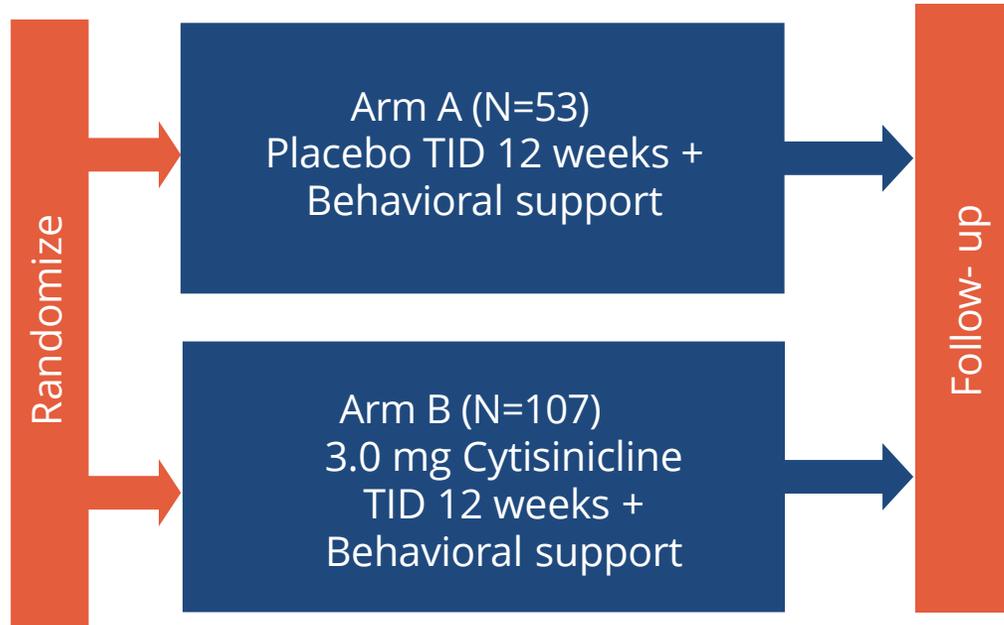
- CNPV program accelerates the review of products that align with national priorities
- Selected products must address large emerging public health needs such as crises, provide innovative cures, address unmet medical needs or enhance national security through drug development and manufacturing to advance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

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

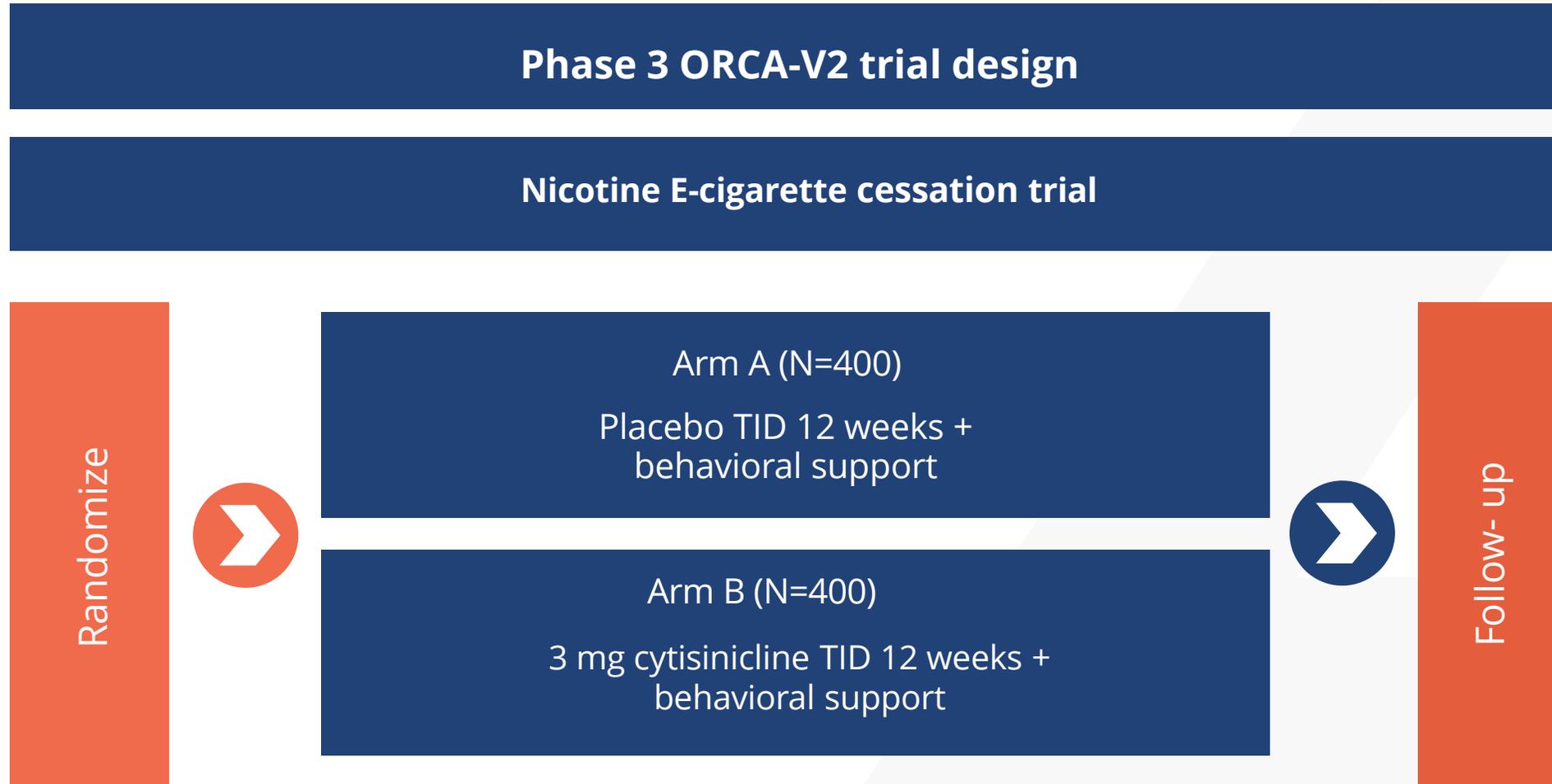
Phase 3 warranted

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



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 annually¹
- ~50% who saw an HCP received advice about quitting⁵
- <10% successfully quit¹

No new FDA-approved options **in nearly 20 years**



CDC estimates 36% of people who smoke utilize Rx and OTC cessation treatments annually⁵

1. VanFrank B, Malarcher A, Cornelius ME, et al. Adult Smoking Cessation United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633-641

2. Estimate of \$500/mo. Chantix pricing - 1 mo.. Rx/patient

3. Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: <https://dx.doi.org/10.15620/cdc/174583>

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

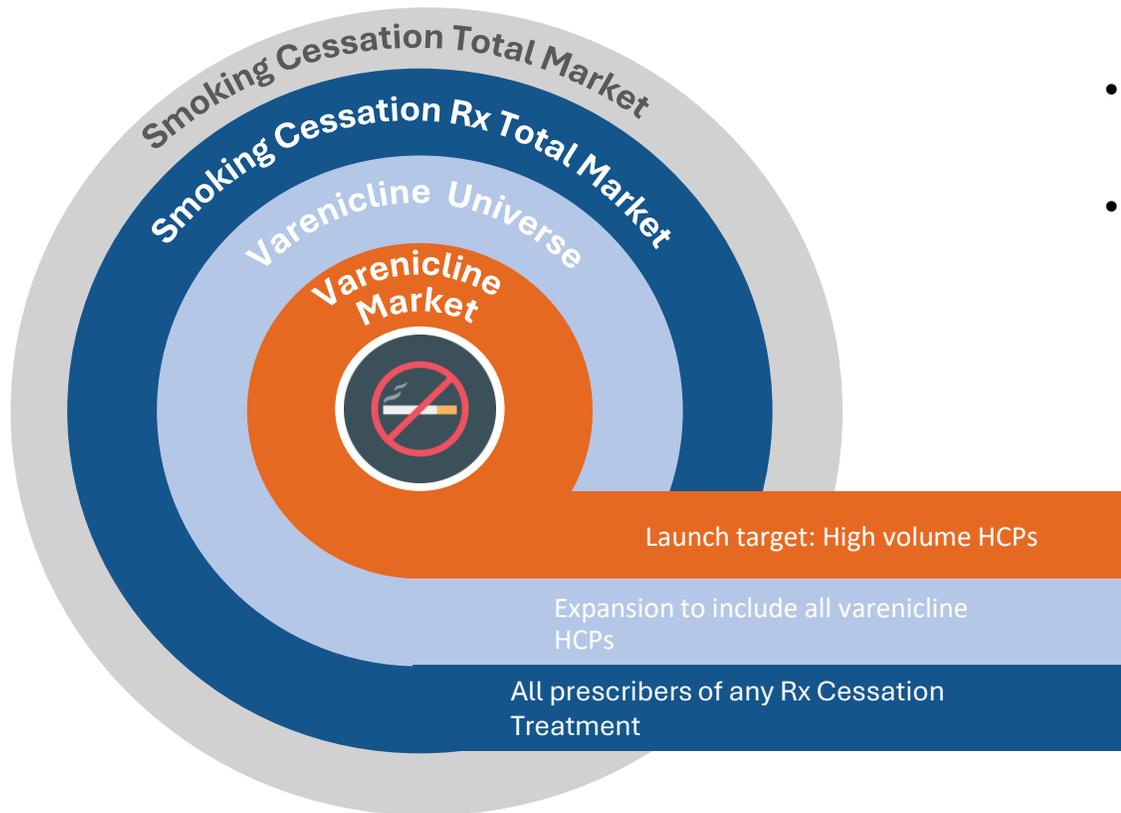
Highly Motivated Quitters

- 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 strategy

Built for growth: initial target on varenicline market share

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



- 1** — Market share launch strategy: Phased digital + F2F/virtual promotion to high-decile prescribers
- 2** — 2nd wave expansion option: Extend promotion efforts to additional targets
- 3** — 3rd wave expansion option: Conversion of bupropion, NRT, and market growth

Traditional pharma promotional model is evolving

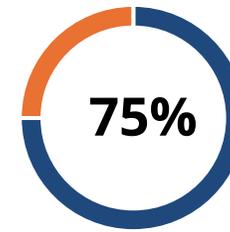
HCP access and engagement preferences have changed

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 reps¹



Time HCPs give rep for in-person discussion²



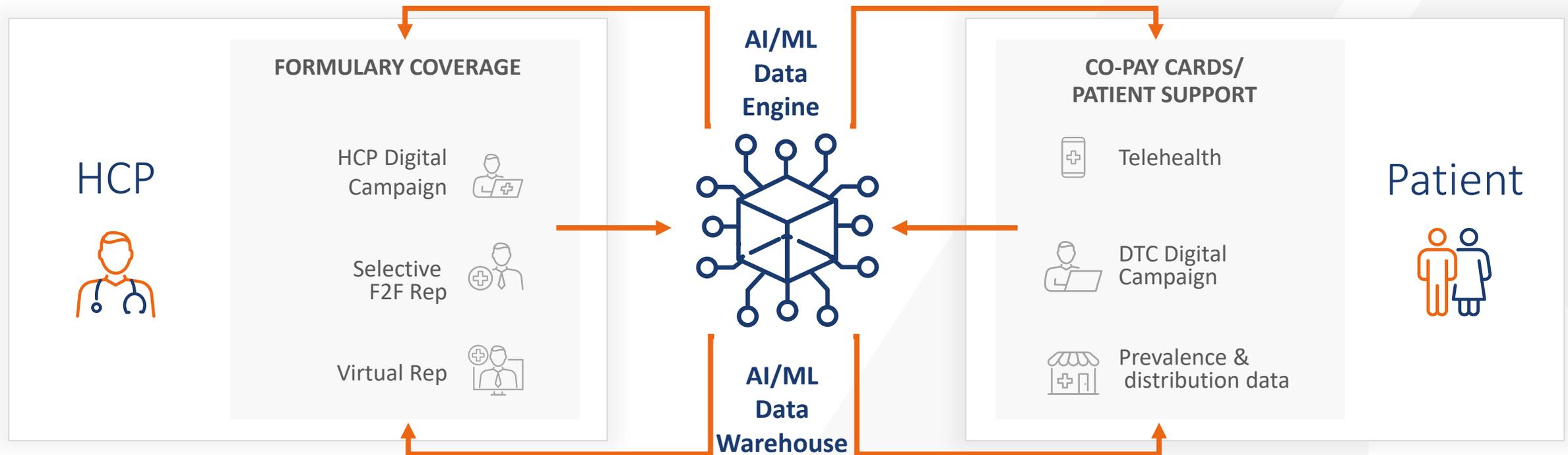
Average time HCP spends daily engaging with non-branded affiliated digital and social channels³

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

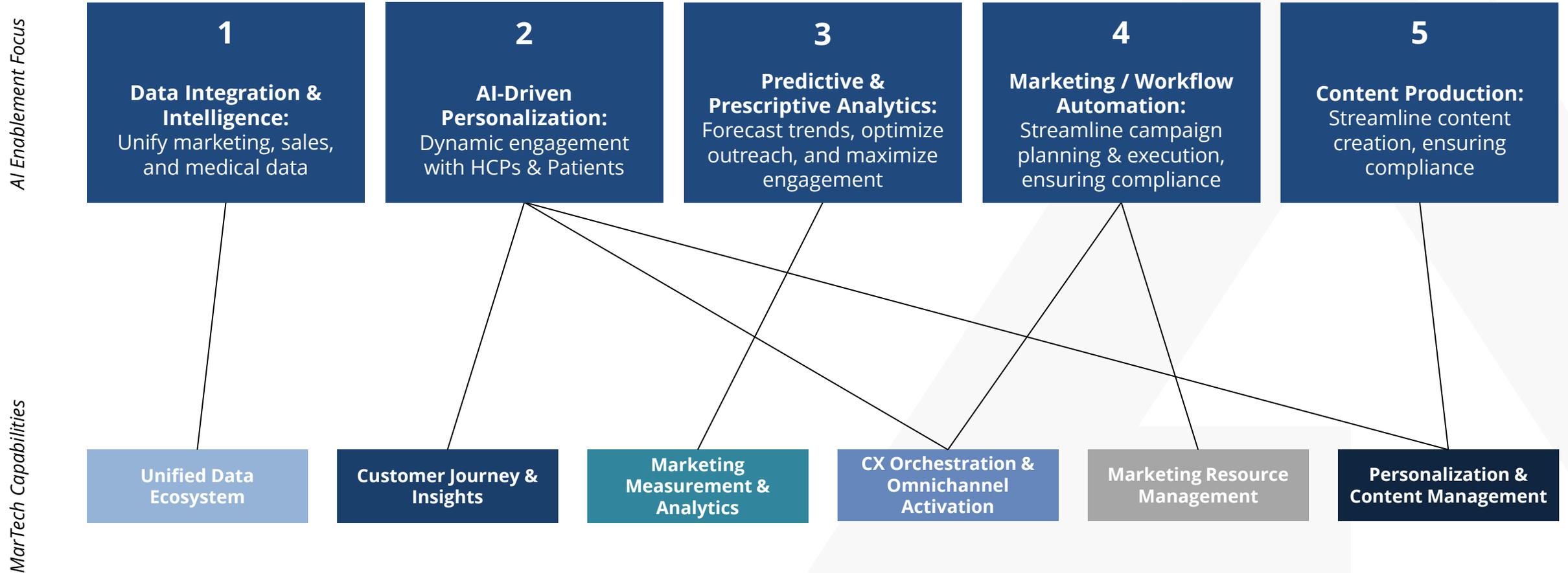
HCP access and engagement preferences have changed

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

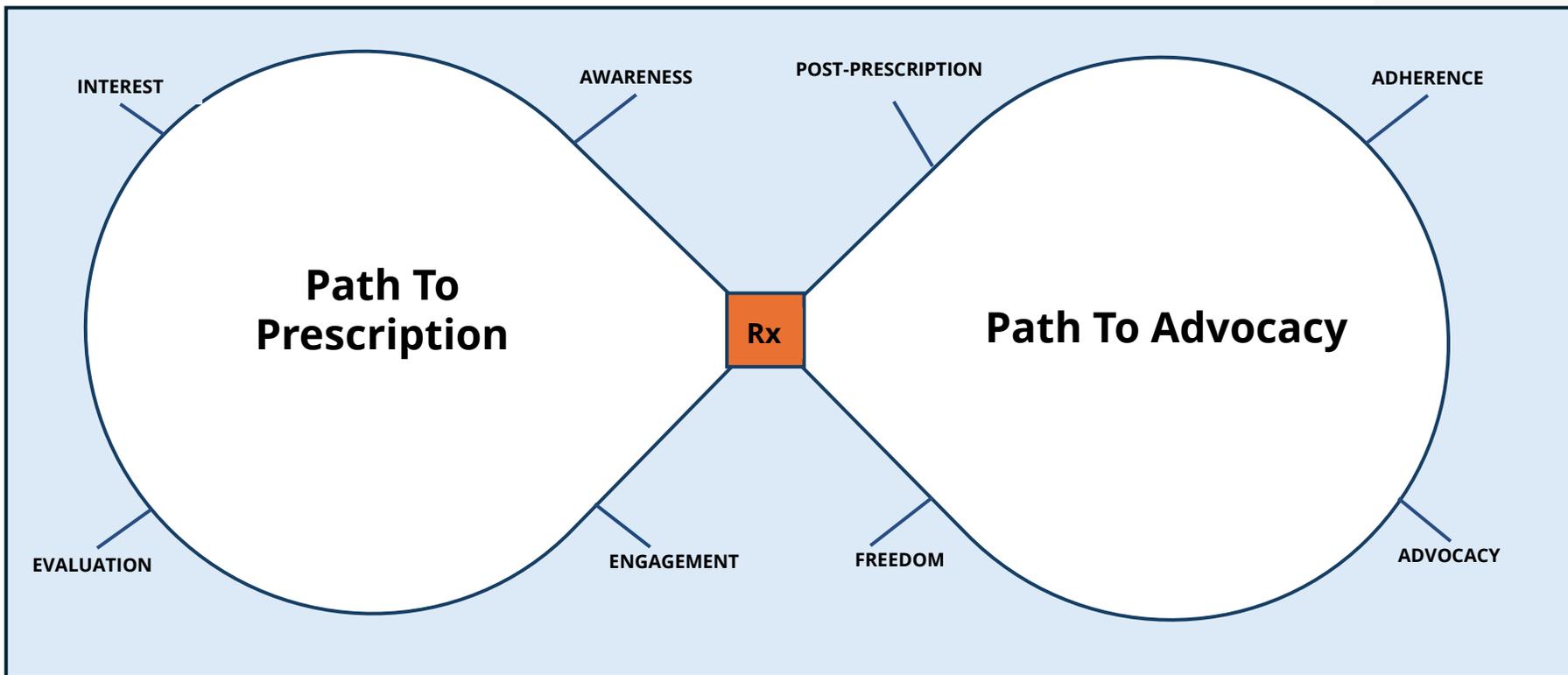
Enable targeting precision through enriched profiles

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



Data Warehouse



Data Engine





**Transforming 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.¹
Covered by the Affordable Care Act.²

Near-term solution

With a compelling data package and differentiated product profile, we believe cytisinicline 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 cytisinicline IP pending.

Cash position

Cash runway into the second half of 2026.

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!