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## Alpha Cognition’s Oral Therapy ZUNVEYL® Receives FDA Approval to Treat Alzheimer's Disease

*The Second Oral Therapy Approved This Decade, ZUNVEYL’s Dual MOA Was Designed to Eliminate Drug Absorption in the Gastrointestinal (GI) Tract, Potentially Addressing Certain Tolerability Issues with Leading Alzheimer’s Disease (AD) Medications, Combined with a Long-Term Efficacy Profile*

*ZUNVEYL’s Innovative Approach Targets AD Symptoms Directly, Designed to Provide Patients with Significant Benefits to Cognitive and Global Function and the Ability to Perform Daily Living Activities*

*Alzheimer’s Disease, the Most Common Form of Dementia, Affects Nearly 7million People in the United States, including 70% of All Nursing Home Residents and is the Leading Cause of Nursing Home Admissions and Deaths*

**VANCOUVER, B.C., and Dallas, July 29, 2024 - Alpha Cognition (CSE: ACOG) (OTCQB: ACOGF)** (Alpha Cognition “ACI”, or the “Company”), a biopharmaceutical company developing novel therapeutics for debilitating neurodegenerative disorders, announces that the U.S. Food and Drug Administration (FDA) has granted approval for ZUNVEYL® (benzgalantamine) previously known as ALPHA-1062, for the treatment of mild-to-moderate Alzheimer's disease. Alzheimer’s disease (AD) is a progressive brain disorder that slowly destroys memory, thinking skills, and eventually the ability to do simple tasks, like carry on a conversation. AD is the most common form of dementia affecting nearly 7 million people, and is the leading cause of nursing home admissions and deaths, with 70% of all nursing home residents suffering with AD.

A novel oral therapy, ZUNVEYL has a dual mechanism of action designed to eliminate drug absorption in the GI tract, potentially addressing certain tolerability issues with leading AD medications, combined with the efficacy and long-term benefit profile of galantamine. Tolerability affects therapy adherence, with data showing that 55% of AD patients discontinue their medication after one year, mainly due to GI side effects and insomnia. Medication discontinuation can cause risk to patients themselves, and dissatisfaction and burden among nursing home staff, physicians, and caregivers.

ZUNVEYL, a prodrug of AD treatment galantamine and an acetylcholinesterase inhibitor (AChEI), is postulated to exert its therapeutic effect by preventing the breakdown of acetylcholine, the important brain neurotransmitter involved in memory, motivation, and attention functions. It is also an allosteric potentiator of  $\alpha$ -7 nicotinic acetylcholine and  $\alpha$ 4 $\beta$ 2 receptors. This action facilitates the release of acetylcholine from the presynaptic neurons, giving clinical significance to its dual mode of action. ZUNVEYL targets AD symptoms, to provide patients with long-lasting benefits to cognitive and global function and the ability to perform daily activities that are impaired by AD. Galantamine, FDA-approved since 2001, has extensive and positive data related to long-term outcomes, demonstrating activity among multiple brain receptors, anti-inflammatory effects, and is associated with improved memory, attention, and a significantly lower risk of death. It also has the strongest effect on cognitive decline in the AChEI class of medications and demonstrated significant risk reduction of developing severe dementia. Due to its prodrug properties, ZUNVEYL is effectively converted into the active moiety of galantamine after it passes through the GI tract, therefore achieving the same therapeutic effects of galantamine. It was also uniquely designed to eliminate drug absorption in the GI tract, potentially addressing certain tolerability issues and has a CNS safety profile that includes no incidence of insomnia. Information about ZUNVEYL’S pivotal clinical studies are included further in this press release, and in the ZUNVEYL prescribing information.



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"I am very excited about the approval of ZUNVEYL, which we believe offers better tolerability for patients with Alzheimer's disease. We have always believed in the efficacy of galantamine but have been limited in its use due to tolerability issues. To now have an agent with the efficacy of galantamine, but that also offers the hope of better tolerability, will provide physicians a great option to treat patients," said Elaine Peskind, MD, the Friends of Alzheimer's Research Professor of Psychiatry at the University of Washington School of Medicine. "This advancement marks a meaningful step forward in improving the quality of life for those living with Alzheimer's and their families. As a geriatric psychiatrist specializing in Alzheimer's disease, I am eager to incorporate this new treatment into our practice and see the positive difference it will make."

"The approval of ZUNVEYL is a pivotal moment in the fight against Alzheimer's disease as it is only the second oral AD treatment to be approved in more than a decade. ZUNVEYL was designed to address a critical need for a tolerable and effective treatment that can potentially enhance patients' daily lives with improved long-term outcomes," stated Alpha Cognition Chief Executive Officer Michael McFadden. "We are delighted, as this represents a major breakthrough in Alzheimer's treatment, providing hope to millions of patients, families, and caregivers affected by this devastating disease."

#### **About the Pivotal ZUNVEYL Clinical Studies**

ZUNVEYL's approval was based on chemistry, manufacturing, and controls information and data demonstrating the bioequivalence and tolerability of ZUNVEYL compared to galantamine immediate-release tablets and galantamine extended-release capsules. Importantly, there were minimal adverse events reported in these trials.

- **Efficacy, Tolerability, Safety:** The efficacy of ZUNVEYL is based upon 3 bioavailability studies in healthy adults comparing galantamine immediate-release tablets and galantamine extended-release capsules to ZUNVEYL. GI adverse events documented across all studies for ZUNVEYL were less than 2% and no insomnia was observed.
- **Dual Mechanism of Action:** While precise mechanism of action is not known, it is believed that ZUNVEYL works through two distinct pathways to enhance neurotransmitter activity and protect neuronal health, leading to improved cognitive and functional outcomes.
- **Long-Term Benefits:** Clinical trials for galantamine (ZUNVEYL's active moiety) have demonstrated sustained improvements in cognitive function and quality of life over extended periods of treatment.

#### **Availability**

ZUNVEYL will be available by prescription in pharmacies nationwide in Q1 2025. Alpha Cognition is committed to ensuring broad access to this innovative treatment and will work closely with healthcare providers, insurers, and patient advocacy groups to support its distribution.

"We are excited to launch ZUNVEYL and bring this much-needed treatment option to patients suffering from Alzheimer's disease," said Lauren D'Angelo, Alpha Cognition's Chief Operating Officer. "Over the coming months, our team will work diligently to prepare for this launch, ensuring that healthcare providers have the information and patients have the resources and support they need. ZUNVEYL offers dual-action benefits with



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the established efficacy of galantamine and no insomnia. It was uniquely designed to bypass the gut with the potential of minimizing GI side effects. We believe that ZUNVEYL's unique combination of these attributes will make a meaningful difference in the lives of those affected by this debilitating disease. We look forward to collaborating with our partners to ensure a successful rollout and broad accessibility."

#### **About Alpha Cognition Inc.**

Alpha Cognition Inc. is a clinical stage, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease and Cognitive Impairment with mild Traumatic Brain Injury ("mTBI"), for which there are currently no approved treatment options.

ZUNVEYL, previously ALPHA-1062, is a novel patented oral Alzheimer's disease therapy with a dual mechanism of action designed to eliminate drug absorption in the GI tract, potentially addressing certain tolerability issues with leading AD medications, combined with the efficacy and long-term benefit profile of galantamine. As a new generation acetylcholinesterase inhibitor, it was developed to demonstrate a potentially improved GI side effect profile and has a CNS safety profile that includes no incidence of insomnia. While precise mechanism of action is not known, it is believed that ZUNVEYL works through two distinct pathways to enhance neurotransmitter activity and protect neuronal health, leading to improved cognitive and functional outcomes.

Separately, ZUNVEYL is also being developed in combination with memantine to treat moderate-to-severe Alzheimer's dementia, and as an intranasal formulation for Cognitive Impairment with mTBI. For more information about ZUNVEYL, please visit [www.zunveyl.com](http://www.zunveyl.com) or contact [info@alphacognition.com](mailto:info@alphacognition.com) and connect with us on [Twitter](#) and [LinkedIn](#).

#### **INDICATION**

ZUNVEYL (benzgalantamine) is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults.

#### **IMPORTANT SAFETY INFORMATION**

##### **INDICATION**

ZUNVEYL® (benzgalantamine) is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults.

##### **IMPORTANT SAFETY INFORMATION**

##### **Contraindications**

ZUNVEYL is contraindicated in patients with known hypersensitivity to benzgalantamine, galantamine, or any inactive ingredients in ZUNVEYL.

##### **Warnings and Precautions**

- **Serious Skin Reactions:** Serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving galantamine (the active metabolite of (ZUNVEYL) tablets. If signs or symptoms suggest a serious skin reaction, use of this drug should not be resumed and alternative therapy should be considered.



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- **Cardiovascular conditions:** Cholinesterase inhibitors, including ZUNVEYL, may have vagotonic effects on the sinoatrial and atrioventricular nodes. These effects may manifest as bradycardia or heart block in patients both with and without known underlying cardiac conduction abnormalities. Syncopal episodes have been reported in association with the use of donepezil.
- **Peptic ulcer disease and gastrointestinal bleeding:** Cholinesterase inhibitors, including ZUNVEYL, may increase gastric acid secretion. Patients should be monitored closely for active or occult gastrointestinal bleeding, especially those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDs).
- **Genitourinary conditions:** Although not observed in clinical trials of ZUNVEYL, bladder outflow obstruction may occur.
- **Pulmonary conditions:** Cholinesterase inhibitors, including ZUNVEYL, should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease. Monitor for respiratory adverse effects.

#### Adverse Reactions

The most common adverse reactions with galantamine tablets ( $\geq 5\%$ ) were nausea, vomiting, diarrhea, dizziness, headache, and decreased appetite.

#### Drug Interactions

Cholinesterase inhibitors, including galantamine, have the potential to interfere with the activity of anticholinergic medications. A synergistic effect may be expected when cholinesterase inhibitors are given concurrently with succinylcholine, similar neuromuscular blocking agents, or cholinergic agonists such as bethanechol.

These are not all of the possible side effects of ZUNVEYL. You can report side effects to the FDA.

Visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088). Please click here for [Full Prescribing Information](#).

Field Code Changed

#### Forward-looking Statements

This news release includes forward-looking statements within the meaning of applicable securities laws. Except for statements of historical fact, any information contained in this news release may be a forward-looking statement that reflects the Company's current views about future events and are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "target," "seek," "contemplate," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements may include statements regarding the ZUNVEYL efficacy and tolerability, ZUNVEYL long-term benefits, the Company's timing and planned activities to launch ZUNVEYL, potential timing for the availability of ZUNVEYL, potential future developments of ZUNVEYL, the potential market size for ZUNVEYL, the Company's business strategy, market size, potential growth opportunities, capital requirements, clinical development activities, the timing and results of clinical trials, regulatory submissions, potential regulatory approval and commercialization of the Company's products. Although the Company believes to have a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the



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future, about which we cannot be certain. The Company cannot assure that the actual results will be consistent with these forward-looking statements. These forward-looking statements are subject to certain risks, including risks regarding our ability to raise sufficient capital to implement our plans to commercialize ZUNVEYL, risks regarding the efficacy and tolerability of ZUNVEYL, risks related to ongoing regulatory oversight on the safety of ZUNVEYL, risk related to market adoption of ZUNVEYL, risks related to the Company's intellectual property in relation to ZUNVEYL, risks related to the commercial manufacturing, distribution, marketing and sale of ZUNVEYL, risks related to product liability and other risks as described in the Company's filings with Canadian securities regulatory authorities and available at [www.sedar.com](http://www.sedar.com) and the Company's filings with the United States Securities and Exchange Commission (the "SEC"), including those risk factors under the heading "Risk Factors" in the Company's Form S-1 registration statement as filed with the SEC on June 14, 2024 and available at [www.sec.gov](http://www.sec.gov). These forward-looking statements speak only as of the date of this news release and the Company undertakes no obligation to revise or update any forward-looking statements for any reason, even if new information becomes available in the future, except as required by law.

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