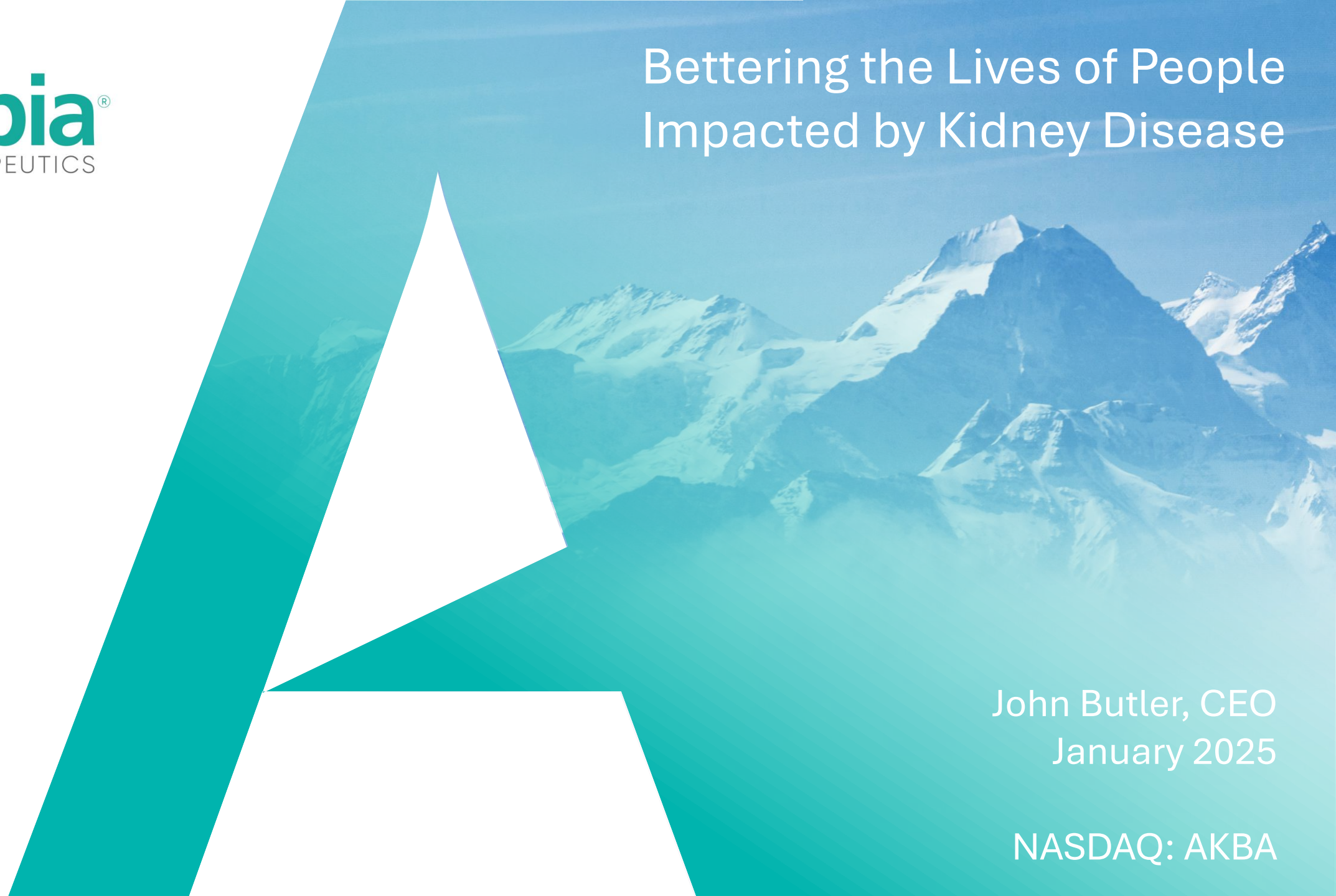
Akebia® THERAPEUTICS

# Bettering the Lives of People Impacted by Kidney Disease



John Butler, CEO
January 2025

NASDAQ: AKBA

# Cautionary note on forward-looking statements

Statements in this presentation regarding Akebia Therapeutics, Inc.'s ("Akebia's") strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia's plans, strategies and prospects for its business; Akebia's plans with respect to its U.S. commercial launch of Vafseo®, including the potential U.S. market opportunity and target patient population and ability to execute a successful launch; statements regarding commercial supply contract coverage for Vafseo with dialysis organizations and Akebia's ability to make Vafseo available to nearly 100% of U.S. dialysis patients; statements regarding Vafseo's potential to become standard of care for treatment of anemia due to CKD; statements regarding Akebia's ability to execute a successful commercial launch of Vafseo, including statements regarding the demand for Vafseo from prescribers; Akebia's ability to drive Vafseo toward a potential standard of care and demonstrate the potential additional benefits of Vafseo for patients and support label expansion, and expectations regarding the timing of full enrollment of the VOICE trial; Akebia's beliefs that it is positioned to succeed in the dialysis market and to chart a path to capitalize on a significantly larger non-dialysis market opportunity; Akebia's plans and expectations with respect to potential Vafseo label expansion to treat anemia in late-stage CKD patients who are not on dialysis, including the timing of a Phase 3 clinical trial, statements regarding correspondence with the FDA and expectations regarding the potential data package; Akebia's expectations related to the market opportunity, including payor dynamics and net price, for Vafseo in the U.S. non-dialysis patient population; statements regarding Akebia's early hypoxia-inducible factor (HIF) research and the potential therapeutic applications of the HIF pathway targeting high unmet needs, including Akebia's expectations about market opportunity and ability to execute on its development plans and expectations on the timing of a first in human trial for AKB-9090; and Akebia's goals, objectives and expectations with respect to its operating plan, expenses, cash resources and sources of funding for its cash runway, including that its existing cash and cash from operations will be sufficient to fund its operations for at least two years.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the commercial availability of Vafseo; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia® and Vafseo, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia and Vafseo, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation.

# First Vafseo® (vadadustat) Shipment on January 9

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# Leading commercial-stage company focused on kidney disease

Vafseo® (vadadustat) launched as treatment for anemia due to chronic kidney disease for adult patients on dialysis
*~$1billion U.S. market opportunity in dialysis patient population[1]*

Pursuing label expansion of Vafseo for late-stage non-dialysis CKD population
*Multi-billion-dollar U.S. market opportunity with Phase 3 trial planned in mid-2025*

Nobel prize-winning Hypoxia-Inducible Factor (HIF)-based platform enables development of novel chemical entities

Advancing pipeline of additional assets in kidney and rare disease targeting high unmet medical needs

Expect existing cash resources and cash from operations will be sufficient to fund current operating plan for at least two years



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# Vafseo launch underway


Vafseo® (vadadustat) Tablets indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months

Click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

FDA approval
March 2024

Transitional Drug Add-On Payment Adjustment (TDAPA) reimbursement granted
October 2024

Contracts secured covering nearly 100% of U.S. dialysis patients
January 2025

First Product Shipped
January 9, 2025





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# Current standard of care for patients on dialysis – erythropoiesis-stimulating agents (ESAs) – has remained unchanged for 30 years


Nearly 25% of patients with anemia due to CKD fall below target hemoglobin levels [2]

Patients who are ESA hyporesponders (~20% of patients on dialysis) have higher rates of hospitalization and higher one-year mortality[3]

MACE risk increases as dose of an ESA increases[4]

Suboptimal approach for home dialysis patients since ESAs need to be injected subcutaneously or intravenously

In Akebia market research, more than 2 out of 3 nephrologists identify an unmet need for a treatment for anemia due to CKD, with some of the primary reasons being a **treatment with good efficacy**, is **orally administered** and is an **option for ESA treatment-resistant patients.**[5]



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# An oral HIF-PH inhibitor with the potential to become standard of care for treatment of anemia due to CKD

Vafseo® (vadadustat) Tablets

- Unique mechanism of action built on Nobel Prize-Winning science
- Stimulates body's natural response to hypoxia
- Enhances body's natural production of EPO
- Activates iron mobilization
- Controls hemoglobin (Hb) levels over time
- Simple titration and fewer dose modifications
- Convenient oral dosing

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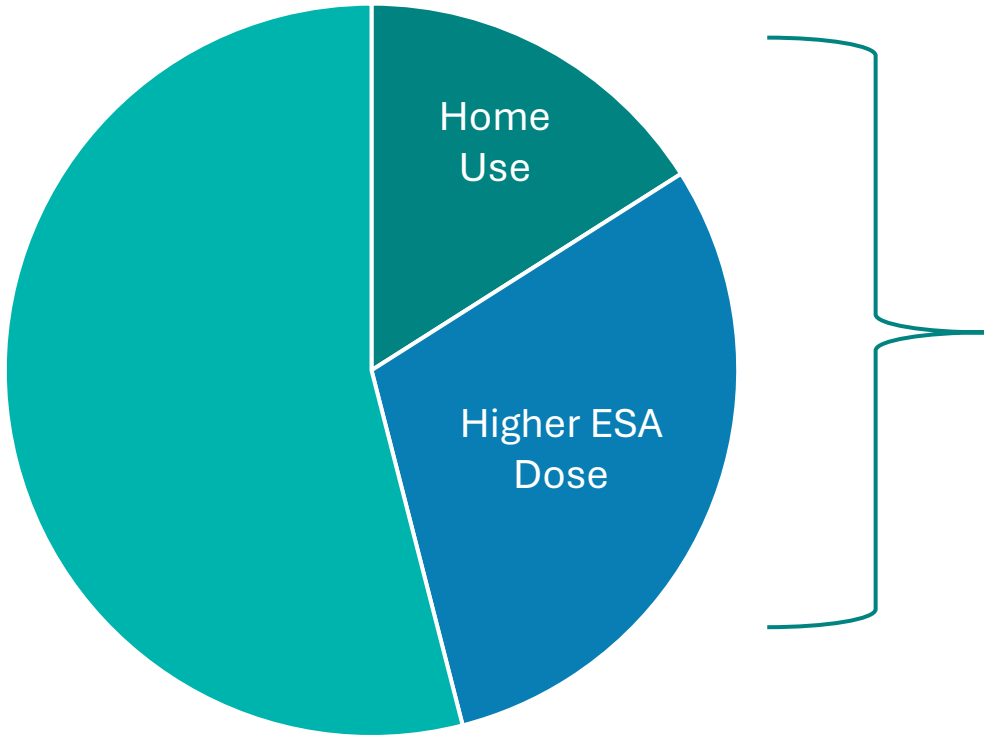
# Home dialysis and higher ESA dose dialysis patients are particularly underserved segments of a billion-dollar U.S. market opportunity

U.S. Dialysis Patients Treated for Anemia
~500K Patients[1]




**Home use = ~80K patients[6]**

Injectable ESAs are particularly cumbersome in the home setting

Home dialysis is a growing segment of market

**Higher ESA Dose = ~150K patients[7]**

May be associated with all-cause mortality and cardiovascular complications independent of hemoglobin level[8]



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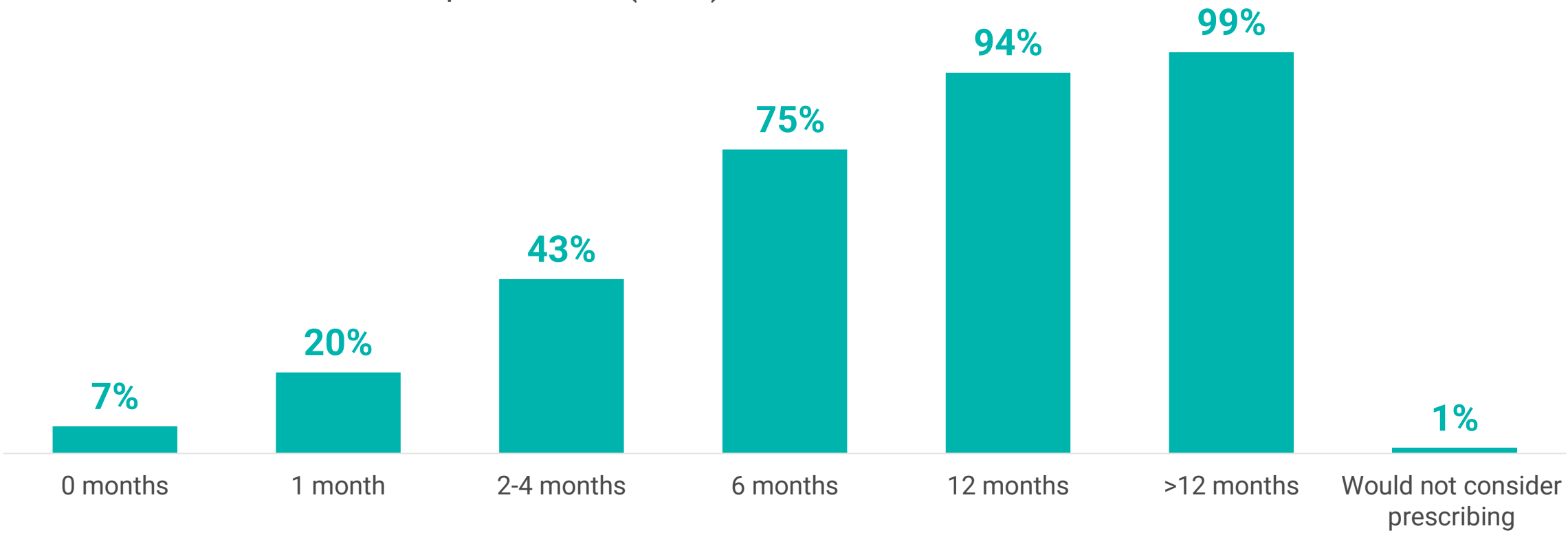
# Strong operational execution sets stage for successful launch

| | |
|---|---|
| **Secured commercial contracts** | **Contracts in place with dialysis organizations covering nearly 100% of U.S. CKD patients on dialysis** |
| **Established pricing** | **Wholesale Acquisition Cost = ~$15,500 per patient annually** |
| **Secured TDAPA reimbursement** | **Transitional Drug Add-On Payment Adjustment provides two years of reimbursement in addition to the ESRD bundled rate** |
| **Built prescriber demand** | **Commercial and Medical teams completed more than 20,000 interactions with potential customers since approval** |

# Nephrologist feedback indicates most would consider prescribing Vafseo

Cumulative percentage of respondents who would consider prescribing Vafseo after the indicated timeframe post-launch (n=75)[9]



# Driving toward potential standard of care

Additional studies initiated and planned to demonstrate potential additional Vafseo benefits and support label expansion

U.S. RENAL CARE®

Collaborative Clinical Trial

More than 650 subjects enrolled as of January 10, 2025

## VOICE

The Vafseo Outcomes In-Center Experience trial

Patients randomized to oral Vafseo 300 mg tablets administered three times per week or ESA

**~2,200 = Target Patient Enrollment**

**Timing = 18 Months from Last Patient Randomized**

**PRIMARY ENDPOINT:** All-Cause Mortality

**SECONDARY ENDPOINT:** All-Cause Hospitalization

Trial Powered to Demonstrate Non-Inferiority for All-Cause Mortality and Superiority for a 10% Reduction in All-Cause Hospitalization

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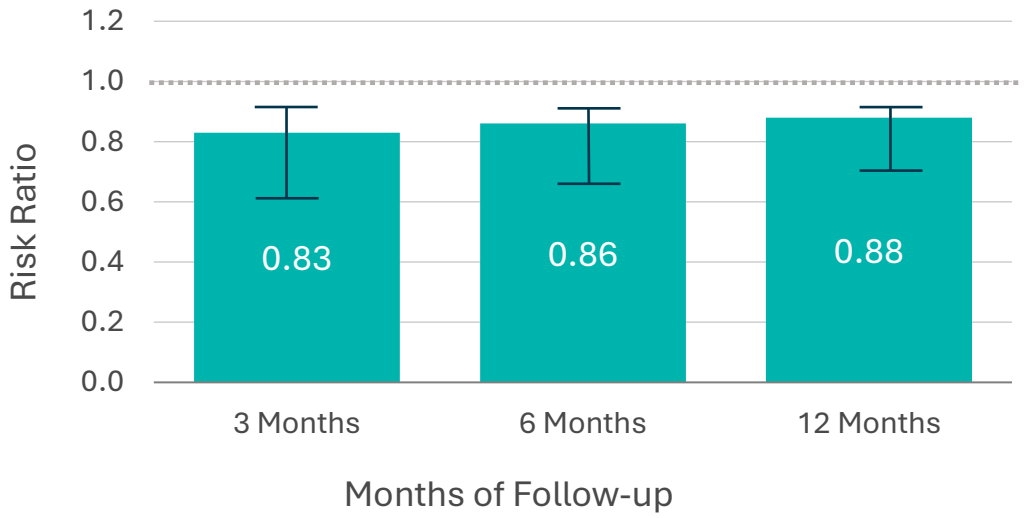
## We believe we are positioned to succeed in the dialysis market....

...and to chart a path to capitalize on significantly larger non-dialysis market opportunity.

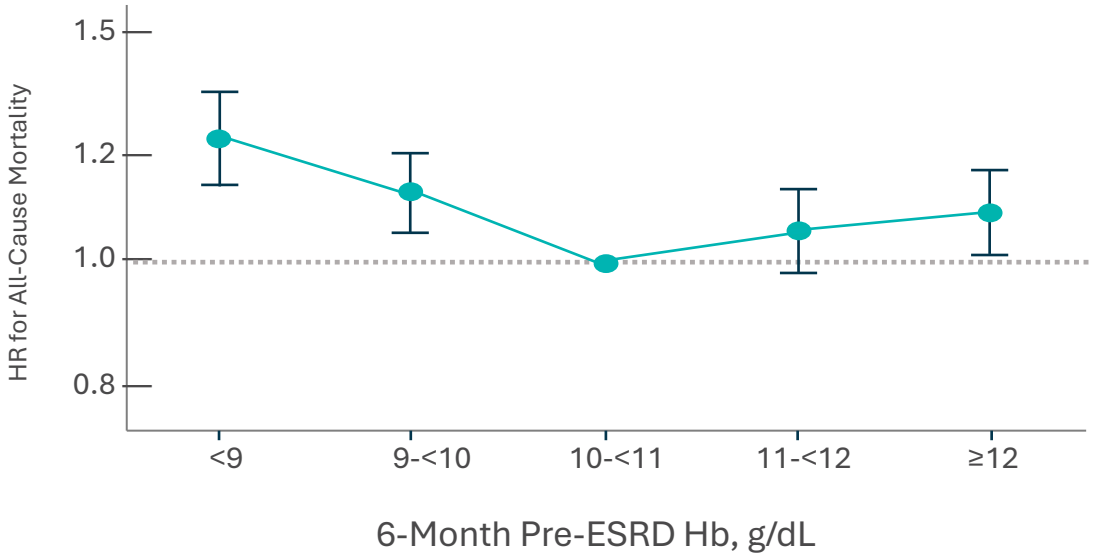
# Anemia may not be optimally managed in CKD non-dialysis population

In patients with pre-hemodialysis Hb <9.0 g/dL (n=4855), 73.4% did not receive ESA pre-HD[10]

**All-cause Mortality Risk in Patients With Pre-HD Hb ≥9.0 g/dL (n=3662) vs <9.0 g/dL (n=4461)[11]**




**Association of 6-Month Pre-ESRD Hb Levels With 12-month Post-ESRD All-cause Mortality (n=31,472)[12]**




All-cause mortality risk was lower in patients with pre-HD Hb ≥9.0 g/dL vs <9.0 g/dL[11]

Post-HD mean Hb levels were similar between patient groups[11]

All-cause mortality rate was higher in patients with Hb <10 g/dL vs Hb 10-<11 g/dL pre-ESRD[12]

All Hb groups were corrected toward 11-12 g/dL within the first few months post-ESRD[12]



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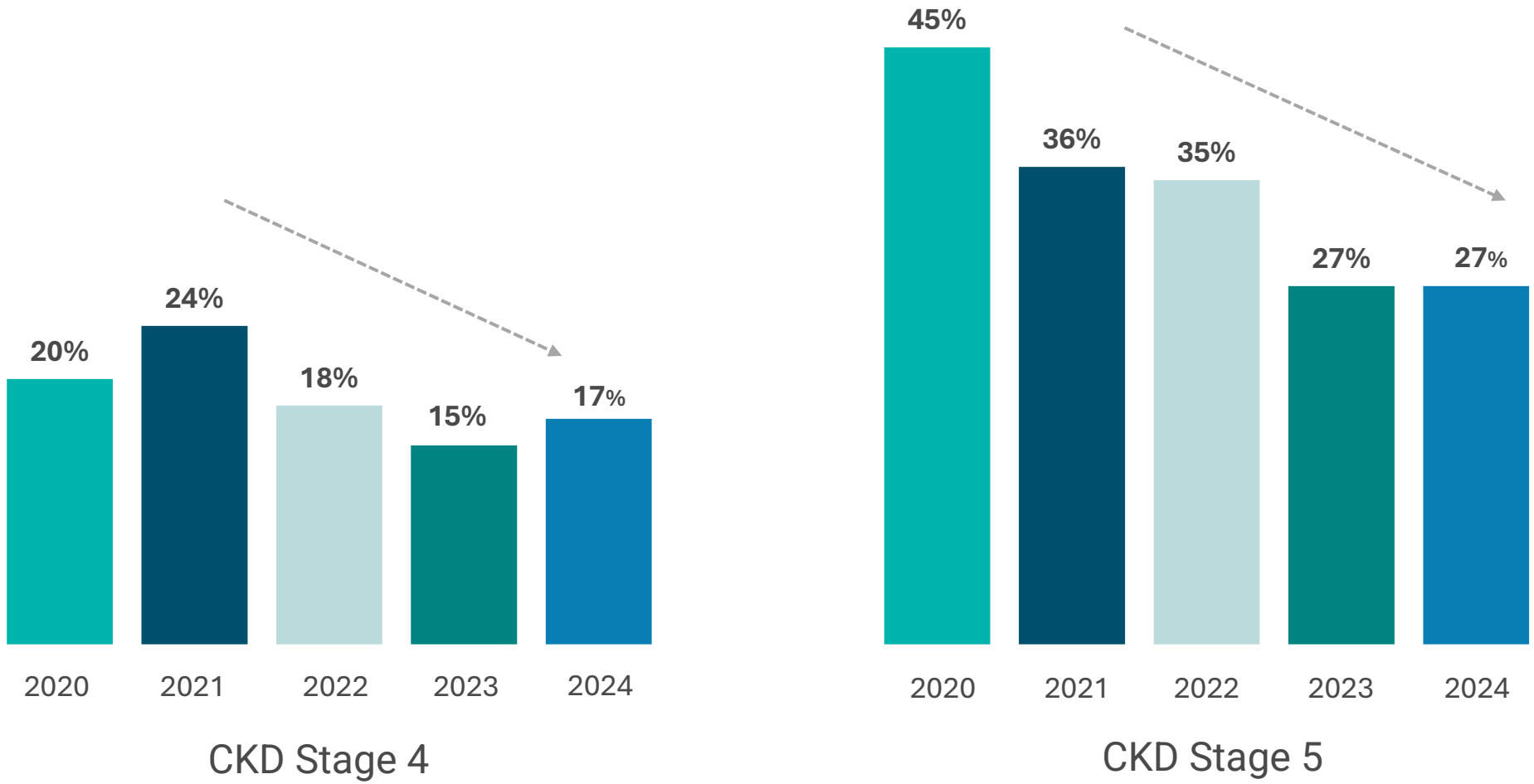
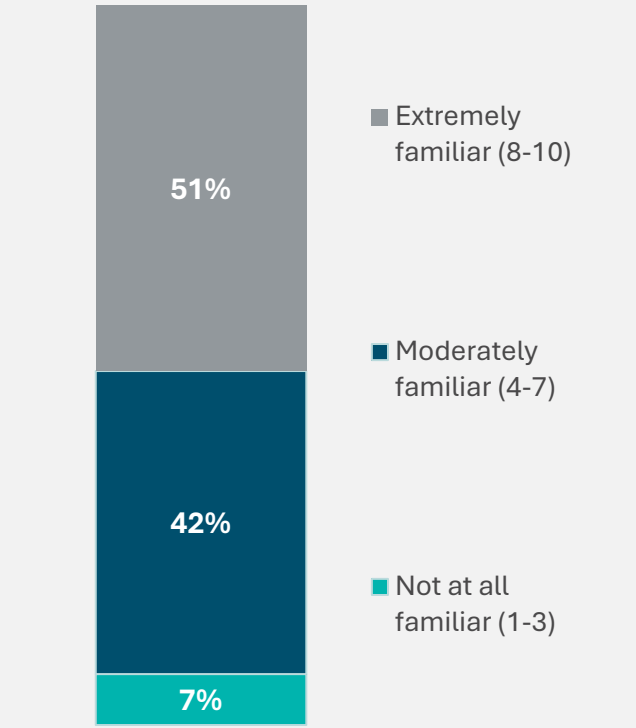
# Frustration with ESA use driving declining treatment rates in CKD non-dialysis anemia[13]

Percentage of patients treated with ESAs[14]

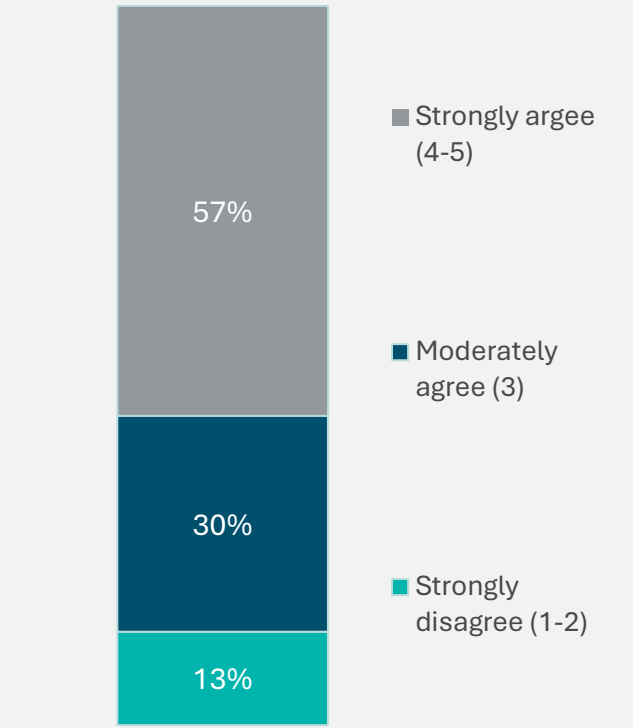


# Opportunity for Vafseo as HIF-based approach in CKD non-dialysis anemia is viewed favorably[15]

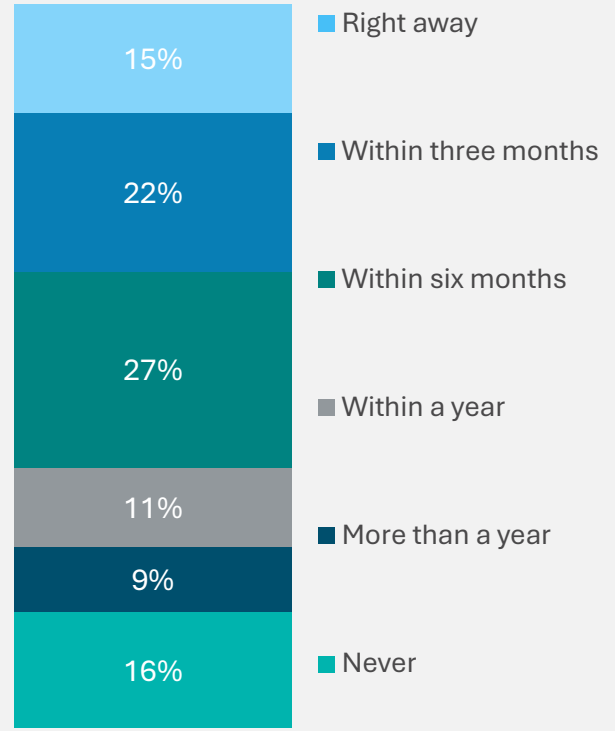
**Nephrologist familiarity with HIF-PH inhibitors**
*% of respondents (n=197)*



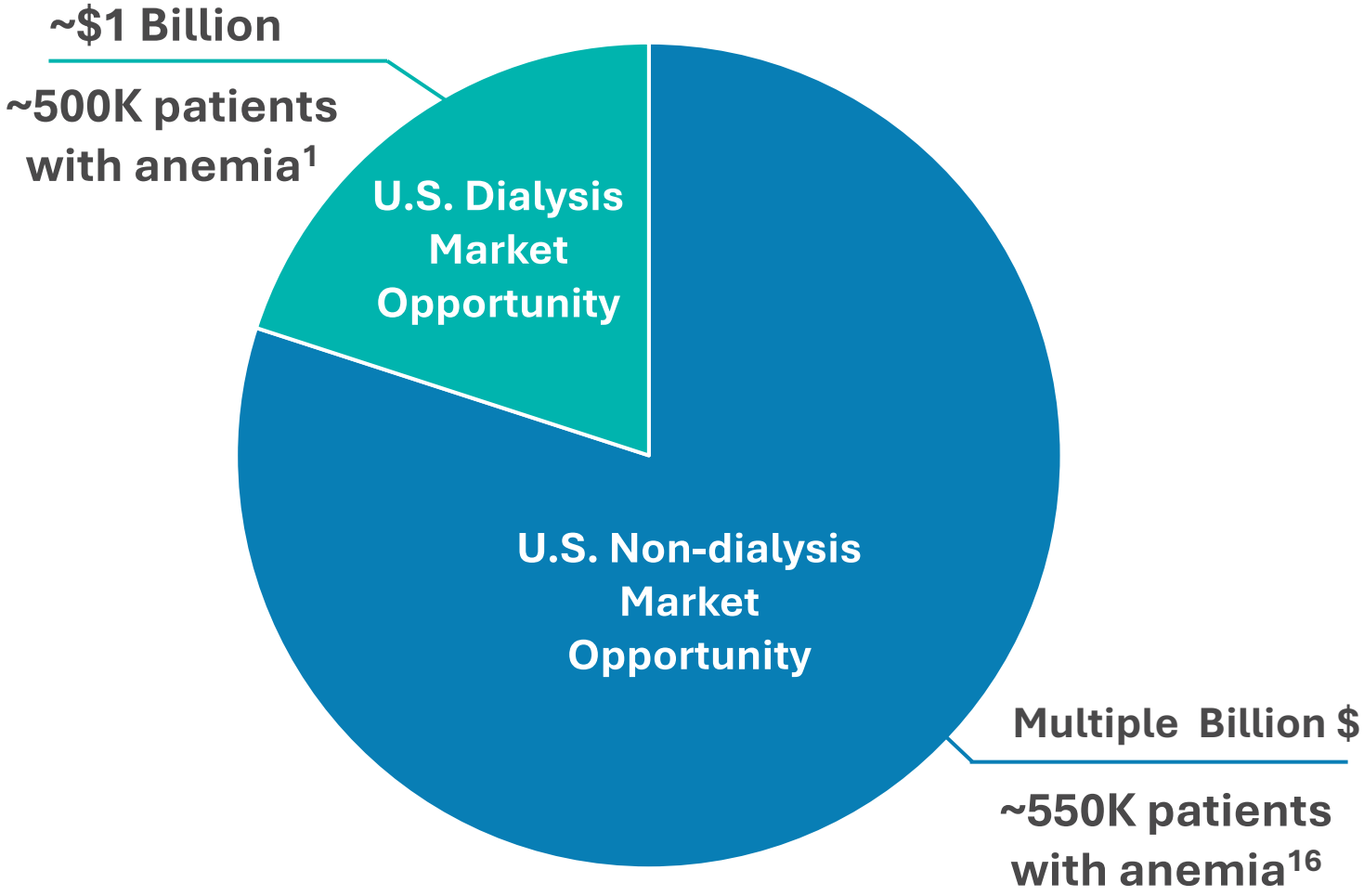

**Nephrologist treatment of anemia in CKD NDD will increase substantially if HIF-PH inhibitors are FDA approved**
*% of respondents (n=197)*




**Nephrologist promptness of switching eligible patients to HIF-PH inhibitors from ESA if FDA approved**
*% of ESA-treated patients*



# Payor dynamics for anemia treatment in non-dialysis segment drive significantly larger market opportunity vs. dialysis segment




## U.S. non-dialysis market payor dynamics:

- Predominantly private and unbundled government payment
- Therefore, expected to garner higher net pricing vs. dialysis



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# Prespecified U.S. analysis in global PRO$_2$TECT study demonstrated no increased MACE risk versus ESA in the subpopulation[17]

The NEW ENGLAND JOURNAL of MEDICINE

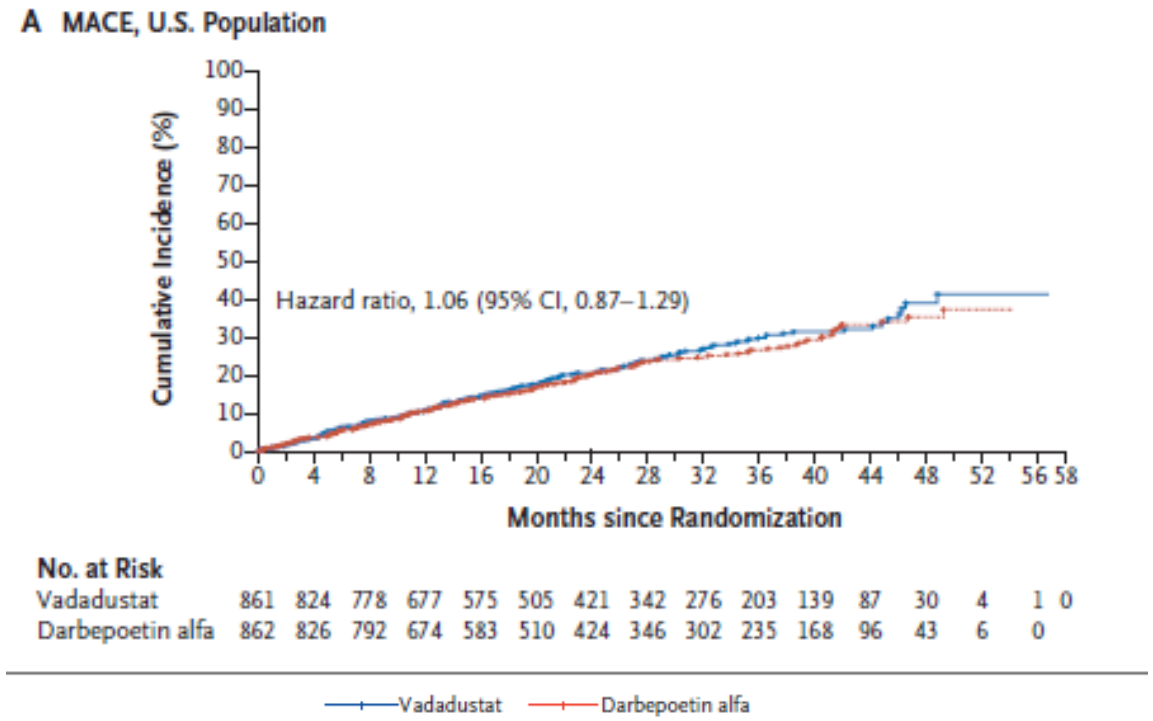


**Table S3. MACE Hazard Ratios by Age as Dichotomous and Age as Continuous Variable in US and non-US Regions**

| | Age as a dichotomous variable | | Age as a continuous variable | |
|---|---|---|---|---|
| | US* (N=1723)<br>Event N<br>HR (95% CI) | Non-US† (N=1748)<br>Event N<br>HR (95% CI) | US* (N=1723)<br>Event N<br>HR (95% CI) | Non-US† (N=1748)<br>Event N<br>HR (95% CI) |
| MACE | 400<br>1.06 (0.87, 1.29) | 326<br>1.30 (1.05, 1.62) | 400<br>1.01 (0.83, 1.23) | 326<br>1.29 (1.03, 1.60) |
| Expanded MACE | 511<br>1.02 (0.86, 1.21) | 364<br>1.24 (1.01, 1.52) | 511<br>0.99 (0.83, 1.18) | 364<br>1.23 (1.00, 1.51) |
| All-Cause Mortality | 325<br>0.92 (0.74, 1.15) | 301<br>1.28 (1.02, 1.61) | 325<br>0.86 (0.69, 1.07) | 301<br>1.27 (1.01, 1.60) |
| CV MACE | 224<br>1.20 (0.92, 1.55) | 152<br>1.09 (0.79, 1.50) | 224<br>1.16 (0.89, 1.52) | 152<br>1.08 (0.78, 1.49) |
| CV Mortality | 136<br>0.96 (0.68, 1.34) | 122<br>1.05 (0.73, 1.50) | 136<br>0.92 (0.65, 1.29) | 122<br>1.04 (0.72, 1.48) |

*US Hb target range, 10-11 g/dL
†Ex-US Hb target range, 10-12 g/dL

Global study missed primary MACE endpoint



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# Planned Vafseo Phase 3 clinical trial in patients with late-stage CKD anemia not on dialysis

***FDA correspondence with Akebia acknowledges an unmet need for safer and orally available therapies to treat anemia due to CKD in certain non-dialysis patients.***

## Planned Phase 3 Trial Design:

Cardiovascular Outcomes Study

Expected to begin in mid-2025

**TARGET PATIENT ENROLLMENT:**
~1,500 U.S. subjects with Stage 4 or 5 CKD not on dialysis

**COMPARATOR:**
Standard of care, including ESA-treated patients

Expect data package to include $PRO_2TECT$ U.S. data set, in-market U.S. dialysis patient safety data, and in-market dialysis and non-dialysis patient safety data from Japan.

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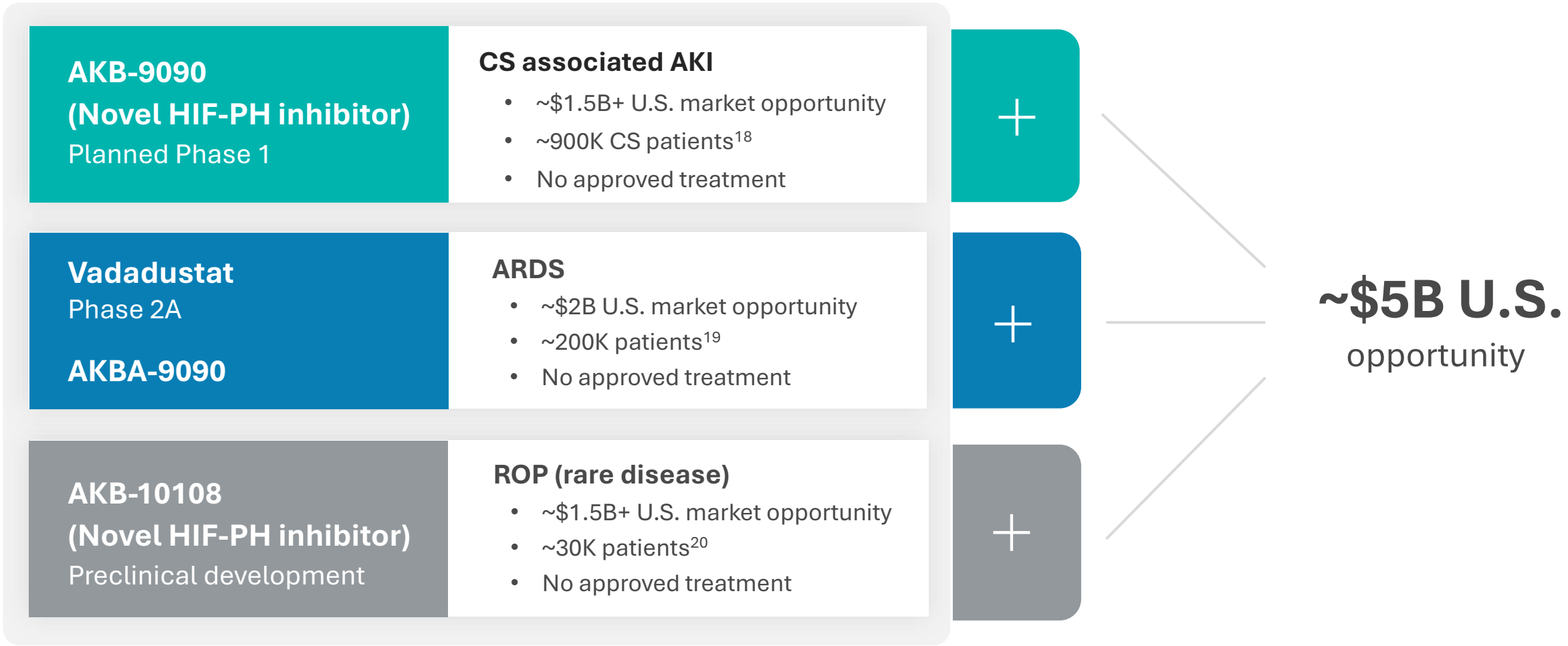
# Pipeline

# Advancing HIF-based pipeline targeting high unmet needs






AKI is acute kidney injury; CS is cardiac surgery; ARDS is Acute Respiratory Distress Syndrome; ROP is Retinopathy of Prematurity

# Our Transformation Begins

# Key 2025 objectives and catalysts

Execute Vafseo U.S. commercial launch

Initiate Vafseo Phase 3 trial in non-dialysis patients in mid-2025

Fully enroll VOICE Trial

Advance pipeline including initiating first in human trial for AKB-9090

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# Q&A

# IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets

**WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.**

*See full prescribing information for complete boxed warning.*

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.



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# IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets(continued)

**CONTRAINDICATIONS**

- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

**WARNINGS AND PRECAUTIONS**

**Increased Risk of Death, Myocardial Infarction, Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**

A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with ESAs, which also increase erythropoietin levels. No specific Hb target level, dose of VAFSEO, or dosing strategy has been identified to avoid these risks. Use the lowest effective dose and adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis. Advise patients to seek immediate medical attention if they develop signs or symptoms of myocardial infarction, stroke, venous thromboembolism, or thrombosis of vascular access. Evaluate and manage promptly if these occur.

**Hepatotoxicity**

Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. All events were asymptomatic and resolved after discontinuation of VAFSEO. The time to onset was generally within the first 3 months of treatment. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.

**Hypertension**

Worsening of hypertension was reported in 14% (9.4 per 100 person-years [PY]) of patients receiving VAFSEO and 17% (11.8 per 100 PY) of patients receiving darbepoetin alfa. Serious worsening of hypertension was reported in 2.7% (1.7 per 100 PY) of patients receiving VAFSEO and 3% (1.8 per 100 PY) of patients receiving darbepoetin alfa. Cases of hypertensive crisis including hypertensive encephalopathy and seizures have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.

**Seizures**

Seizures occurred in 1.6% (1.0 per 100 PY) of patients who received VAFSEO and 1.6% (1.0 per 100 PY) of patients who received darbepoetin alfa. Following initiation of VAFSEO, monitor patients closely for premonitory neurologic symptoms. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.

# IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets(continued)

**Gastrointestinal Erosion**
Gastric or esophageal erosions occurred in 6.4% (4.0 per 100 PY) of patients receiving VAFSEO and 5.3% (3.3 per 100 PY) of darbepoetin alfa-treated patients. Serious gastrointestinal (GI) erosions, including GI bleeding and the need for red blood cell transfusions were reported in 3.4% (2.1 per 100 PY) and 3.3% (2.0 per 100 PY) of those receiving VAFSEO and darbepoetin alfa, respectively. Consider the risk of GI erosion in high-risk patients, including those with a history of GI erosion, peptic ulcer disease, and tobacco or alcohol use. Advise patients of the signs and symptoms of erosions and GI bleeding and urge them to seek prompt medical care if present.

**Serious Adverse Reactions in Patients with Anemia Due to Chronic Kidney Disease and Not on Dialysis**
The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, myocardial infarction, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.

**Malignancy**
VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% (1.3 per 100 PY) of patients treated with VAFSEO and 3.0% (1.8 per 100 PY) of patients treated with darbepoetin alfa. No evidence of increased carcinogenicity was observed in animal studies.

**ADVERSE REACTIONS**
The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

**DRUG INTERACTIONS**
**Iron supplements and iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before products containing iron.
**Non-iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.
**BCRP substrates:** Monitor for signs of substrate adverse reactions and consider dose reduction.
**Statins:** Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin (20 mg) and rosuvastatin (5 mg).

**USE IN SPECIFIC POPULATIONS**
**Pregnancy:** May cause fetal harm.
**Lactation:** Breastfeeding not recommended until two days after the final dose.
**Hepatic Impairment:** Not recommended for use in patients with cirrhosis or active, acute liver disease.

**Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.**



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# SOURCES


**1** USRDS(https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities);DOPPS (https://www.dopps.org/DPM/DPMSlideBrowser.aspx); Based on internal estimates and industry reports estimating ESA pricing

**2** A) United States Renal Data System. 2023 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023. B) Dialysis Outcomes and Practice Patterns Study (Feb 2021 & Aug 2022) Accessed March 23, 2024. https://www.dopps.org/DPM-HD/DPMSlideBrowser.aspx. C) Karaboyas A. Identifying optimal anemia management practices in hemodialysis. Dissertation. University of Michigan; 2019. D) Cizman B, Smith HT, Camejo RR, et al. Clinical and economic outcomes of erythropoiesis-stimulating agent hyporesponsiveness in the post-bundling era. Kidney Med. 2020;2(5):589-599.e1. E) Sarnak MJ, Agarwal R, Boudville N, et al. Vadadustat for treatment of anemia in patients with dialysis-dependent chronic kidney disease receiving peritoneal dialysis. Nephrol Dial Transplant. 2023; 38:2358-2367.

**3** Cizman B, Smith HT, Camejo RR, et al. Clinical and economic outcomes of erythropoiesis-stimulating agent hyporesponsiveness in the post-bundling era. Kidney Med. 2020;2(5):589-599.e1.

**4** Evans M, Bower H, Cockburn E, Jacobson SH, Barany P, Carrero JJ. Contemporary management of anaemia, erythropoietin resistance and cardiovascular risk in patients with advanced chronic kidney disease: a nationwide analysis. Clin Kidney J. 2020 May 1;13(5):821-827. doi: 10.1093/ckj/sfaa054. PMID: 33123358; PMCID: PMC7577763 (https://pmc.ncbi.nlm.nih.gov/articles/PMC7577763/)

**5** Vafseo ATU Baseline; Presented by Instar Research; April 2024; Produced for Akebia Therapeutics

**6** FMC Capital Markets Day 2023 presentation, DaVita 2022 Annual Report and Akebia internal calculations

**7** DOPPS.org: Weekly IV epoetin dose received (30 day average)

**8** Evans M, Bower H, Cockburn E, Jacobson SH, Barany P, Carrero JJ. Contemporary management of anaemia, erythropoietin resistance and cardiovascular risk in patients with advanced chronic kidney disease: a nationwide analysis. Clin Kidney J. 2020 May 1;13(5):821-827. doi: 10.1093/ckj/sfaa054. PMID: 33123358; PMCID: PMC7577763 (https://pmc.ncbi.nlm.nih.gov/articles/PMC7577763/)

**9** Vafseo Pulse: Q3 2024 September 2024; Presented by Instar Research; September 2024; Produce for Akebia Therapeutics

**10** Retrospective analysis of 20,454 patients who initiated HD from the 2012-2013 USRDS ESRD Database and CROWNWeb. Pre-HD ESA use is defined by data from Medicare Parts A and B claims, Medicare Part D claims, or the ESRD Medical Evidence Report. Post-HD ESA use was determined from ESRD monthly dialysis claims; Wetmore JB, et al. PLoS One. 2018;13(9):e0203767

**11** Retrospective analysis of 20,454 patients who initiated HD from the 2012-2013 USRDS ESRD Database and CROWNWeb. HR adjusted for demographic factors, primary cause of ESRD, duration of pre-dialysis nephrology care, and comorbid conditions. Patients with pre-HD Hb ≥9.0 g/dL received ESA pre- and post-HD; those with pre-HD Hb <9.0 g/dL received ESA post-HD and had increased Hb.; Wetmore JB, et al. PLoS One. 2018;13(9):e0203767

**12** Analysis of 31,472 veterans from the USRDS Special Study Center Transition of Care in CKD who transitioned to ESRD between October 2007 and March 2014. HR adjusted for case-mix and MICS.; Kleine CE, et al. Am J Nephrol. 2018;47:333-342

**13** Spherix Global Insights; Patient Chart Dynamix; Chronic Kidney Disease, ND (US) 2024

**14** Spherix Global Insights; Patient Chart Dynamix; Chronic Kidney Disease, ND (US) 2024




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# SOURCES

**15** Spherix Global Insights; Patient Chart Dynamix; Chronic Kidney Disease, ND (US) 2024
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