Akebia® THERAPEUTICS

INNO$_2$VATE TOP-LINE DATA

MAY 5, 2020

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Statements in this presentation regarding 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, including but not limited to statements regarding our activities relating to COVID-19 and our assessment of impacts from COVID-19, including that our fundamentals remain strong, our intent to continue taking precautionary measures and monitoring the evolving situation, and our business continuity plans; expectations regarding financial position, including cash runway and the components thereof; the assessment of the data from INNO$_2$VATE; safety and efficacy of vadadustat; the potential indications for and benefits of vadadustat; vadadustat clinical trial data and results and the anticipated timing of the availability and reporting thereof; market size, distribution activities, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat; the potential for vadadustat to set a new standard of care for treating all populations of dialysis patients, if approved; sharing vadadustat clinical data, including the full data set from INNO$_2$VATE and PRO$_2$TECT, with regulators and others; sharing, as well as the timing and forum thereof; submitting filings for marketing approval of vadadustat, and the timing thereof; the anticipated first regulatory approval for vadadustat, and the timing thereof; the potential launch and commercialization of vadadustat if approved by regulatory authorities; Akebia's momentum and potentially transformational near-term milestones; our intellectual property position; access to a Priority Review Voucher for vadadustat; and the potential to bring vadadustat to patients and the potential timing thereof by utilizing the Priority Review Voucher. The terms "anticipate," "believe," "expect," "opportunity," "planned," "potential," "target," "will" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials, including PRO$_2$TECT; the risk that clinical trials may not be successful; manufacturing risks; risks associated with the Priority Review Voucher for vadadustat; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize our commercial product, vadadustat and other product candidates and operate the Company, and the actual expenses associated therewith; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; market acceptance and coverage and reimbursement of our commercial product and vadadustat, if approved; the risks associated with potential generic entrants for our commercial product and vadadustat, if approved; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete preclinical and clinical studies; the competitive landscape for our commercial product and vadadustat; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for our commercial product, vadadustat and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 31, 2019, 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 Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation. Vadadustat is an investigational drug and has not yet been approved by the U.S. Food and Drug Administration or any regulatory authority.

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OUR PURPOSE

To Better the Life of Each Person Impacted by Kidney Disease

Global Phase 3 INNO$_2$VATE Program

Studies of Vadadustat for Treatment of Anemia due to Chronic Kidney Disease (CKD) in Adult Patients on Dialysis

INNO$_2$VATE Consists of Two Randomized, Open-Label, Active-Controlled, Non-Inferiority Phase 3 Cardiovascular Outcomes Studies

INNO$_2$VATE CORRECTION CONVERSION

Incident Dialysis

N = 369

Vadadustat vs Darbepoetin Alfa

N= 3,923

INNO$_2$VATE CONVERSION

ESA Treated

N = 3,554

Vadadustat vs Darbepoetin Alfa

PRIMARY EFFICACY ENDPOINTS:

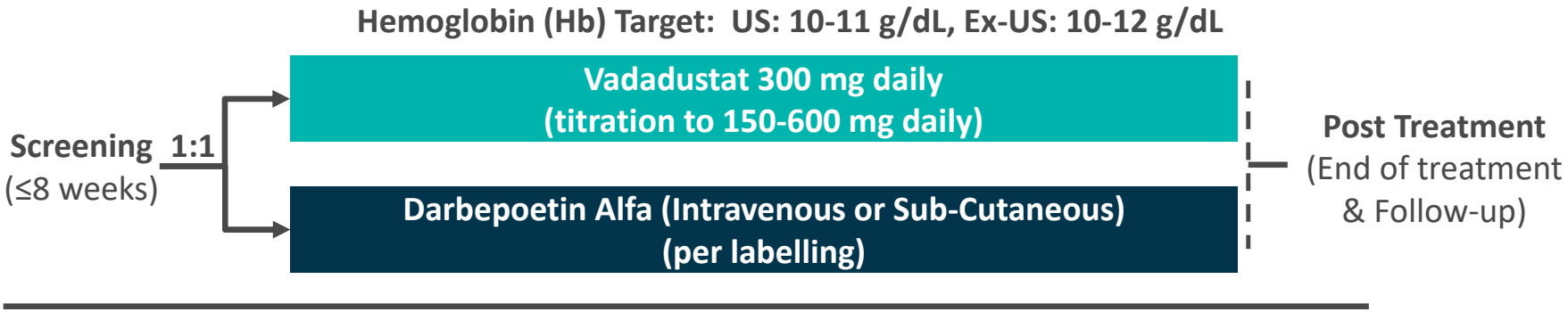
- Mean change in hemoglobin (Hb) between baseline and the primary evaluation period (weeks 24 to 36)
- Non-inferiority margin of -0.75 g/dL

PRIMARY SAFETY ENDPOINT:

- Time to first occurrence of major adverse cardiovascular events (MACE) which is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke
- Non-inferiority margin for hazard ratio 1.25

Darbepoetin alfa is an erythropoiesis-stimulating agent (ESA).
Non-inferiority margins referenced are regulatory agency-approved non-inferiority margins.

Global Phase 3 INNO$_2$VATE Program



	Key Inclusion Criteria	
	INNO$_2$VATE (Correction/ Conversion)	INNO$_2$VATE (Conversion)
CKD Status	Incident Dialysis Patient (≤ 16 weeks on dialysis)	Chronic ESA Treated Dialysis Patient
Hemoglobin (Hb, g/dL)	8-11	US: 8-11 Ex-US: 9-12
ESA Status	No recent use OR on ESA	On ESA
Iron Status	Ferritin ≥100 ng/mL and TSAT ≥20%	

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Baseline Demographics

	INNO$_2$VATE (Conversion)		INNO$_2$VATE (Correction/Conversion)	
Characteristic	Vadadustat (N=1,777)	Darbepoetin Alfa (N=1,777)	Vadadustat (N=181)	Darbepoetin Alfa (N=188)
Age (yrs), mean (SD)	57.9 (13.9)	58.4 (13.8)	56.5 (14.8)	55.6 (14.6)
Proportion male (%)	55.7%	56.5%	59.1%	60.1%
BMI (kg/m^2), mean (SD)	28.6 (7.2)	28.6 (7.2)	27.6 (6.1)	27.5 (6.0)
Duration of Dialysis (yrs), mean (SD)	4.0 (4.0)	3.9 (4.0)	0.14 (0.09)	0.15 (0.28)
Baseline Hb (g/dL), mean (SD)	10.25 (0.85)	10.23 (0.82)	9.37 (1.07)	9.19 (1.14)
Comorbidities (%)				
Cardiovascular disease	48.8%	52.4%	38.1%	38.8%
Diabetes	54.6%	56.2%	58.0%	51.1%

BMI is body mass index.

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Primary and Key Secondary Efficacy Endpoint Results

Vadadustat achieved the primary and key secondary efficacy endpoint in each of the two $INNO_2VATE$ studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin (Hb) between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52).

Pre-specified non-inferiority margin: -0.75 g/dL	$INNO_2VATE$ (Conversion)		$INNO_2VATE$ (Correction/ Conversion)	
	Primary Endpoint (Weeks 24 to 36)			
	Vadadustat	Darbepoetin Alfa	Vadadustat	Darbepoetin Alfa
Number of Patients	1,777	1,777	181	188
Mean (SD), baseline Hb (g/dL)	10.25 (0.85)	10.23 (0.83)	9.37 (1.07)	9.19 (1.14)
Mean (SD), Hb (g/dL), W24-36, Observed and Imputed	10.36 (1.01)	10.53 (0.96)	10.36 (1.13)	10.61 (0.94)
Difference (Hb, g/dL), LS mean (95% CI), (Vadadustat - Darbepoetin Alfa)	-0.17 (-0.23, -0.10)		-0.31 (-0.53, -0.10)	
	Key Secondary Endpoint (Weeks 40 to 52)			
Mean (SD), Hb (g/dL), W40-52, Observed and Imputed	10.40 (1.04)	10.58 (0.98)	10.51 (1.19)	10.55 (1.14)
Difference (Hb, g/dL), LS mean (95% CI), (Vadadustat - Darbepoetin Alfa)	-0.18 (-0.25, -0.12)		-0.07 (-0.34, 0.19)	

CI is confidence interval
LS is least square mean

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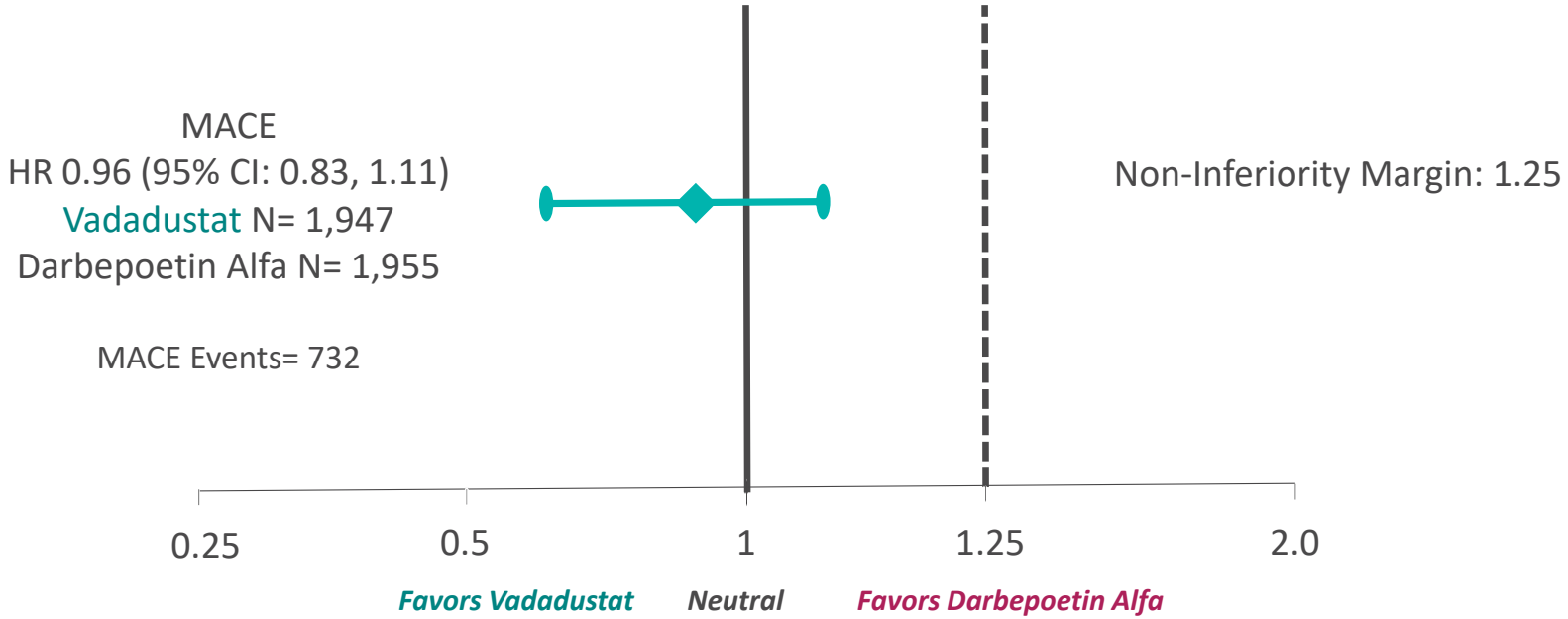
Primary Safety Major Adverse Cardiovascular Events (MACE) Endpoint

To assess MACE, a combined analysis of time to first MACE event from the two INNO$_2$VATE studies (*Conversion* and *Correction/Conversion*) was performed. Vadadustat achieved the primary safety endpoint of the INNO$_2$VATE program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of MACE (HR 0.96 (95% CI: 0.83, 1.11)).



HR is hazard ratio. The non-inferiority margin of 1.25 was prospectively agreed to by U.S. Food and Drug Administration (FDA). MACE is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke. The INNO$_2$VATE program's primary safety endpoint, MACE, was independently and blindly assessed by the Brigham and Women's Hospital's Clinical Endpoint Center (BWH CEC) in Boston, MA.

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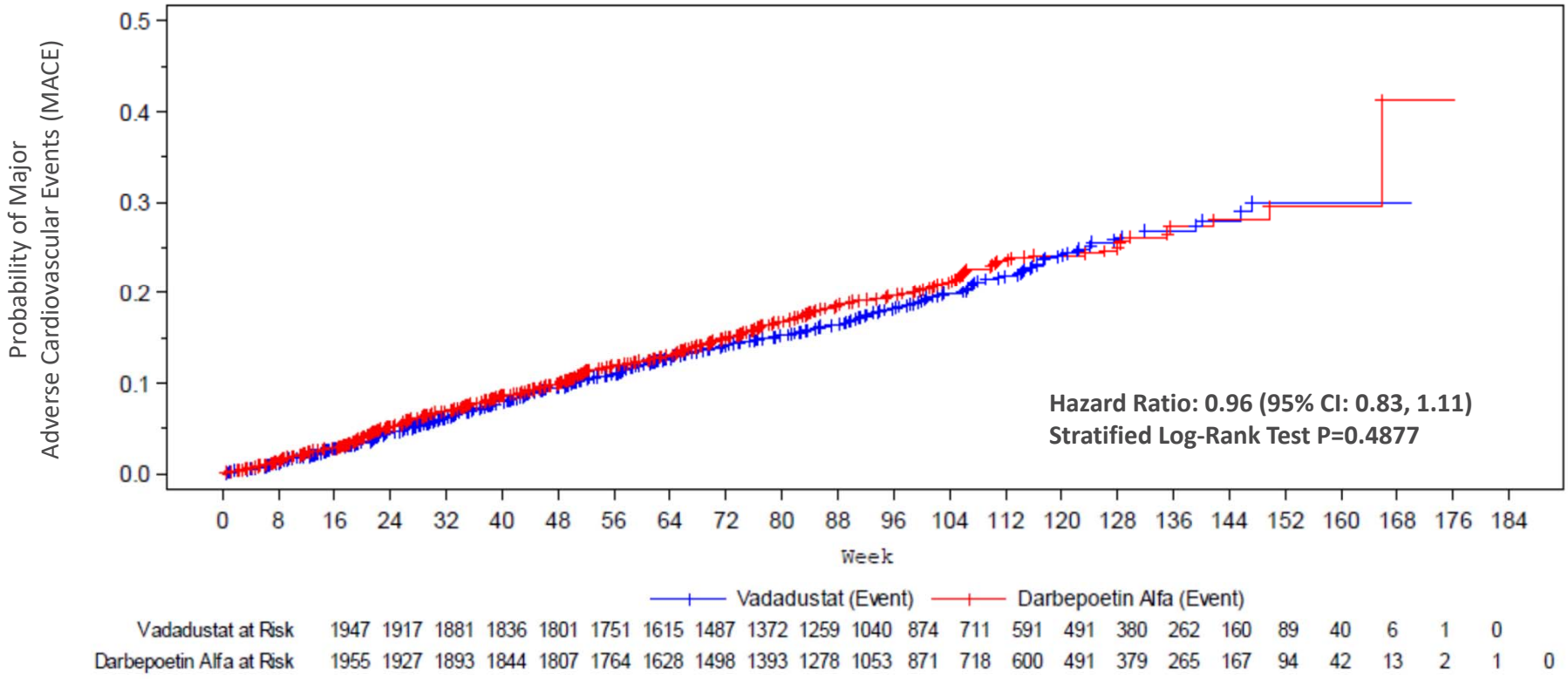
Kaplan-Meier Curve of Time to Major Adverse Cardiovascular Events (MACE)



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Overview of Treatment Emergent Adverse Events (TEAEs)

INNO$_2$VATE (Conversion)		
Category, N (%)	Vadadustat (N=1,768)	Darbepoetin Alfa (N=1,769)
Patients with any TEAE	1562 (88.3%)	1580 (89.3%)
Serious TEAEs	973 (55.0%)	1032 (58.3%)
TEAEs ≥10%		
Diarrhea	230 (13.0%)	178 (10.1%)
Pneumonia	195 (11.0%)	172 (9.7%)
Hypertension	187 (10.6%)	244 (13.8%)
Hyperkalemia	160 (9.0%)	191 (10.8%)

INNO$_2$VATE (Correction/Conversion)		
Category, N (%)	Vadadustat (N=179)	Darbepoetin Alfa (N=186)
Patients with any TEAE	150 (83.8%)	159 (85.5%)
Serious TEAEs	89 (49.7%)	105 (56.5%)
TEAEs ≥10%		
Hypertension	29 (16.2%)	24 (12.9%)
Diarrhea	18 (10.1%)	18 (9.7%)

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Thank You!

We want to extend our sincerest appreciation to our investigators and their staff for participating in the $INNO_2VATE$ program.

Most importantly, thank you to our patients who participated in this program. Because of their commitment, we are a step closer to fulfilling our purpose to better the life of each person impacted by kidney disease.

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