Akebia® THERAPEUTICS

PRO$_2$TECT TOP-LINE DATA

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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 the opportunity for vadadustat to advance the standard of care; Akebia's belief that the totality of the data from its global Phase 3 program for vadadustat supports the cardiovascular safety of vadadustat, regulatory submissions, regulatory approval in both the dialysis and non-dialysis indications, and establishing vadadustat as an oral once daily standard of care for treatment of anemia due to chronic kidney disease (CKD); the path forward for vadadustat in dialysis and non-dialysis; the potential challenges with respect to achieving an approval for vadadustat in the non-dialysis indication; the assessment of the data from PRO2TECT; safety and efficacy of vadadustat; the potential indications for and benefits of vadadustat; sharing vadadustat clinical data, including the full dataset from INNO2VATE and PRO2TECT, at an upcoming medical conference, in peer reviewed journals and with health authorities and others, as well as the timing and forum thereof; the timing of meetings with regulators, including the pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA); our cash runway; submitting filings for marketing approval of vadadustat, and the timing thereof; the potential launch and commercialization of vadadustat if approved by regulatory authorities; and market opportunity, clinical opportunity, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat. The terms "believe," "expect," "goal," "look forward," "opportunity," "planned," "potential," "promising," "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 timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the actual time it takes to make regulatory submissions for vadadustat to health authorities, including the submission of the NDA to the FDA and the Marketing Authorization Application to the European Medicines Agency; risks associated with the Priority Review Voucher for vadadustat; 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; manufacturing and quality risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to continue to commercialize our commercial product, to develop and commercialize vadadustat, and to operate the Company; 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 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 collaborations partners and vendors; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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 with the exception of Japan's Ministry of Health, Labour and Welfare.

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OUR PURPOSE

To Better the Life of Each Person Impacted by Kidney Disease

Global Phase 3 PRO$_2$TECT Program

Studies of Vadadustat for Treatment of Anemia due to Chronic Kidney Disease (CKD) in Adult Patients Not on Dialysis

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

PRO$_2$TECT CORRECTION

Not ESA Treated
N=1,751

Vadadustat vs
Darbepoetin Alfa

N =3, 476

PRO$_2$TECT CONVERSION

ESA Treated
N=1,725

Vadadustat vs
Darbepoetin Alfa

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

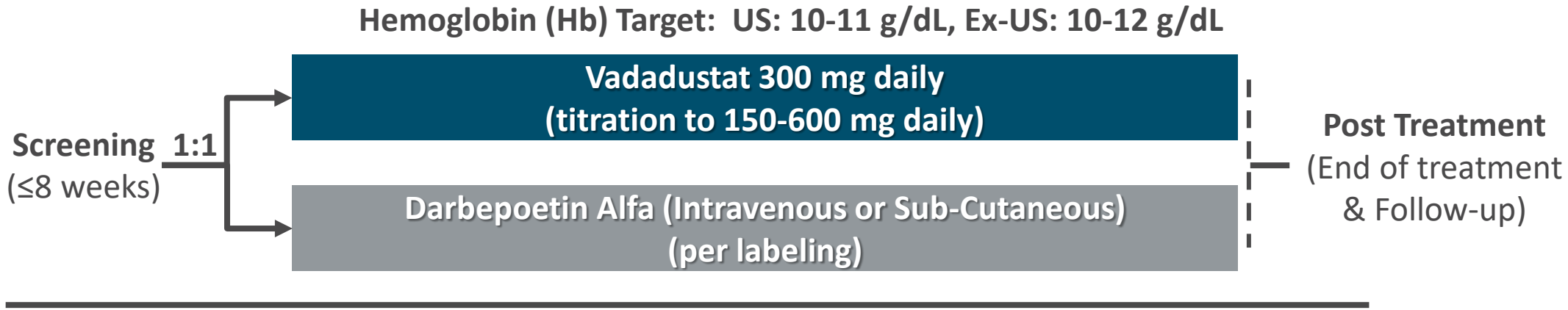
PRIMARY EFFICACY ENDPOINTS:

- 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, and non-fatal stroke
- Non-inferiority margin for hazard ratio 1.25

Global Phase 3 PRO$_2$TECT Program



	Key Inclusion Criteria	
	PRO$_2$TECT (Correction)	PRO$_2$TECT (Conversion)
Hemoglobin (Hb, g/dL)	8-11	US: 8-11 Ex-US: 9-12
ESA Status	Not ESA Treated	ESA Treated
Iron Status	Ferritin ≥100 ng/mL and TSAT ≥20%	

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Baseline Demographics

Characteristic	PRO$_2$TECT (Correction)		PRO$_2$TECT (Conversion)	
	Vadadustat (N=879)	Darbepoetin Alfa (N=872)	Vadadustat (N=862)	Darbepoetin Alfa (N=863)
Age (yrs), mean (SD)	65.2 (14.3)	64.9 (13.7)	67.3 (13.1)	66.5 (13.5)
Proportion male (%)	46.0%	42.0%	45.7%	43.5%
BMI (kg/m^2), mean (SD)	29.7 (7.2)	29.8 (7.2)	29.1 (7.1)	29.6 (7.3)
Baseline Hb (g/dL), mean (SD)	9.11 (0.80)	9.14 (0.78)	10.42 (0.89)	10.39 (0.94)
Comorbidities (%)				
Cardiovascular disease	46.2%	47.2%	43.5%	46.6.%
Diabetes	66.1%	68.7%	60.0%	60.0%

SD is standard deviation.
Hb is hemoglobin.
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 PRO_2TECT 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	PRO_2TECT (Correction)		PRO_2TECT (Conversion)	
	Primary Endpoint (Weeks 24 to 36)			
	Vadadustat	Darbepoetin Alfa	Vadadustat	Darbepoetin Alfa
Number of Patients	879	872	862	863
Mean (SD), baseline Hb (g/dL)	9.11 (0.80)	9.14 (0.78)	10.42 (0.89)	10.39 (0.94)
Mean (SD), Hb (g/dL), W24-36, Observed and Imputed	10.39 (0.99)	10.35 (1.03)	10.77 (0.98)	10.77 (0.99)
Difference (Hb, g/dL), LS mean (95% CI), (Vadadustat - Darbepoetin Alfa)	0.05 (-0.04, 0.15)		-0.01 (-0.09, 0.07)	
	Key Secondary Endpoint (Weeks 40 to 52)			
Mean (SD), Hb (g/dL), W40-52, Observed and Imputed	10.48 (1.05)	10.45 (1.01)	10.80 (1.04)	10.79 (1.05)
Difference (Hb, g/dL), LS mean (95% CI), (Vadadustat - Darbepoetin Alfa)	0.04 (-0.06, 0.14)		0.00 (-0.10, 0.09)	

SD is standard deviation. 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 PRO_2TECT studies (*Correction* and *Conversion*) was performed. PRO_2TECT did not meet the primary safety endpoint, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of MACE (HR 1.17 (95% CI: 1.01, 1.36)).

PRO_2TECT (Correction and Conversion) Vadadustat (N=1,739) Darbepoetin Alfa (N=1,732)			
	Non-Inferiority Margin	Hazard Ratio	Confidence Interval
Primary Safety MACE Endpoint	1.25	1.17	(95% CI: 1.01, 1.36)

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, and non-fatal stroke. The PRO_2TECT 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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Overview of Treatment Emergent Adverse Events (TEAEs)

PRO$_2$TECT (Correction)		
Category, N (%)	Vadadustat (N=878)	Darbepoetin Alfa (N=870)
Patients with any TEAE	798 (90.9%)	797 (91.6%)
Serious TEAEs	573 (65.3%)	561 (64.5%)
TEAEs ≥10%		
End stage renal disease	305 (34.7%)	306 (35.2%)
Hypertension	155 (17.7%)	192 (22.1.%)
Hyperkalemia	108 (12.3%)	136 (15.6%)
Urinary tract infection	113 (12.9%)	104 (12.0%)
Diarrhea	122 (13.9%)	87 (10.0%)
Oedema peripheral	110 (12.5%)	91 (10.5%)
Fall	84 (9.6%)	87 (10%)
Nausea	88 (10%)	71 (8.2%)

PRO$_2$TECT (Conversion)		
Category, N (%)	Vadadustat (N=861)	Darbepoetin Alfa (N=862)
Patients with any TEAE	767 (89.1%)	756 (87.7%)
Serious TEAEs	504 (58.5.%)	488 (56.6%)
TEAEs ≥10%		
End stage renal disease	237 (27.5%)	245 (28.4%)
Hypertension	124 (14.4%)	128 (14.8%)
Urinary tract infection	105 (12.2%)	125 (14.5%)
Diarrhea	119 (13.8%)	76 (8.8%)
Oedema peripheral	85 (9.9%)	87 (10.1%)
Pneumonia	86 (10.0%)	84 (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 PRO_2TECT 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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