Akebia Announces Vadadustat Efficacy and Safety Data to be Presented at American Society of Nephrology Kidney Week 2021

October 18, 2021

CAMBRIDGE, Mass., Oct. 18, 2021 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA) today announced that vadadustat efficacy and safety data related to clinical outcomes among patients with anemia due to chronic kidney disease (CKD) will be presented at the American Society of Nephrology Kidney Week 2021 (ASN Kidney Week), which is taking place virtually November 4 – November 7, 2021. Vadadustat is Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor, a potential first-in-class product in the U.S. for the treatment of anemia due to CKD, which is currently under review by the U.S. Food and Drug Administration with a scheduled Prescription Drug User Fee Act (PDUFA) date of March 29, 2022.

Akebia will also present data on Auryxia® (ferric citrate), including a poster on the trial design of a collaborative clinical study on the use of Auryxia to prevent renal failure in adults with advanced CKD. All accepted vadadustat poster abstracts and other abstracts from Akebia are now available online on the ASN Kidney Week abstract portal: https://www.asn-online.org/education/kidneyweek/2021/program-search-abstract.aspx.

"We look forward to ASN as an opportunity to continue to share rich data on vadadustat with the nephrology community," said John P. Butler, Chief Executive Officer of Akebia Therapeutics. "We believe these data demonstrate the efficacy and safety profile of vadadustat as a potential oral treatment for patients living with anemia due to chronic kidney disease."

The following abstracts have been accepted for presentation at ASN Kidney Week:

Vadadustat Presentations		
W. Winkelmayer, S. Fishbane, J. Tumlin, Y. Farag, W. Luo, R. Anders, C. Solinsky, D. Vargo, M. Koury	Iron-Related Outcomes in Patients with Dialysis-Dependent CKD Randomized to Vadadustat vs Darbepoetin Alfa	Poster # PO0457
M. Koury, P. Pergola, P. Roy-Chaudhury, Y. Farag, W. Luo, R. Anders, C. Solinsky, D. Vargo, W. Winkelmayer	Iron-Related Outcomes in Patients with Non–Dialysis-Dependent CKD Randomized to Vadadustat vs Darbepoetin Alfa	Poster # PO0482
R. Agarwal, D. Vargo, W. Luo, B. Maroni, C. Solinsky, G. Chertow	Comprehensive Safety Profile of Vadadustat from Global Phase 3 Clinical Trials	Poster # PO0460
G. Chertow, N. Boudville, P. Chowdhury, C. Gonzalez, L. Kooienga, W. Luo, B. Maroni, K. Ntoso, D. Vargo, K. Eckardt	Vadadustat for Treatment of Anemia in Patients with Dialysis-Dependent CKD Receiving Peritoneal Dialysis	Poster # PO0464
R. Agarwal, D. Vargo, W. Luo, B. Maroni, C. Solinsky, G. Chertow	Vadadustat, an Oral HIF-PHI, Is Not Associated with Increased Risk of Neoplasm in Patients with Anemia Due to CKD	Poster # PO0461
P. Parfrey, W. Luo, B. Maroni, R. Anders, D. Vargo, P. McCullough	Thromboembolic Events with Vadadustat vs Darbepoetin Alfa for Anemia Treatment in Patients with Dialysis-Dependent CKD	Poster # PO0463
P. McCullough, W. Luo, B. Maroni, R. Anders, D. Vargo, P. Parfrey	Assessment of Thromboembolic Events with Vadadustat vs Darbepoetin Alfa for Treatment of Anemia in Patients with Non–Dialysis-Dependent CKD	Poster # PO0462
Ferric Citrate Presentation		
G. Block, M. Block, S. Brillhart, M. Dittrich, G. Chertow, N. Tangri	Trial Design of FRONTIER: Ferric Citrate for the Prevention of Renal Failure in Adults with Advanced Chronic Kidney Disease	Poster # PO2381
Additional Presentations		
E. Szabo, C. Ferro, G. Dieguez, S. Metz, J. Moore, T. Berner, C. Kovesdy	Real-World Use of Phosphate Binder Agents Among Dialysis-Dependent Patients with Chronic Kidney Disease in Medicare Fee-for-Service	Poster # PO0799
G. Courbon, M. Martinez-Calle, J. Spindler, X. Wang, B. Hunt-Tobey, A. Martin, V. David	Distinct effects of FGF23, Iron and Phosphate on mineral metabolism and kidney function in mice with CKD	Poster # TH-OR16
G. Molnar, S. Z, S. Danthi, V. Csizmadia, J. Liu, S. Rao Allu, M. Rabinowitz, A. Zuk	HIF prolyl-4-hydroxylase inhibitor AKBX27922 induces cellular metabolic adaptation	Poster # PO2031

About Vadadustat

Vadadustat is a potential first-in-class oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor in the U.S. that is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. The New Drug Application (NDA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) is under review by the U.S. Food and Drug Administration (FDA). Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. The company was founded in 2007 and is headquartered in Cambridge, Massachusetts.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA® (ferric citrate) CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis:** Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please see full Prescribing Information

Forward-Looking Statements

Statements in this press release regarding Akebia's or Otsuka'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 efficacy and safety of vadadustat as a potential oral treatment for patients living with anemia due to chronic kidney disease and vadadustat's potential to be a first-in-class HIF-PH inhibitor in the U.S. The terms "expect," "will," "confident," "expect," "plan," "continue," "potential," 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, but not limited to: the timing of certain regulatory approvals; interactions with FDA, including reviews and inspections, the timing related thereto and the outcome thereof; the potential therapeutic benefits, safety profile and effectiveness of vadadustat, including the risk that vadadustat may cause undesirable side effects or have other properties that delay or limit its commercial potential or prevent its marketing approval; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions. 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, 2021, 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 press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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View original content to download multimedia:https://www.prnewswire.com/news-releases/akebia-announces-vadadustat-efficacy-and-safety-data-to-be-presented-at-american-society-of-nephrology-kidney-week-2021-301401831.html

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