Company Overview

December 2022

URICA THERAPEUTICS

Company Description

- Urica Therapeutics Inc. is a clinical-stage biopharmaceutical company developing novel drugs to address the significant unmet needs for the treatment of gout and other conditions associated with hyperuricemia

- Urica's lead asset, Dotinurad, is a differentiated oral URAT1 inhibitor approved in Japan with long patent life, excellent long-term efficacy and a strong safety profile

- In the U.S. market, Dotinurad may have $1B sales potential for the treatment of gout and potential for multi-billion dollar expansion opportunities in other indications (Urica also owns exclusive rights for the EU, UK, and Canada)

- Dotinurad is being developed based on a proven regulatory pathway with Phase 1 trials currently underway in the U.S., and a plan to launch a Phase 2 trial in 2023; successful Phase 2 trial may lead to significant value creation

Dotinurad Products are investigational and not approved for use in the United States.

Lead Asset – Dotinurad

- **Dotinurad is approved in Japan for hyperuricemia with or without gout**[1,2]
- **Japanese approval is based on 1000+ subjects treated in 17 clinical trials**
  - 500+ patients received Dotinurad in 3 Phase 3 trials up to 58 weeks in duration[4-6]
  - 4mg Dotinurad achieved 100% patient sUA <6mg/dL at 58 weeks[3]
  - Well-tolerated with excellent adverse event profile
  - No significant cardiovascular, hepatic or renal adverse events[4-6]
  - Label allows use in gout patients with mild-to-moderate CKD
- **Dotinurad has been widely licensed:**
  - Eisai – China & Southeast Asia
  - Standard Chem & Pharm Co. Ltd – Taiwan
  - Urica – U.S., EU, UK, and Canada

富士薬品

1. https://pubmed.ncbi.nlm.nih.gov/31754883/
2. https://www.fujiyakuhin.co.jp/medicine/m-fujiyakuhin/
3. 2mg Dotinurad resulted in 89.1% and 91.3% sUA under target Week 34 and 58
4. https://pubmed.ncbi.nlm.nih.gov/31980978/
5. https://pubmed.ncbi.nlm.nih.gov/31970593/
6. https://pubmed.ncbi.nlm.nih.gov/31875931/

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Markets

- **Gout market is directly addressable by Dotinurad**
  - More than 10 million U.S. adults are diagnosed with gout
  - Currently available gout drugs are limited by either moderate efficacy or considerable safety issues
  - Estimated 2.5 million U.S. gout patients could directly benefit from Dotinurad

- **Chronic kidney disease (CKD) market is potentially addressable by Dotinurad**
  - Kidney disease is the leading cause of death in U.S. and ~37 million U.S. adults have CKD
  - There is a significant overlap between patients with gout and CKD
  - Japanese clinical data suggest that Dotinurad may confer a renal protective effect
  - Dotinurad has the potential to address the massive CKD market with a novel mechanism

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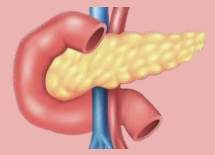
Current and Future Treatment Algorithm for Gout

	First-line therapy	Second-line therapy	Third-line therapy
Type of therapy	Xanthine Oxidase Inhibitors (XOI)	URAT-1 Inhibitors (Currently not available in U.S.)	Uricases
Treatment overview	• Allopurinol is the standard of care • Febuxostat is more potent than allopurinol but used less because of black box warning	• Lesinurad was approved in 2015 but withdrawn due to dose-limiting side effects and limited efficacy at tolerated doses • Ardea Bioscience, the developer of Lesinurad, was acquired by AstraZeneca for $1.3 billion in 2012 based on the promise of the class after P2 • Dotinurad is the successor with what appears to be improved efficacy and safety profile	• Uricase, i.e. Krystexxa®,requires supervised administration due to the potential of life-threatening side effects • Sales of Krystexxa® were $566 million in 2021 with double digit year-on-year growth
Annual cost	$100 - $1,000	~$5,000	$300,000+
Eligible patients	Newly diagnosed patients	XOI-refractory patients	Chronic refractory patients

Severity of Disease

Beyond Gout, Hyperuricemia is associated with other Chronic Conditions

Diabetes



- There is significant overlap between HU and type 2 diabetes
- It has been suggested that there is a bidirectional association between gout and diabetes

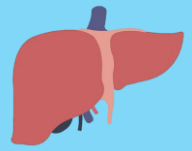
CKD/Kidney Stone

- HU can induce nephropathy and uric acid kidney stones
- Reducing serum uric acid can mitigate risk of renal failure due to nephropathy
- Urate lowering therapy has been shown to reduce albuminuria in CKD[1]

Hypertension/CVD

- HU is considered a predictor for the development of hypertension and CVD
- Urate lowering therapy has been shown to reduce blood pressure of adolescents with HU and essential hypertension[2]

Fatty Liver Disease



- HU increases the risk of NAFLD[3]
- Urate lowering therapy using Dotinurad has been shown to attenuate diet-induced hepatic steatosis and fat metabolism in animal models[4]

1. Am J Kidney Dis . 2021 Apr;77(4):481-489; **2.** JAMA . 2008 Aug 27;300(8):924-32; **3.** Eur J Gastroenterol Hepatol. 2016 Feb;28(2):132-8; **4.** Mol Metab. 2022 Jan;55:101411

Development Plan

- Phase 1 trials are currently underway to determine the pharmacodynamics, pharmacokinetics and safety of Dotinurad in U.S. subjects
- A Phase 2 proof of concept gout study is anticipated to launch in 2023
- Successful completion of the funded trials is expected to lead to significant value creation and the possibility of multiple potential exit options, such as an IPO or a corporate partnership, by as early as 2024

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The Company has Assembled an All-Star Team

Executive Management **Jay Kranzler, MD PhD** *Chairman, Chief Executive Officer & Director*	• Founding Member, McKinsey Pharmaceutical Practice • 24 years as CEO of 2 public companies (with 2 rheumatology product approvals), followed by senior executive position at Pfizer • Professor at NYU Medical & Business Schools • Founder, Board Member, and Advisor to an extensive number of companies and institutions
Raymond Zheng, PhD MBA *Founder and Chief Scientific Officer*	• Experienced Biotech Entrepreneur with combined 20+ years of experience in drug research, discovery and development • Previously held multiple business development roles at Fortress Biotech, Agenus, and Harvard Medical School • PhD from University of California, Riverside; Fellowship at Harvard Medical School; MBA from Rutgers University
Scott Baumgartner, MD *Interim Chief Medical Officer*	• Previously VP of Medical Affairs at AstraZeneca/Ardea Biosciences and Amgen • Experienced in the clinical development and post-launch activities of Lesinurad and Verinurad • MD from University of Washington with 20 years of clinical rheumatology experience
Board of Directors **Paul Brooke** *Co - Chairman*	• Chairman Emeritus of the Board of Caelum Biosciences, acquired by AstraZeneca in Oct 2021 • Founder and former Managing Partner of venBio, a pharmaceutical investment company • Former global head of healthcare research and strategy at Morgan Stanley
Lindsay Rosenwald, MD *Founder & Director*	• Chairman, President, and CEO at Fortress Biotech (NASDAQ: FBIO) • Previously, Founder of multiple biotech companies: Cougar Biotechnology (acquired by JNJ), Caelum Biosciences (acquired by Astra Zeneca), Chelsea Therapeutics (acquired by Lundbeck), Indevus Pharma (acquired by Endo), Biocryst, Keryx, CorMedix, and Ziopharm
Vibeke Strand, MD *Director*	• Renowned rheumatologist and Consultant and Advisor for three decades to companies, FDA, and professional societies in the field • Participated in 30+ rheumatology drug approvals • Academic appointments at UCSF and Stanford, each for 10+ years with ~500 publications in the field
Scientific Advisory Board **Robert Terkeltaub, MD** *Univ. of California, San Diego, Chief of Rheumatology*	• Professor of Medicine, UCSD, and Section Chief of Rheumatology at the VA Medical Center in San Diego • Associate Editor of Arthritis and Rheumatism, and serves on numerous NIH Study Sections in arthritis • Graduate of McGill University, where completed his medicine residency and rheumatology fellowship
Dr. Michael Pillinger, MD *New York Univ., Chief of Rheumatology*	• Chief of Rheumatology at VA NY Harbor Healthcare System, Professor of Medicine at NYC Grossman School of Medicine • Received medical degree from NYU School of Medicine; has practiced rheumatology for more than 20 years
Dr. Lee Simon, MD *Medical and Regulatory Consultant*	• FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products (2001-2003) • Long-time NIH-funded investigator, two-term ACR Board of Directors, Chair of Education for the ACR and National Arthritis Foundation