UTILITY Therapeutics Announces Leadership Changes

Wednesday 1 April, 2020

- Alan S. Roemer appointed Chairman of the Board of Directors
- Dr. Morten Sommer appointed Interim Chief Executive Officer
- Establishment of Business Advisory Board

April 01, 2020

UTILITY therapeutics Ltd., a company focused on the U.S. development and commercialization of European-approved antibiotics for the treatment of urinary tract infections, announced changes to the company's leadership as it progresses towards a U.S. New Drug Approval submission and increases focus on U.S. pre-commercialization efforts.

UTILITY has appointed Alan S. Roemer, M.B.A., M.P.H. as Chairman of the Board of Directors, replacing Dr. Francesco Granata, who is stepping down from the Board. Mr. Roemer was a Founding Leadership Team member of Roivant Sciences, and he currently serves as a director and Audit Committee Chair of NexImmune. In addition, Morten Sommer, Ph.D. has been appointed Interim CEO of UTILITY, replacing Mark Beards, who will transition to a Business Advisor. Dr. Sommer is a Co-Founder of multiple biotechnology companies, including UTILITY, and a Professor of Microbiology and Antibiotic Resistance at the Technical University of Denmark.

Anders Kronborg, CFO of LEO Pharma, a majority shareholder in UTILITY, and an observer of the UTILITY Board of Directors, expresses; "Mark Beards and Francesco Granata have done a tremendous job in bringing UTILITY to its current stage of development. On behalf of the entire UTILITY team and majority shareholders, I would like to express our sincere appreciation for their tireless efforts and successful contributions to the company. We look forward to continuing collaboration with both Mark and Francesco going forward. At the same time, we are excited to welcome Alan and Morten into their new roles and look forward to bringing EU-approved pivmecillinam and mecillinam to the U.S. for the treatment of urinary tract infections."

Dr. Granata further explains the leadership transition; "UTILITY has made tremendous progress since the company was founded in 2018, and it is time to increase focus on the U.S. market. I look forward to continuing a close collaboration with the UTILITY team and support the company in bringing critical infectious disease medicines to U.S. patients."

Incoming Interim CEO of UTILITY, Dr. Morten Sommer comments, "Despite the threat of antibiotic resistance to the U.S. healthcare system and economy, commercial interest in developing and launching new antibiotics has been declining. As highlighted by the COVID-19 crisis, the systemic cost and human suffering from not having an appropriate armamentarium of medicines for infectious disease can be enormous. In response to this paradox, and to ensure that as many patients as possible will eventually have access to the medicines offered by UTILITY, we will continue close collaborations with physicians, regulatory authorities, payers and commercial organizations to substantiate the unique and differentiated profile of our antibiotic therapies. Ultimately, our goal is to ensure that as many U.S. patients as possible will have access to these proven medicines."

UTILITY has also established a Business Advisory Board comprised of John Krayacich, Peter Aksel Villadsen and former CEO, Mark Beards. Mr. Krayacich is currently the Senior Vice-President and Head, Global Business Development at LEO Pharma and has previously served in senior roles at Novartis, Pfizer and several biotech ventures. Peter Aksel Villadsen, a Co-Founder of UTILITY, currently serves as Leo Pharma's Vice President, Head of Global Procurement & Accounts Payable and Global Facility Management. The Business Advisory Board will support UTILITY with U.S. commercialization planning, as well as facilitating operational and business development activities.

Contact:
info@utilitytherapeutics.com

ABOUT

UTILITY therapeutics Ltd.

Related Sectors:

Business & Finance :: Health :: Medical & Pharmaceutical ::

Related Keywords:

Mecillinam :: Pivmecillinam :: UUTI :: UTI :: Antibiotics :: Resistance :: Bacterial :: Bacteria :: NDA :: Pharma :: Roemer :: Therapeutics :: Denmark :: FDA :: Utility :: USA :: UK ::

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UTILITY has exclusive U.S. commercial rights to two drugs that are already approved in Europe: pivmecillinam, an oral antibiotic with a unique mechanism of action for infections caused by Gram negative bacteria (including extended-spectrum beta-lactamases, or ESBL), and mecillinam, an intravenous (IV) prodrug of pivmecillinam. UTILITY received the FDA's qualified infectious disease product (QIDP) designation for pivmecillinam for the treatment of both uncomplicated and complicated urinary tract infections (uUTI and cUTI, respectively). This regulatory designation allows up to 10.5 years of market exclusivity, Fast Track status and Priority Review to enable an accelerated path to launch of pivmecillinam for uUTI.

uUTI is a specialty care indication with a concentrated set of physician prescribers, including urologists, Ob/Gyn, geriatric specialists and internal medicine. Pivmecillinam is already included as a first-line therapy in the Infectious Diseases Society of America (IDSA) guidelines for uUTI, despite not yet being approved in the U.S. The currently available first-line therapies for uUTI are increasingly suffering from resistance that causes recurrent uUTIs, as well as more serious infections. Pivmecillinam has the potential to address an important unmet medical need in the U.S. for a first-line line uUTI treatment with lower levels of antibiotic resistance or safety issues.

UTILITY is also developing a first-line therapy for cUTI utilizing a high-dose, oral formulation of pivmecillinam and an IV formulation of mecillinam. This treatment would be carbapenem-sparing and allow for IV/oral switch, thus enabling patients with cUTI to finish their treatments outside of the hospital. This could significantly reduce the economic burden of cUTI to patients and payers.

The product profiles of pivmecillinam and mecillinam, along with extensive real-world evidence in European markets, are recognized by leading KOLs and physicians for use as a first-line treatment. In Denmark, where pivmecillinam has approximately 80% market share for uUTI treatment, there are consistently low, single-digit resistance rates. This makes pivmecillinam and mecillinam important and commercially attractive medicines for an indication challenged by significant antibiotic resistance in the U.S.

Alan S. Roemer, M.B.A., M.P.H.

Alan Roemer is an entrepreneurial life sciences executive and board member who has launched three biotechnology companies, raised over $1.5 billion in private and public capital, and consummated three IPOs. Mr. Roemer was a Founding Leadership Team member of Roivant Sciences, where he served in various senior management roles responsible for Finance & Operations and Corporate Development. He also served as Chief Financial Officer of Axovant Sciences, a Roivant subsidiary. Prior to launching Roivant and Axovant, Mr. Roemer was a Managing Director of the Trout Group, Chief Financial Officer & Treasurer of Zelos Therapeutics, and Vice President of Pharmasset (acquired by Gilead). Mr. Roemer is a Director and Audit Committee Chair of NexImmune, a Trustee of the Helene Fuld College of Nursing, and a Management Committee Member of DC Brau Brewing. He previously served as a director of SomPharmaceuticals (acquired by Amryt Pharma). Mr. Roemer received a B.S.B.A. from Georgetown University and M.B.A. and M.P.H. degrees from Emory University's Goizueta Business School and Rollins School of Public Health.

Morten Sommer, Ph.D.

Dr. Morten Sommer is a Professor and serial entrepreneur of multiple biotech companies, including UNION Therapeutics, SNIPR Biome, Biosyntia, Clinical-Microbiomics, UTILITY therapeutics, and Microlytic (acquired by Anatrace in 2014). Dr. Sommer is also a Professor and Scientific Director at the Technical University of Denmark with a laboratory of 20+ Ph.D. and post-doctoral researchers working primarily in the field of antibiotic resistance and the human microbiome. He has published >50 peer-reviewed papers – including publications on UTILITY's products – in journals such as Science and Cell and Nature. Dr. Sommer is a co-inventor on >25 patents and patent applications that have been licensed to public and private companies in the U.S. and Europe. Dr. Sommer holds a M.Sc. in Physics from University of Copenhagen and a Ph.D. in Biophysics from Harvard University from the laboratory of Professor George Church.

John Krayacich, M.B.A.

John Krayacich is the Senior Vice-President and Head, Global Business Development where he is responsible for all in-licensing, out-licensing, divestments and M&A activities for Leo Pharma. Prior to joining LEO Pharma in 2019, John was the Vice-President Business Development and Strategy for Novartis (USA). Before re-joining Novartis, John led two biotech companies, Marinus and Ambrose Pharmaceuticals. Earlier John held senior positions with Novartis in Global Project Management and Pfizer in Global and US Marketing and New Product Planning. Before joining Pfizer in 2000, John worked at Warner-Lambert/Parke-Davis, where he held various positions of increasing responsibility in Canada

and the USA in sales, marketing, and global marketing planning. His last position at Warner-Lambert was Senior Director of Global Marketing planning with responsibilities for global marketing strategy for the early and late stage atherosclerosis products including, Lipitor. Mr. Krayacich received his H.B.Sc. and M.Sc. in Physiology from The University of Western Ontario, as well as his M.B.A. from the Ivey Business School at The University of Western Ontario.

Company Contact:

UTILITY therapeutics

E. info@utilitytherapeutics.com
W. https://utilitytherapeutics.com/

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