Aytu BioPharma Announces Formation of New Scientific Advisory Board to Support Development of AR101 for Vascular Ehlers-Danlos Syndrome

Chaired by Dr. Hal Dietz and joined initially by Dr. Xavier Jeunemaitre, Dr. Shaine Morris, Dr. Bart Loeys, and Dr. Peter Byers with additional advisors to be added

ENGLEWOOD, CO / September 9, 2021 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products, today announced the formation of its Scientific Advisory Board, chaired by Dr. Hal Dietz, Professor of Genetic Medicine at the Johns Hopkins University School of Medicine. Other initial members of the SAB include Dr. Xavier Jeunemaitre, Professor of Genetics at University Paris Descartes, Dr. Shaine Morris, Medical Director of Cardiovascular Genetics at Texas Children's Hospital and Associate Professor at Baylor College of Medicine, Dr. Bart Loeys, Professor at the Center for Medical Genetics of the Antwerp University Hospital and Radboud University Medical Center in Nijmegen, and Dr. Peter Byers, Professor in the Department of Laboratory Medicine and Pathology and Department of Medicine (Medical Genetics) at the University of Washington. These prominent physicians will advise Aytu BioPharma to advance the global development of AR101 (enzastaurin), a pivotal study-ready therapeutic candidate initially targeting the treatment of Vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disorder typically diagnosed in childhood and characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. There are currently no U.S. Food and Drug Administration (FDA)-approved treatments for VEDS.

"We are honored to have our chair, Dr. Hal Dietz, as well as our key advisors Dr. Xavier Jeunemaitre, Dr. Shaine Morris, Dr. Bart Loeys, and Dr. Peter Byers join this newly formed SAB. Their collective expertise will prove invaluable as we progress toward a single pivotal study of AR101 in VEDS and seek strategies to minimize the clinical risk associated with the trial and hopefully advance this novel potential treatment option so that we can positively impact patients diagnosed with this devastating disease," commented Josh Disbrow, Chief Executive Officer of Aytu BioPharma. "We look forward to adding additional key opinion leaders to the SAB to lend their expertise to the development of AR101 in VEDS."

Hal Dietz, M.D. – Chairman of the Scientific Advisory Board

Dr. Dietz conducted the landmark research to date supporting AR101 in VEDS. He is Victor A. McKusick Professor of Pediatrics, Medicine, and Molecular Biology & Genetics in the Department of Genetic Medicine at the Johns Hopkins University School of Medicine and an Investigator at the Howard Hughes Medical Institute. As a physician scientist, he has dedicated his entire career to the care and study of individuals with heritable connective tissue disorders with primary perturbations of extracellular matrix homeostasis and function. His lab has identified the genes for many of these conditions, for which he uses model

systems to elucidate disease mechanisms. Dr. Dietz has received multiple prestigious awards including the Curt Stern Award from the American Society of Human Genetics, the Colonel Harland Sanders Lifetime Achievement Award in Medical Genetics, the Taubman Prize for excellence in translational medical science, the Harrington Prize from the American Society for Clinical Investigation and the Harrington Discovery Institute, the Pasarow Award in Cardiovascular Research, the InBev-Baillet Latour Health Prize from the country of Belgium, and the Research Achievement Award from the American Heart Association. He is an inductee of the American Society for Clinical Investigation, American Association for the Advancement of Science, Association of American Physicians, National Academy of Medicine, and National Academy of Sciences.

Xavier Jeunemaitre, M.D., Ph.D.

Dr. Jeunemaitre is Professor of Genetics at University Paris Descartes, the Head of the Department of Genetics at the Hospital Pompidou (HEGP) and the Director of the INSERM research team 3, U970, at the Paris Cardiovascular Research Centre, Paris, France. Dr. Jeunemaitre received his M.D. and Ph.D. in human genetics at the University P&M Curie, Paris, France. He was trained as an internist and specialized in cardiology before training in molecular genetics at the College de France in Paris and in human genetics during a post-doctoral fellowship at the Institute of Human Genetics, Salt Lake City, University of Utah, USA. Dr Jeunemaitre is the head of the National Referral Centre for Rare Vascular Diseases at HEGP which provides advice and care for more than 1,000 patients a year and is involved in epidemiological surveillance, registries, and clinical research. His laboratory of molecular genetics at HEGP provides genetic testing for rare cardiovascular and renal diseases as well as endocrine cancers (conducting approximately 2,500 tests a year).

Shaine A. Morris, M.D., M.P.H.

Dr. Morris is a pediatric cardiologist and Medical Director of the Cardiovascular Genetics Program at Texas Children’s Hospital and Associate Professor at Baylor College of Medicine. Dr. Morris received her M.D. at University of Texas Southwestern Medical Center and M.P.H. at Harvard School of Public Health. She trained in pediatrics at Boston Children’s Hospital and Boston Medical Center, followed by cardiology training at Texas Children’s Hospital/Baylor College of Medicine and advanced cardiovascular imaging at Boston Children’s Hospital. The Cardiovascular Genetics Program provides comprehensive diagnosis, counseling, and cardiovascular management for young people with genetic conditions and cardiovascular disease, specifically focusing on genetic conditions affecting the aorta and other arteries. Dr. Morris’ research interests align with her clinic interests and focus primarily on improving outcomes for the young population with genetically-mediated aortic disease. Specifically, she performs epidemiologic and clinical outcomes research involving cardiovascular imaging, molecular diagnostics, and deep phenotyping to improve risk stratification and optimize therapies based on individual patient characteristics.

Bart Loeys, M.D., Ph.D.

Dr. Loeys is professor of medical genetics and cardiogenomics at the Center for Medical Genetics of the Antwerp University Hospital in Belgium and in the department of Human Genetics in the Radboud University Medical Center in Nijmegen, The Netherlands. He trained as a pediatrician in Ghent, Belgium and as a clinical geneticist in the McKusick-Nathans Institute for Genetic Medicine at the Johns Hopkins University Hospital in Baltimore, Maryland. His special interests include connective tissue disorders, specifically heritable aortic aneurysm syndromes. He obtained a medical degree at the Ghent University in 1995 and subsequently started a pediatric residency training at the Ghent University Hospital. During this training program (1998-2002), he combined clinical and research activities and worked as a junior clinical investigator of the Fund for Scientific Research-Flanders in the Center for Medical Genetics of the Ghent University. His research project, entitled "Genotype and phenotype study of inherited defects of the elastic fiber," resulted in a PhD degree of Doctor in Medical Sciences (2004). From 2002 to 2005, he was accepted into the fellowship program in medical genetics of the Johns Hopkins Medical Institute. Together with his colleague, Dr. Hal Dietz from the Johns Hopkins University, he identified a new aortic aneurysmal disorder, now called Loeys-Dietz syndrome. At the end of his fellowship, he successfully obtained the certification for clinical genetics from the American Board of Medical Genetics. Since 2005, upon his return to Belgium, he has been a senior clinical investigator of the fund for scientific research – Flanders, initially in the Center for Medical Genetics-Ghent and since December 2010 in the Center for Medical Genetics of the University Hospital in Antwerp with a joint appointment at the Radboud University Medical Center in Nijmegen. Over the years he became an internationally renowned expert in the genetic basis of aortic aneurysmal disease. He was recently awarded the Francqui-Collen Prize, the so-called Belgian Nobel prize for translational biomedical research.

Peter Byers, M.D.

Dr. Byers is a board-certified physician with the Genetic Medicine Clinic and Center on Human Development and Disability and Pathology Services at University of Washington Medical Center and a University of Washington professor of Medicine, Pathology and Medical Genetics and an adjunct professor of Genome Sciences and Oral Health Sciences. Dr. Byers' philosophy is "get it right the first time." His research has the objective of understanding the molecular pathogenesis of inherited disorders of connective tissue. Dr. Byers earned his M.D. at Case Western Reserve University in Cleveland, Ohio. He is board certified in both Internal Medicine and Clinical Genetics. His research has focused on disorders that affect collagen genes and the enzymes involved in the post-translational modification of collagens.

Additional background information on the SAB members can be found on our website at https://aytubio.com/VEDS.

About Aytu BioPharma, Inc.

Aytu BioPharma is a specialty pharmaceutical company with a growing commercial portfolio of prescription therapeutics and consumer health products. The company's primary prescription products treat attention deficit hyperactivity disorder (ADHD) and other common pediatric conditions. Aytu markets ADHD products Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), and Adzenys-ER® (amphetamine) extended-release oral suspension (see Full Prescribing Information, including Boxed WARNING). The company's other pediatric products include Karbinal® ER (carbinoxamine maleate), an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. The company's evolution has been driven by strategic in-licensing, acquisition-based transactions and organic product growth. Aytu is building a complimentary therapeutic development pipeline including a prospective treatment (AR101/enzastaurin) for vascular Ehlers-Danlos Syndrome (VEDS), a rare genetic disease resulting in high morbidity and a significantly shortened lifespan. VEDS is a devastating condition for which there are no currently approved treatments. AR101 is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways. AR101 has been studied in more than 3,300 patients across a range of solid and hematological tumor types, and we are now planning a randomized, controlled, pivotal clinical study with AR101 in VEDS. To learn more, please visit aytubio.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. All statements other than statements of historical facts contained in this presentation, are forward-looking statements, including but not limited to any statements relating to the AR101 asset purchase, clinical development program, and any of the company's plans relating to AR101. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the potential contributions made by our recently formed AR101 scientific advisory board, the anticipated start dates,

durations and completion dates, as well as the potential future results, of the company's ongoing and future clinical trials, the anticipated designs of the company's future clinical trials, and the anticipated future regulatory submissions, potential adverse changes to our financial position or our business, the results of operations, strategy and plans, changes in capital markets and the ability of the company to finance operations in the manner expected, risks relating to gaining market acceptance of our products, risks related to the ongoing COVID-19 pandemic and its impact on our operations, our ability to effectively integrate operations and manage integration costs following our acquisitions, our partners performing their required activities, our anticipated future cash position and future events under current and potential future collaboration. We also refer you to (i) the risks described in 'Risk Factors' in Part I, Item 1A of Aytu's Annual Report on Form 10-K and in the other reports and documents it files with the Securities and Exchange Commission and (ii) the Risk Factors set forth in Aytu's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC.

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View source version on accesswire.com:
https://www.accesswire.com/663188/Aytu-BioPharma-Announces-Formation-of-New-Scientific-Advisory-Board-to-Support-Development-of-AR101-for-Vascular-Ehlers-Danlos-Syndrome