News Release

ASTRAZENECA ESTABLISHES SCIENTIFIC REVIEW BOARD TO SUPPORT CLINICAL TRIAL DATA TRANSPARENCY COMMITMENT

19 March 2015

AstraZeneca today announced the creation of a Scientific Review Board that will act independently to assess requests from external researchers which include patient level data. The Board of independent clinicians and academics has been established as part of AstraZeneca's commitment to the European Federation of Pharmaceutical Industries and Associations (EFPIA) and Pharmaceutical Research and Manufacturers of America (PhRMA) Responsible Data Sharing Principles, as well as the new European Medicines Agency Clinical Trial Policy and Regulation.

The Board is chaired by Peter Kowey, MD, System Chief, Division of Cardiovascular Diseases for the Lankenau Heart Institute, part of Main Line Health. The other members of the Board are:

- Stephen Rennard, MD, Larson Professor of Medicine, University of Nebraska Medical Centre
- Simon Day, PhD, Director, Clinical Trials Consulting and Training
- Alexander Walker, MD DrPH, Principal, World Health Information Science Consultants, LLC.

The Scientific Review Board will meet on a regular basis to consider all external requests for access to data from AstraZeneca clinical trials. The Board will assess the scientific validity of each request and how provision of the information may enhance scientific understanding and patient care. In addition to approving or rejecting requests, the Board will also have the option of granting conditional approvals or providing suggestions on how to resubmit requests in order to secure approval.

Professor Peter Kowey, Chair of the Board, said: "I am excited to be leading the Scientific Review Board for AstraZeneca and contributing to furthering transparency for the purposes of developing better drugs to help patients across the globe."

The creation of the Scientific Review Board is part of AstraZeneca's broader Clinical Trial Transparency Policy, which includes posting the results of all AstraZeneca sponsored clinical trials in all stages of clinical development on several public websites, regardless of outcome. Other new components of the AstraZeneca policy that will be implemented in 2015 include:

- Creation of a Data Transparency Portal through which researchers can submit requests to access anonymised patient level data.
- Creation of Lay Language Summaries of clinical trial results, to be made available to all patients that participate in AstraZeneca sponsored clinical trials, and publically through websites including astrazenecaclinicaltrials.com.
- Clinical Data packages, including Clinical Overviews and Clinical Summaries, Clinical Study Reports, and some of their Appendices (Study Protocols, sample Case Report Forms and Study Statistical Analysis Plans), to be made available via astrazenecaclinicaltrials.com and the new EU portal when it comes online in 2016.

Dr Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: “AstraZeneca has a longstanding commitment to clinical trial transparency and these new developments are part of the evolution of that policy. We believe that transparency enhances the scientific understanding of how our medicines work and is in the medical interest of our patients. We are delighted to underpin our policy with the establishment of the Scientific Review Board and are pleased to have such an experienced panel on board to support us.”

To access AstraZeneca’s dedicated website and for more information on the Company’s clinical trial data disclosure commitment, visit: astrazenecaclinicaltrials.com.

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NOTES TO EDITORS

About the AstraZeneca Scientific Review Board
The Scientific Review Board will be responsible for reviewing requests for AstraZeneca clinical trial data that meet the following criteria:

- The data relate to AstraZeneca-sponsored interventional Phase I to Phase IV patient studies.
- The data have been provided to health authorities to support approved (or discontinued) indications in either the US, EU or Japan and have completed the approval process in the relevant regions.
- The data relate to studies that were initiated from 2009 onwards.

About the Scientific Review Board members
Peter Kowey, MD, is a Cardiologist and researcher. He is currently System Chief, Division of Cardiovascular Diseases for the Lankenau Heart Institute, part of Main Line Health, practicing primarily at Lankenau Medical Center. Kowey also holds the William Wikoff Smith Chair in Cardiovascular Research at Lankenau Institute for Medical Research. He spent 9 years as a member of the Cardiorenal Drug Advisory Committee of the FDA, 4 years on the Cardiovascular Devices Committee of the FDA and was on the Expert Advisory Panel of the US Pharmacopeial convention. He is the author or co-author of over 400 papers and scientific reports. He has led or participated in many landmarks trials, mainly in the field of cardiac rhythm disturbances.

Stephen Rennard is Larson Professor of Medicine in the Pulmonary, Critical Care, Allergy and Sleep Medicine Section of the Department of Internal Medicine, Courtesy Professor in the Department of Pathology and Microbiology and the Department of Genetics, Cell Biology and Anatomy and Adjunct Professor in the School of Health, Physical Education and Recreation, University of Nebraska Medical Center, Omaha. He serves on the Board of Directors of the COPD Foundation and the Alpha-1 Foundation. He is Chair of the Steering Committee for SPIROMICS and Co-chair of the COPD Biomarkers Qualification Consortium. He was previously governor for the American College of Chest Physicians. He has over 400 research publications in peer-reviewed journals.

Simon Day is a biostatistician who has worked in regulatory agencies and in the pharmaceutical industry for 30 years. He is past president of the International Society for Clinical Biostatistics and a Fellow of the Society for Clinical Trials. He is joint editor of Statistics in Medicine and previously joint editor of the Journal of the Royal Statistical Society. He is the author of numerous research publications and of the book “Dictionary for Clinical Trials”.

Alexander Walker is a Principal at the World Health Information Science Consultants. WHISCON performs research in the safety of pharmaceuticals using epidemiologic methods.

Dr Walker is the former Chair of the Epidemiology Department at the Harvard School of Public Health where he continues his teaching in pharmacoepidemiology. Dr Walker is widely published with 300 manuscripts in peer-reviewed journals.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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