NDA Partners Introduces Quantitative Drug Development Strategies Practice

NDA Partners announced today the formation of a specialized practice area in quantitative drug development strategies (QDDS). The QDDS Practice is led by Roger Williams, MD, a Partner in the firm, and includes top-tier Experts Consultants with extensive industry and regulatory agency experience in quantitative clinical pharmacology, the application of Bayesian approaches in biostatistics and clinical trial design, and clinical trial modeling and simulation.

ROCHELLE, VIRGINIA (PRWEB) January 10, 2018 -- NDA Partners Chairman Carl Peck, MD, announced today the formation of a specialized practice area in quantitative drug development strategies (QDDS) to address the needs of its clients. Utilizing state-of-the-art quantitative methodologies and data-driven approaches, including quantitative clinical pharmacology, PKPD and PBPK modeling, clinical trial simulation, and adaptive trial designs, the new QDDS Practice is intended to help clients address important issues such as predicting optimal dose and clinical outcomes more accurately, optimizing information value and efficiency of clinical trial designs, identifying patients who would benefit most from therapy, and producing compelling evidence of effectiveness. By focusing on the most clinically relevant development questions, NDA Partners will support the design and execution of clinical trials that can accelerate development programs and that produce high-quality regulatory packages containing the data needed to secure regulatory approval without delays.

The new QDDS Practice is led by Roger Williams, MD, a Partner in the firm. Before joining NDA Partners, Dr. Williams was Chief Executive Officer and Chair of the Council of Experts at the US Pharmacopeial Convention; Director of the Office of Generic Drugs at the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER); and Deputy Center Director and Director, FDA Office of Pharmaceutical Sciences (CDER). He is an expert in clinical pharmacology, has been board certified in clinical pharmacology and internal medicine, and conversant with all elements of quantitative clinical pharmacology and their application in therapeutics.

The QDDS Practice consists of some of the most recognized leaders and well-respected industry, academic, and regulatory professionals in the world. They have played a key role in pioneering the field of quantitative clinical pharmacology and the application of Bayesian approaches in biostatistics and clinical trial design. In prior industry and regulatory agency roles, they have been instrumental in strengthening clinical pharmacology activities and contributed to many regulatory guidances on topics of safety, efficacy, quality, and regulatory communications, as well as biopharmaceutic, clinical pharmacology, and pediatric drug studies. They have had extensive interactions with global regulatory authorities to ensure acceptance of product development plans and support regulatory submissions, including INDs, NDAs, MAAs, BLAs, and ANDAs.

“I am pleased to head up this important new practice area within NDA Partners”, said Dr. Williams. “Biopharmaceutical companies face a wide range of complex technical challenges in developing novel therapies, and require approaches that meet these challenges efficiently and within inevitable resource constraints. Our new QDDS Practice will support industry and regulatory efforts to meet the most complex technical challenges of modern drug development through the application of advanced quantitative techniques by some of the world’s top experts in this field.”

Members of the QDDS Practice area include:
Carl Peck, MD is Chairman, a Partner and founding Member of NDA Partners, and former Director of FDA CDER, founding Director of the Center for Drug Development Science at Georgetown University Medical Center, and Assistant US Surgeon General. Dr. Peck is a pioneer in the field of quantitative clinical pharmacology and expert in the application of model-informed and Bayesian approaches in clinical trial design.

Alasdair Breckenridge, MD is a Partner in the firm, a global thought leader, and former Chair of the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. Sir Alasdair is a renowned clinical pharmacologist and after training at the Royal Postgraduate Medical School, was appointed to the Chair of Clinical Pharmacology at the University of Liverpool.

Anthony DiSanto, PhD, was formerly Vice President, Worldwide Drug Delivery R&D, Upjohn Company; Vice President R&D, Somerset Pharmaceuticals; and Vice President Drug Development, Alamo Pharmaceuticals. Dr. DiSanto is an expert in drug formulation development of human and veterinary NCE’s, clinical biopharmaceutic and pharmacokinetic studies conducted in support of existing products and product line extensions, and assessing and implementing bioavailability/pharmacokinetic studies in support of 505(b)(2) applications, particularly those for pediatric drugs.

Michael Eldon, PhD was formerly Vice President Clinical Pharmacology, Nektar Therapeutics, and Director of Regulatory Affairs and Chairman of Clinical Development Committee, Inhale Therapeutic Systems. He is an expert in product registration strategies, including the use of surrogate markers of drug effect, interaction with global regulatory authorities, PKPD data analysis, and application of quantitative clinical pharmacology. Dr. Eldon has broad experience in the development and registration of prodrugs and products using novel drug delivery technologies, including systemic drug delivery via the pulmonary route.

Peter Feldschreiber, MD is dually qualified as a Barrister and physician, specializing in medical and healthcare law. He serves on the Committee of Safety of Devices and the Code of Conduct Committee of the Association of British Health Industry. Dr. Feldschreiber is a former Senior Medical Assessor and Special Litigation Coordinator, MHRA Commission on Human Medicines, and Medical Director, Cardiovascular and Anesthetic clinical development, Glaxo Pharmaceuticals. He is an expert in evaluation of the risk-benefit profiles of medical products and assessments of legal and regulatory risks.

Theo Guentert, PhD, PharmD is an Associate Professor in Pharmacy, University of Basel. He was formerly Associate Head of Clinical Pharmacology, Head of Nonclinical Drug Safety, and Head of Nonclinical Development, at F. Hoffmann-La Roche. Dr. Guentert is an expert in nonclinical and clinical development, pharmacokinetics, clinical pharmacology, and drug metabolism.

Kazem Kazempour, PhD, is President and CEO of Amarex Clinical Research, LLC, a CRO that works closely with NDA Partners. He is an Adjunct Professor at the Medical Center of George Washington University, and Senior Staff Fellow and Mathematical Statistician in the Biometrics Division at the FDA. Dr. Kazempour is an expert in biometrics, biostatistics and clinical trial design.

Nicholas Holford, MD is a Professor of Clinical Pharmacology at the University of Auckland, New Zealand; Honorary Professor of Clinical Pharmacology at UCSF; Fellow of the American Association of Pharmaceutical Scientists; and Member of the Royal College of Physicians (UK). He is an expert in clinical pharmacology and pharmometric modeling and simulation.
In-Jin Jang, MD, PhD was formerly Director, Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine. He is an expert in early phase clinical trials for companies in the Asia-Pacific region including FIH, ADME, hepatic insufficiency and drug-drug interaction studies. Dr. Jang is highly skilled in the use NONMEM, Simcyp, and LMNE/Pharsight.

Xavier Luria, MD was formerly Head, Safety and Efficacy of Medicines, European Medicines Agency (EMA), where he oversaw authorizations of all drug and biologic products and was responsible for implementation of eCTD. He was previously International Medical Director and Head of Research, Almirall (Barcelona). Dr. Luria is an expert in regulatory strategies, clinical pharmacology, and health technology assessment (HTA).

Gary Novack, PhD is a Visiting Professor of Pharmacology and Ophthalmology at the School of Medicine at the University of California, Davis. He is a former Director of Inspire Pharmaceuticals Inc.; President and Founder of PharmaLogic Development, Inc.; and Associate Director of Glaucoma, Ophthalmology Clinical Research at Allergan Pharmaceuticals. Dr. Novak is an expert in drug and device development strategies, clinical pharmacology, and preparation of IND, IDE, NDA, PMA, and PLA submissions.

Malcolm Rowland, PhD is a Partner and founding Member of NDA Partners. He is Professor Emeritus and former Dean, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Adjunct Professor, School of Pharmacy, UCSF; Founder and Director of Medieval Ltd. (a CRO); Vice-President of the International Pharmaceutical Federation; and President of the European Federation of Pharmaceutical Sciences. Dr. Rowland is a renowned innovator and world leader in the fields of pharmacokinetics and drug metabolism.

Dan Spyker, MD, PhD is currently Adjunct Professor of Clinical Pharmacology at the Uniform Services University of Health Sciences (Bethesda); Adjunct Professor of Biopharmaceutical Sciences, UCSF; and Adjunct Professor of Emergency Medicine, Oregon Health and Sciences University. He was formerly acting Deputy Director, FDA Division of Cardiovascular, Respiratory, and Neurological Devices (CDRH); Medical Officer, CDER Pilot Drug Evaluation Staff; Senior Director of Drug Safety and Pharmacovigilance, Alexza Pharmaceuticals; and Director, Pharmacokinetics and Pharmacodynamic Sciences, Genentech. Dr. Spyker is an expert in toxicology, PKPD analysis, biostatistics, and REMS.

Frank Voci, PhD is currently President, Friends Research Institute, and former Deputy Director, National Institute on Drug Abuse (NIH). He was a Consultant for World Health Organization (WHO); Deputy Chief, Drug Abuse Staff, FDA CDER; and Reviewing Pharmacologist, FDA. Dr. Voci is an expert in addictive disorders, quantitative pharmacology, and pharmacometric analyses, including modeling and simulation.

Gregory Campbell, PhD was formerly Director of the FDA Division of Biostatistics; Chief, Analytical Biometrics, NIH; Acting Chief, Laboratory of Statistical and Mathematical Methodology, NIH; and Chief, Statistical Methodology Section, NIH. He was the leader of several FDA committees including the Guidance on Principles of Study Design for Medical Device Premarket Clinical Investigations, Guidance on the Use of Bayesian Statistics for Medical Device Clinical Trials, and Draft Guidance on Adaptive Designs for Medical Device Clinical Studies. Dr. Campbell is an expert in biostatistics, adaptive and Bayesian clinical trials, evaluation of diagnostic tests, ROC curves, and statistical image analysis.

Joachim Vollmar, MSc was formerly Executive Vice President, Global Product Development Services, and
Managing Director of European Operations, PRA International, where he was a company co-founder; and Head of the Department of Risk Analysis Therapeutics, Boehringer Mannheim. He is an expert in biostatistics, adaptive clinical trial design, clinical statistics, data management, and pharmacology.

About NDA Partners
NDA Partners is a strategy consulting firm specializing in expert product development and regulatory advice to the medical products industry and associated service industries such as law firms, investment funds and government research agencies. The highly experienced Principals and Premier Experts of NDA Partners include three former FDA Center Directors; the former Chairman of the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK; an international team of more than 100 former pharmaceutical industry and regulatory agency senior executives; and an extensive roster of highly proficient experts in specialized areas including nonclinical development, toxicology, pharmacokinetics, CMC, medical device design control and quality systems, clinical development, regulatory submissions, and development program management. Services include product development and regulatory strategy, expert consulting, high-impact project teams, and virtual product development teams.

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