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Engineering & Scientific Consulting

Tim Morley, Ph.D., FRCPATH

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Professional Profile

Dr. Morley is an Executive Research and Development Director with over 25 years experience in the Pharmaceutical Industry with small molecules, peptides, antibodies and natural products, directing discovery, safety evaluation and regulatory development from Chemical hit to IND. He also has expertise in Medical Device Safety & Biocompatibility and was the Site Director of Global Medtech Research Centre, establishing Centre of excellence for Biocompatibility, Safety & Efficacy.

Dr. Morley is a Board-certified Toxicologist with additional expertise in DMPK, Clinical Chemistry, Pharmacology, Bioanalysis, CMC, Medical Affairs and Pharmacovigilance.

Previously Dr. Morley was an Independent Industrial Advisor to Wellcome Trust directing the development of a Multiple Sclerosis Programme, a Member of EPSRC Centre for Innovative Manufacturing in Medical Devices External Advisory Board and a member of the CH/194 Biological evaluation of Medical Devices BSI eCommittee.

He has a track record of team building, budget management, managing organisational change and directing therapeutic projects from Chemical Hit to IND managing US and EU Regulatory process. He also has experience in supporting Orthopaedic, Sports Medicine & wound healing devices to successful 510K approval.

Dr. Morley has experience of negotiating R&D collaboration contracts, managing industry/academic & biotech/Pharma collaborations, due diligence for in-licence agreements and corporate acquisition. He was a Senior management team member responsible for successful IPO of a UK start-up company.

Academic Credentials & Professional Honors

Ph.D., Medicine, University of Aberdeen, 2002

M.S., Biopharmacy, King's College, University of London, UK, 1991

B.Sc., Pharmacology, North East Surrey College of Technology, 1989

B.Sc., Applied Biochemistry, Liverpool John Moores University, 1984

Academic Appointments

Industrial Academic Liaison Advisory Board, Aberdeen University, 2010

Invited Lecturer, Research & Innovation – Institute of Medical Sciences, Aberdeen University, 2010

Invited Lecturer, MSc in Drug Discovery and Translational Biology, University of Edinburgh, 2011

Prior Experience

Managing Director, Advotox Ltd. April 2017 to 2022

Chief Scientific Officer, Orphan (formerly GMPorphan) 2017 to 2021

Site Director Research Centre (Senior Director, Preclinical Research) Smith & Nephew 2013 to 2017

Chief Scientific Officer, Aquapharm Biodiscovery. 2010 to 2013

Research and Strategic Project Director. Quotient Biodiagnostics. 2008 to 2010

Vice President Preclinical Sciences. Ardana Bioscience 2004 to 2008

Senior Director Molecular & Cellular Pharmacology. Vernalis 2003 to 2004

Senior Director Biological Research. Vernalis June 2001 - Oct 2003

Director Preclinical Evaluation. Vernalis 2000 – June 2001

Section Head, DMPK Vernalis 1997 to 1999

Senior Scientist, Toxicology AgrEvo 1996 to 1997

Scientist, Bioanalysis and Drug Metabolism. Wellcome Research Laboratories 1987 to 1996

Scientific Officer, Biochemistry Department. Hillingdon Hospital 1985 to 1987

Professional Affiliations

Member of Chemical & Biological Metrology Programme Expert Group

Fellow of the Royal College of Pathologists

Patents

Timothy James Morley, Ronnie Maxwell Lawrence and Naseem Amin. Crystalline form of Triethylenetetramine tetrathydrochloride and its pharmaceutical use. US Patent 10,988,436 (Granted April 2021)

Timothy Morley and Stephen Wright. The identification of novel (macrocycle) compounds and their putative use as bioactive agents, especially as antimicrobial agents and anti-cancer agents. British Patent Application No. 1221880.6 (Dec 2012)

Timothy Morley and Stephen Wright. The present invention is based on the identification of novel compounds and their putative use as bioactive agents, especially as antimicrobial agents. British Patent Application No. 1221859.0 (Dec 2012)

Morley, Timothy James; Julian Fisher. Method of bulk manufacturing process for preparing a composition of bigel for the application of 1% Testosterone. PCT/GB2007. Appl 31/12/2007 005023

Morley, Timothy James; Julian Robert Walker Fisher: Method of producing a composition from an oleogel

and an aqueous gel and the composition. Filed December 31 2007. Publication Date June 30, 2011. WO 2008081175 A2

Bentley Jonathan Mark; Bickerdike Michael John; Hebeisen Paul; Kennett Guy Anthony; Lightowler Sean; Mattei Patrizio; Mizrahi Jacques; Morley Timothy James; Plancher Jean-Marc; Richter Hans; Roever Stephan; Taylor Sven; Vickers Steven Paul. Indole derivatives and their use as 5-HT_{2B} and 5-HT_{2C} receptor ligands. European Patent Office (EPO) Document Number: EP1347979 Publication date : 1st October 2003

Bentley Jonathan Mark; Bickerdike Michael John; Hebeisen Paul; Kennett Guy Anthony; Lightowler Sean; Mattei Patrizio; Mizrahi Jacques; Morley Timothy James; Plancher Jean-Marc; Richter Hans; Roever Stephan; Taylor Sven; Vickers Steven Paul. Novel Indole Derivatives. US20020160997 A1 Publication Date Oct 31 2002

Publications

John Foster, Kharmen Billimoria, Maria Estela del Castillo, Stanislav Stekopytov, Heidi Goenaga-Infante and Timothy Morley. Accumulation of molybdenum in major organs following repeated oral administration of bis-choline tetrathiomolybdate in the Sprague Dawley rat. Journal of Applied Toxicology May 2022 (in Press)

Karl Heinz Weiss, Catherine Thompson, Peter Dogterom, Yi-Jin Chiou, Tim Morley, Brinley Jackson, Naseem Amin, Camille Omar Farouk Kamlin. Comparison of the Pharmacokinetic Profiles of Trientine Tetrahydrochloride and Trientine Dihydrochloride in Healthy Subjects Eur J Drug Metab Pharmacokinet. 2021 Sep;46(5):665-675.

M. Estela del Castillo-Busto, Susana Cuello-Nunez, Christian Ward-Deitrich, Tim Morley and Heidi Goenaga-Infante. A fit-for-purpose copper speciation method for the determination of 1 exchangeable copper relevant to Wilson's disease. Analytical and Bioanalytical Chemistry. (June 2021)

SVETLANA V. DOBRITSA, IOK TENG KUOK, HAI NGUYEN, JEFFREY WEBSTER, ANDREW MEARN SPRAGG, TIMOTHY MORLEY, and GRANT J. CARR. Development of a High-Throughput Cell-Based Assay for Identification of IL-17 Inhibitors. Journal of Biomolecular Screening (Volume 18 Issue 1 January 2013 pp. 74 - 83).

Zhicai Yang, Xiaomin Jin, Michael Guaciaro, Bruce F. Molino, Ursula Mocek, and Tim Morley. The Revised Structure, Total Synthesis, and Absolute Configuration of Streptophenazine A. Organic Letters. American Chemical Society. September 29, 2011

Morley, T. J.; Goodwin, D. A.; Read, N. G.; Hodgson, S. T.; Hawksworth, G. M. (1997). Mechanisms of renal glomerular toxicity of an N-hydroxyurea 5-lipoxygenase inhibitor. Human & Experimental Toxicology. Vol. 16, No. 7, pp. 412.

Morley T J; Evans G O; Goodwin D A; Read N G; Hodgson S T; Hawksworth G M. Structure-activity relationship for two lipoxygenase inhibitors and their potential for inducing nephrotic syndrome. Toxicology and Applied Pharmacology. (1997 Oct), 146 (2), 299-308.

Morley T J; Dickins M. (1990). A Study to investigate the cytotoxicity of the neuromuscular blocking agent Atracurium using primary rat hepatocyte culture. Human & Experimental Toxicology. Vol 9 (5), 345-346.

Parsons, Derrick N.; Dickins, Maurice; Morley, Timothy J. (1995). Lamotrigine: Absorption, distribution, and excretion. Antiepileptic drugs, Fourth edition. pp. 877-881. Levy, R. H.; Mattson, R. H.; Meldrum, B. S. [Eds].

Dickins, Maurice; Sawyer, David A.; Morley, Timothy J.; Parsons, Derrick N. (1995) Lamotrigine: Chemistry and biotransformation. Antiepileptic drugs, Fourth edition. pp. 871-875. Levy, R. H.; Mattson,

R. H.; Meldrum, B. S. [Eds].

Presentations

Kharmen Billimoria, Timothy Morley, Maria Estela del Castillo, Stanislav Stekopytov, Heidi Goenaga-Infante, John Foster. Accumulation of molybdenum in major organs following chronic oral administration of bischoline tetrathiomolybdate in Sprague Dawley rats. EASL Conference April 2022.

S. McDougall and T. Morley. Defining the range of healthy volunteer non ceruloplasmin copper using a new copper protein speciation assay. 14th European Bioanalytical Forum. Barcelona. Nov 2021.

Wilson's Webinar Orphan. 16th September 2021. Recent developments in Wilson's Disease Management and Follow Up. "Non Ceruloplasmin Bound Copper: The development of a reliable and precise biomarker for monitoring Wilson's Disease Patients" Dr Tim Morley PhD FRCPATH. Chief Scientific Officer, Orphan. London, UK "Recent Clinical Development in Wilson's Disease: the awaited evidence" Professor David Cassiman Hospital and University of Leuven. Leuven, Belgium

T. MORLEY, H. GOENAGA-INFANTE, E. DEL CASTILLO, S. MCDUGALL, K. D'HOLLANDER, and O. KAMLIN. Novel Copper Protein Speciation method for calculating Serum Non Ceruloplasmin Copper: A Comparative Analysis. EASL Conference August 2021.

T. MORLEY, H. GOENAGA-INFANTE, E. DEL CASTILLO, S. MCDUGALL, K. D'HOLLANDER, and O. KAMLIN. Defining the range of healthy volunteer Non Ceruloplasmin Copper using a new Copper Protein Speciation assay. EASL Conference August 2021.

Aurelia Poujois, Tim Morley, Catherine Thompson. Comparative Pharmacokinetic profile of two distinct trientine salt formulations used for treatment of Wilson's disease. Foundation Rothchild Paris France March 2021.

Karl Heinz Weiss, Tim Morley, Catherine Thompson. Comparative Pharmacokinetic profile of two distinct trientine salt formulations used for treatment of Wilson's disease. EASL Conference August 2020.

Tim Morley. Exploring the Chemical Characterisation risk assessment approach and complying with ISO-10993-18 Informa's Life Science's 7th Biocompatibility Testing and Evaluations for Medical Devices. Dublin Ireland 2015.

Project Experience

- US litigation – Pharmaceutical Breach of Contract
- Supporting Drug development
- Support QSAR analysis of Pharmaceutical API and impurities
- Support Biological active manufacture safety measures
- Support Device 510K submission
- Support Risk assessment of device failure analysis
- Support ISO 10993 Biocompatibility Device testing
- Support CAPA advice for Industrial spillage in Clean room

Additional Education & Training

DipRCPATH - Biochemical Toxicology

FRCPath - Toxicology

Advisory Appointments

Member of Scientific Advisory Board - Jellagen UK