Focus day overview:
With a growing industry focus on alternative delivery approaches to replace intravitreal drug delivery and novel drug development, the new Ophthalmic Drugs Focus Day will explore innovations in R&D of novel delivery methods. Mechanisms including implants for IOP control, an antagonist prodrug for sustained reduction of intraocular pressure and alternatives to intravitreal delivery will be discussed, highlighting the challenges in developing novel delivery of medication to the eye. Academic perspectives will offer a glance into the future for ocular drug delivery and notified bodies will provide a regulatory insight into this emerging field of ophthalmic drug development.

TOPICS COVERED WILL INCLUDE:
- A regulatory insight into the ocular delivery regulatory framework
- Case studies of innovations in novel delivery platforms
- Outlook of the key challenges in delivery therapeutic levels of medication to the eye
- A panel discussion exploring delivery to the posterior segment of the eye

Panel discussion:
Drug delivery to the posterior segment of the eye
- Novel delivery methods that are currently in the pipeline
- What are the main challenges in delivery to the back of the eye?
- How will we tackle these challenges and learn from recent R&D?

Panel Moderator: Peter Morgan-Warren, Medical Assessor, MHRA
Panelists: Mitchell de Long, Vice President, Chemistry, Aerie Pharmaceuticals
Clive Wilson, Research Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences
Virginia, Calder, Reader – Ophthalmology, UCL

Panelists will offer a variety of perspectives and insights into the latest innovations in ophthalmic drug delivery, including:
- New drug delivery devices: contact lenses, intravitreal implants, depot...
- What will the future bring us?

Panelists:
- Borja Salvador-Culla, Anterior Segment, Cornea and Refractive Surgery Consultant in Ophthalmology, Centro de Oftalmología Barraquer
- Raid Alany, Chair in Pharmaceutical Formulation and Drug Delivery, Kingston University London
- Peter Morgan-Warren, Medical Assessor, MHRA

Schedule:
- 9.00 Chair’s Opening Remarks
  Peter Morgan-Warren, Medical Assessor, MHRA
- 9.10 OPENING ADDRESS
  Safety and Efficacy of a Novel Intracapsular Drug Delivery Platform
  • iVeena has developed an intracapsular drug delivery platform that enables bi-directional drug delivery to anterior and posterior eye segments
  • The initial platform technology application is IVMED-20, a biodegradable demethylamide delivery device placed during cataract surgery to prophylaxis cystoid macular edema, as well as, central inflammation and pain from the procedure
  • IVMED-20 is intended for cataract patients at high risk of developing cystoid macular edema, including concurrent: diabetic retinopathies & edemas, epiretinal membranes, macular hole, retinal vein occlusions, and uveitis
  • IVMED-20 has been studied in an ex-US clinical study. This proof of concept study, albeit not statistically powered, suggest the ability to safely control inflammation, and reduce retinal thickening, without anti-inflammatory eye drops
  Michael Burr, Vice President of Product Development, iVeena
- 9.50 Novel Delivery for the treatment of Glaucoma – a case study
  • Durysta: an implant for IOP control in Glaucoma
  • The Clinical Development of Durysta – Phase 1/2 data
  • Phase 3 outcomes and results
  Simon Chandler, Executive Director, Clinical Development, Allergan
- 10.30 Morning Coffee
- 11.00 Barriers to Posterior Segment Drug Delivery
  • New drugs offer the promise of stopping or even reversing age-related sight impairment but need appropriate methods of delivery
  • Overview of the key issues in systemic or topical administration of drugs for the back of the eye
  • Understand how the ageing eye alters drug distribution from a reservoir
  • Examine tactical approaches to overcoming barrier issues and examine advantages and shortfalls of approaches
  Clive Wilson, Research Professor, Strathclyde Institute of Pharmacy and Biomedical Sciences
- 11.40 PANEL DISCUSSION
  Drug delivery to the posterior segment of the eye
- 12.20 Networking Lunch
- 13.20 Regulatory perspectives on novel ocular drug delivery
  • Novel ocular drug delivery and the regulatory framework – clinical considerations
  • Combination products, devices and borderline products
  Peter Morgan-Warren, Medical Assessor, MHRA
- 13.50 Sustained drug release for managing ocular hypertension and glaucoma
  • Long-lasting therapeutics that effectively lower and maintain IOP remain a substantial unmet medical need
  • Available ocular drug delivery platforms
  • Choice of administration routes: intracameral, subconjunctival or intravitreal injection
  • An injectable formulation of a beta-adrenergic antagonist prodrug for sustained reduction of intraocular pressure
  Jinzong Zhang, Vice President, Graybug Vision
- 14.30 Afternoon Tea
- 15.00 Age-related eye diseases: how can drug delivery research help?
  • Delivery of drugs and biologics to the front and back of the eye is a challenge
  • Dry eye, glaucoma and AMD are prevalent amongst the aging population; they require pharmaceutical intervention using drug(s) that need to be formulated
  • Novel pharmaceutical formulation and drug delivery strategies could offer solutions to unmet ophthalmic needs
  Raid Alany, Chair in Pharmaceutical Formulation and Drug Delivery, Kingston University London
- 15.40 An update on ocular drug delivery pathways: from cornea to retina
  • Difficulties in delivering therapeutical levels of medication to the eye
  • Current pathways of drug delivery to the eye
  • New drug delivery devices: contact lenses, intravitreal implants, depot...
  • What will the future bring us?
  Borja Salvador-Culla, Anterior Segment, Cornea and Refractive Surgery Consultant in Ophthalmology, Centro de Oftalmología Barraquer
- 16.20 Chair’s Closing Remarks and Close of Day One
8.30 Registration & Coffee

9.00 Co-Chairs’ Opening Remarks
Mitchell de Long, Vice President, Chemistry, Aerie Pharmaceuticals
Naj Sharif, Vice President, Global Ophthalmology, Santen Inc., USA

NEW DEVELOPMENTS IN OPHTHALMIC CLINICAL TRIALS AND DRUG DEVELOPMENT – PART I

CHAIRS’ OPENING ADDRESS SPOTLIGHT SESSION
9.10 Launch of Rocklatan in the USA
• An industry outlook of drug development and advances in the ROCK inhibitor class of drugs
• The first PG combination product approved by the FDA and the outlook for Europe approval
• Future outlook for glaucoma treatment
Mitchell de Long, Vice President, Chemistry, Aerie Pharmaceuticals

9.50 Novel Treatment Modalities for Managing Ocular Hypertension (OHT) and Glaucoma
• Compliance issues with topical ocular medications for OHT/Glaucoma treatment
• Omidenepeg Isopropyl (OMDI): novel non-prostaglandin EP2 receptor agonist for treating OHT/Glaucoma
• Use of “PRESERFLO MicroShunt” (formerly known as the InnFocus MicroShunt) to lower and control intraocular pressure in OHT/Glaucoma patients
Naj Sharif, Vice President, Global Ophthalmology, Santen Inc., USA

10.30 Morning Coffee

11.00 Nitric Oxide - A new Mechanism-of-Action for Intracocular Pressure Reduction
• The role of nitric oxide in the control of intraocular pressure
• The Nicox nitric oxide-donating research platform and approved first-generation molecule
• Development of second generation molecule - NCX 470
• The next step – future generation compounds from the Nicox platform
Gavin Spencer, Executive Vice President and Chief Business Officer, Nicox

A REGULATORY OUTLOOK

11.40 Regulatory outlook on ocular drug clinical development
• Current regulatory perspectives for clinical approval of ophthalmic drugs
• Focus on rare diseases – orphan designation, conditional approvals and exceptional circumstances
• Regulatory considerations for biologics and biosimilars
• Regulatory considerations for gene therapy agents
Peter Morgan-Warren, Medical Assessor, MHRA

12.20 Networking Lunch

ADVANCES IN GENE THERAPY

13.20 Establishing efficacy of gene therapy in preclinical ocular models
• Ocular tissue distribution of different viral vectors
• Imaging modalities to detect reporter gene expression in vivo
• Immunosuppression for gene therapy in preclinical ocular models
Giedrius Kalesnykas, President and Chief Executive Officer, Experimentica Ltd

14.00 Clinical Development of Voretigene Neparvovec-ryzl, a gene therapy for Biallelic RPE65 Mutation-associated Inherited Retinal Disease: An Update
• To understand basic characteristics of RPE65 disease
• To understand the clinical development process of voretigene neparvovec-ryzl
• To understand the development/rationale of the primary phase 3 endpoint
Daniel Chung, Global Medical Strategy Lead-Ophthalmology, Spark Therapeutics

14.40 Afternoon Tea

PANEL DISCUSSION

15.10 Gene therapy for inherited retinal diseases
• Latest trends in gene therapy for inherited Retinal Diseases
• Clinical Trial Endpoints for Inherited Retinal Diseases
• Regulatory guidance/thresholds for Clinical Trial Endpoints in Inherited Retinal Diseases
Panel Moderator: Aniz Girach, Chief Medical Officer, ProQR Therapeutics
Panelists: Daniel Chung, Global Medical Strategy Lead-Ophthalmology, Spark Therapeutics
Peter Morgan-Warren, Medical Assessor, MHRA
Virginia Calder, Reader in Ocular Immunology, UCL Institute of Ocular Immunology

15.50 A new genome-editing ocular programme
• An overview of ocular programmes targeting serious disease based on the genome editing platform
• The potential of the CRISPR/Cas9 and CRISPR/Cpf1 genome editing systems
• The challenges and current research in treating LCA10
• What is the future for genome-editing in ophthalmology?
Simon Chandler, Executive Director, Clinical Development, Allergan

16.30 Co-Chairs’ Closing Remarks and Close of Day One
OPHTHALMIC DRUGS
CONFERENCE DAY TWO | Wednesday 20th November 2019

8.30 Registration & Coffee

9.00 Co-Chairs’ Opening Remarks
Mitchell de Long, Vice President, Chemistry, Aerie Pharmaceuticals
Naj Sharif, Vice President, Global Ophthalmology, Santen Inc, USA

NEW DEVELOPMENTS IN OPHTHALMIC CLINICAL TRIALS AND DRUG DEVELOPMENT – PART II

OPENING ADDRESS
9.10 Transforming the future of eye care
• Designing the clinical trials of the future
• Providing individualized medicine
• Understand the burden of disease, tailor treatment to patients
• Delivering novel therapeutics
Parisa Zamiri, Global Head of Clinical Development in Ophthalmology, Novartis Pharmaceutical inc.

9.50 Use of experimental models to identify potential anti-inflammatory drugs in allergic conjunctivitis and uveitis
• Mouse models of conjunctival (EIC) and retinal (EAU) inflammatory disease will be described
• Monitoring conjunctival CD4+T cell subsets, conjunctival fibrosis and identification of ALDH pathways
• Effects of novel therapies on leukocyte migration, CD4+T cell subsets in EAU, and the effect of blocking H4R and LTB4.
Virginia Calder, Reader in Ocular Immunology, UCL Institute of Ocular Immunology

10.30 Morning Coffee

INNOVATIONS IN THE TREATMENT OF OCULAR RARE DISEASES

11.00 Molded Polymer Dosage Forms - Current and Future Applications in Ophthalmic Drug Delivery
• Review of resorbable and biodurable polymers for ophthalmic drug delivery –benefits and disadvantages
• Design considerations for molded and extruded ophthalmic dosage forms
• Examples of novel implants and devices for drug delivery to the eye
James Arps, Ph.D., Director, ProMed Pharma LLC

KEYNOTE ADDRESS
11.40 Thinking outside the IVT box: considerations for oral treatment in retinal drug development
• While IVT is standard of care, significant downsides remain
• Oral drugs are accepted by patients and physicians
• Review of topics to consider in developing oral drugs for retinal disease
Michael Ehrlich, Senior Clinical Program Lead - Retinopathies, Boehringer Ingelheim

12.20 Networking Lunch

13.20 Antisense Oligonucleotides for Inherited Retinal Diseases
• Antisense oligonucleotides have shown much promise in Ph1/2 Clinical Trials in LCA10
• Visual Acuity and other efficacy endpoints have improved in an interim analysis
• Overview of the data available from clinical trials
Aniz Girach, Chief Medical Officer, ProQR Therapeutics

14.00 Using AI for early detection of Diabetic Retinopathy
• Introduction to Eyenuk
• Why screen?
• Importance of detection
• How can we help?
William Dallman, Clinical Development Manager for International Operations, Eyenuk

14.40 Afternoon Tea

INTRAOCULAR MEDICINE SPOTLIGHT SESSION

15.10 Accelerating the development of intraocular medicines with the PK-Eye
• Biological therapies have revolutionized the treatment of blinding diseases during the last 2 decades
• Pharmaceutical development relies on the use of in vitro models to develop new medicines
• The PK-Eye provides a unique platform for ophthalmic drug development
• PK-Eye capabilities include accelerated preclinical dosage form characterisation and optimisation
Steve Brocchini, Academic Staff, UCL School of Pharmacy and UCL Institute of Ophthalmology

15.50 The need of an in vitro ocular model for preclinical testing of intraocular formulations
• The need for longer acting formulations
• Challenges during preclinical development-use of animal models, lack of models in the pharmacopeia and biopharmaceutical formulation challenges
• Development and capabilities of the PK-Eye with a few case studies
Sahar Awwad, CSO, Optceutics Ltd

16.30 Co-Chairs’ Closing Remarks and Close of Day Two