LIVE WEBINAR ONLY
– not available for on-demand viewing

Saturday 7 August 2021
1.30 – 2.30 pm AEST
(Session opens 1.15 pm)
Digital Medical One

INVITATION

Early Australian experience with TRIKAFTA® in CF patients: Case series and discussions

Join Australian CF physicians at the Vertex ACFC satellite symposium as they share their experience with TRIKAFTA (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in the clinical setting

This educational event is for Australian healthcare professionals only.
Registration to ACFC medical conference provides full access to symposium.

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trikafta®
(elexacaftor/tezacaftor/ivacaftor and ivacaftor)
100 mg/50 mg/75 mg and 150 mg tablets

INVITATION

With the addition of TRIKAFTA (elexacaftor/tezacaftor/ivacaftor and ivacaftor) to the CFTR modulator armamentarium come new clinical opportunities and considerations for CF care teams, patients and their families. For CF multidisciplinary teams, there is a plethora of questions to consider: *How should treatment be initiated? What can be done to appropriately manage side effects? What can CF care teams do to best manage patient expectations about commencing TRIKAFTA?*

Vertex invites you to join a panel of Australian CF physicians at an ACFC satellite symposium to learn about their clinical experience with TRIKAFTA.

Panellists will explore a series of case studies as they consider best-practice approaches to CF management and discuss the role of TRIKAFTA in various patient populations. This 1-hour session will provide plentiful opportunities for audience engagement through discussion and Q&A.

Case studies:

Case study 1: **The challenge of abnormal liver function tests following commencement of Trikafta**

Case study 2: **Successful management of skin rash with Trikafta initiation**

Case study 3: **Nutritional benefits following Trikafta therapy**

This event will be delivered virtually on the ACFC Consumer Connect platform and is available to all Australian CF healthcare professionals registered for the ACFC medical conference.

This is a live event only – it will not be available for on-demand viewing.

Date: Saturday 7 August 2021

Time:

ACT, NSW, QLD, TAS & VIC	NT & SA	WA
1.30 - 2.30 pm	1.00 - 2.00 pm	11.30 am - 12.30 pm

Session opens 15 minutes before the start of the event.

Diarise this event today!

For more information about the event, please contact:

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About the faculty

Chairperson

A/Prof Tom Kotsimbos SRN RSCN MSc PhD

A/Prof Tom Kotsimbos has successfully combined multi-disciplinary specialist training in clinical medicine (Respiratory and Infectious Disease) with a strong commitment to basic science, translational and clinical research. Following his MD Thesis [University of Melbourne/WEHI], he was awarded the prestigious Canadian Ludwig Engel Research Scholarship which enabled him to undertake post-doctoral studies at McGill University [Meakins Christie Laboratories]. Upon his return to Australia he was appointed as a full-time Staff Specialist Physician at The Alfred Hospital with primary responsibilities in Adult Cystic Fibrosis Care, Lung transplantation and General Respiratory Medicine.

He is an A/Prof at the Department of Medicine, Monash University and has over 190 international peer reviewed publications that span the clinical breadth and scientific depth of the art and science of respiratory medicine. In keeping with his clinical, scientific and public health background and interests, he remains actively engaged in all aspects related to Cystic Fibrosis pathobiology, management and care.

Case study presenter

Prof Peter Middleton MBBS (Hons), BSc (Med) (Dist), PhD (Lond), FRACP, FThorSoc

Prof Peter Middleton is the CF Centre Director at Westmead Hospital, Sydney, Leader of the CF Research group at Westmead and Clinical Professor at the University of Sydney. Over the last 25 years, he has developed a large clinic caring for people with CF and non-CF bronchiectasis and leads a diagnostic service for assessment of patients with bronchiectasis. Research interests include scientific and clinical studies of new CF therapies including the Phase III trial of Trikafta (elexacaftor/tezacaftor/ivacaftor) in people with CF with a single F508del mutation published in the New England Journal of Medicine in 2019. This landmark study has already been viewed 50,000 times online and has more than 400 citations in the literature. Since then he has written a review of the development of elexacaftor + tezacaftor + ivacaftor to treat the majority of people with CF. He is active in the Sydney PCD clinic, a multidisciplinary paediatric and adult clinic run at Concord Hospital.

Prof Middleton is a member of the Steering Committees of the Australian CF Data Registry and the Australian CF Clinical Trials Network and the Australian Bronchiectasis Registry.

Case study presenter

Prof Phil Robinson B Med Sc, MBBS, FRACP, MD, PhD

Prof Phil Robinson is the Director of the Department of Respiratory and Sleep Medicine at the Royal Children's Hospital in Melbourne. He has worked in the department for over 35 years and has a long-standing involvement in CF care. He was the units CF Centre Director for 14 years during which time he helped co-edit the first edition of the Australian Standards of Care and is actively involved in the current preparation of the second edition.

Prof Robinson runs a clinical respiratory drug trials unit which has been involved in over 20 trials of mutational specific drugs including Ivacaftor, Orkambi, Symdeko and Trikaftor. He has been a core member of the Therapeutic Goods Administration's drug evaluation committee, the Advisory Committee on Medicines (ACM) for over 20 years. He helped establish the Royal Children's Cystic Fibrosis Research Trust in 1999 and remains the Trusts' Medical Chairman.

Case study presenter

A/Prof Keith Ooi MBBS, Dip Paeds, FRACP, AGAF, PhD

Keith Chee Y. Ooi is a fully tenured A/Prof of Medicine at the Faculty of Medicine, University of New South Wales and a Consultant Paediatric Gastroenterologist at Sydney Children's Hospital Randwick, Australia. He has published >100 journal articles and has authored several authoritative and international textbook chapters in CF, paediatric gastroenterology and pancreatology. He has been awarded >AUD8 million in research funding as a chief investigator, including from the National Institutes of Health (USA) and the NHMRC (Australia; Investigator Grant 2021). His areas of clinical and research expertise are in CF gastroenterology and nutrition. His research includes gut microbiome and inflammation studies, and he currently leads the PEARL-CF study (a multicentre RCT evaluating probiotics in young children with CF) as well as his seminal study in unravelling the complex genotype phenotype correlations for CFTR related pancreatitis. He also has expertise in the field of diagnostic issues and challenges in CF, and co-authored the recent updated guidance on the management of children with CRMS/CFSPID.

PBS Information: This product is not listed on the PBS.

Please refer to the full Product Information before prescribing:
www.trikafta.com.au

Name of Product: TRIKAFTA [co pack]: 100 mg of elexacaftor, 50 mg of tezacaftor and 75 mg of ivacaftor as a fixed dose combination tablet and 150 mg of ivacaftor as a single tablet. Pack size of 84 tablets (56 elexacaftor/tezacaftor/ivacaftor tablets and 28 ivacaftor tablets). **Indication:** TRIKAFTA is indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. **Contraindication:** Hypersensitivity to the active substance or to any of the excipients. **Precautions:** Please refer to PI for complete list. Patients with severe hepatic impairment (Child-Pugh Class C) should not be treated with TRIKAFTA. Treatment of patients with moderate hepatic impairment (Child- Pugh Class B) is not recommended. For patients with moderate hepatic impairment, TRIKAFTA should only be used if there is a clear medical need and the benefits are expected to outweigh the risks. Please refer to PI for Dosage Adjustment. Assessments of transaminases (ALT and AST) are recommended for all patients prior to initiating TRIKAFTA, every 3 months during the first year of treatment, and annually thereafter. Cases of non congenital lens opacities have been reported in paediatric patients treated with ivacaftor containing regimens. Baseline and follow up ophthalmological examinations are recommended in paediatric patients initiating treatment with TRIKAFTA. **Interactions:** Please refer to PI for complete list. Elexacaftor, tezacaftor and ivacaftor are substrates of CYP3A. Concomitant use of CYP3A inducers may result in reduced exposures and thus reduced TRIKAFTA efficacy. Elexacaftor and tezacaftor exposures are expected to decrease during co administration with strong CYP3A inducers; therefore, co administration of TRIKAFTA with strong CYP3A inducers is not recommended. The dose of TRIKAFTA should be reduced when co-administered with strong CYP3A inhibitors such as itraconazole. The dose of TRIKAFTA should be reduced when co administered with moderate CYP3A inhibitors such as fluconazole. When used concomitantly with digoxin or other substrates of P-gp with a narrow therapeutic index such as ciclosporin, everolimus, sirolimus, and tacrolimus, caution and appropriate monitoring should be used. When used concomitantly with substrates of OATP1B1 or OATP1B3, caution and appropriate monitoring should be used. **Adverse Effects:** Please refer to PI for complete list. The most common adverse events with an incidence of at least 10% were infective pulmonary exacerbation, sputum increase, headache, cough, diarrhoea, upper respiratory tract infection, nasopharyngitis, oropharyngeal pain, haemoptysis and fatigue. **Dosage and administration:** The recommended dose is two tablets (each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) taken in the morning and one tablet (containing ivacaftor 150 mg) taken in the evening, approximately 12 hours apart. TRIKAFTA should be taken with fat containing food. Date of First Inclusion on ARTG: 24 March 2021. Date of most recent amendment to minimum PI: 17 March 2021.

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This satellite symposium is an educational event funded by Vertex Pharmaceuticals (Australia) Pty Ltd. Content presented during the symposium is developed by the speaker(s) and Chairperson for the meeting, with support from a medical education agency. Vertex Pharmaceuticals (Australia) has had an opportunity to review the materials for scientific accuracy and fair balance. This educational event is for Australian healthcare professionals only and is targeted at professional development. There is no charge for attending this event. All costs will be at the participants' own expense, unless agreed in writing prior to the day of the event. All attendance at Vertex Pharmaceuticals (Australia)-sponsored events is documented.

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