

EAACI CONGRESS BILASTINE

A Lifetime
Companion
for the Treatment
of Allergies



Münich
Germany
2018

Sunday, May 27th
at 5:30p.m.
Room Hall 14c

WELCOME

Dear Colleagues,

It is a great pleasure to invite you to the FAES FARMA and MENARINI group 2018 EAACI Satellite Symposium – Bilastine: A Lifetime Companion for the Treatment of Allergies.

Allergic diseases are among the most common chronic diseases in the world, ranking first in Europe, and their global prevalence continues to grow, particularly in middle- to low-income countries, including in the Asia-Pacific region. GA2LEN acknowledges that one-third of all children are now affected by an allergic disease, and approximately 50% of all Europeans experience at least one form of allergy. The impact and burden of allergy across all stages of life is significant and the requirement for new, effective and safe guideline-recommended antihistamines in paediatric, adult and elderly patients, is critical.

FAES FARMA and the MENARINI group have shown their continued commitment to the field of allergic diseases by developing and launching bilastine, the newest and most modern non-sedating H1-antihistamine. The objective of the 2018 EAACI Symposium is to share the latest clinical evidence regarding the development of the newest H1-antihistamine, bilastine, as a lifetime companion for the treatment of allergies in children, adults and the elderly.

The presentations will include individual overviews of the impact and burden of allergic disease in children, adults and the elderly, and will discuss clinical data on the safe and effective use of bilastine in children, adults and the elderly with allergic rhinitis or urticaria.

We look forward to your active participation in this informative and exciting symposium.

Yours sincerely,

Dr. Marysia Recto & Prof. Giorgio Walter Canonica
The Symposium Chairpersons

PROGRAMME

A Lifetime
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of Allergies

Chairmen:

Prof. G. Walter Canonica, Italy
Prof. M. Recto, The Philippines

17:35

"Bilastine in school-age children"

Prof. Nikkos Papadopoulos, Greece

18:00

"Bilastine in adults with allergic rhinitis"

Dr. Ralph Moesges, Germany

18:10

"Bilastine in adults with urticaria and skin disease "

Prof. Martin Church, UK

18:25

"Bilastine in seniorhood: a multi-faced antihistamine"

Dr. Erminia Ridolo, Italy

18:35

Wrap-up & Q&A session



PROF. G. WALTER CANONICA, ITALY

Professor Giorgio Walter Canonica is Professor of Respiratory Medicine at Humanitas University a Chairman of Personalized Asthma & Allergy Center-Humanitas Research Hospital, a center of excellence for research and treatment of immune system-related disease. Milano Italy.

Professor Canonica initially specialised in pulmonary diseases after having received his medical degree from the University of Genoa, he then specialised in Allergy and Clinical Immunology at Florence University.

He subsequently conducted clinical immunology and allergology research in several European universities and institutes, in addition to two years at the Medical University of South Carolina, USA. Since returning to the University of Genoa in 1995, Professor Canonica has held a number of academic positions including Director of the Speciality School of Allergy and Clinical Immunology, Director of the Speciality School of Pulmonary Diseases and Chairman of the Allergy & Respiratory Diseases Clinic.

He then moved to Humanitas University in December 2016. He is Board Member of ARIA (Allergic Rhinitis and its impact on Asthma) guidelines and GA2LEN (Global Allergy and Asthma European Network).

Professor Canonica's research interests include examination of the molecular events and interactions between immunocompetent cells, inflammatory cells and epithelial cells in allergic inflammation and airway remodelling. He is particularly involved in new strategies in the treatment of allergic disease, including biological response modifiers, such as specific immunotherapy (with a special focus on SLIT – sublingual immunotherapy).

Professor Canonica has published extensively in international journals and acts as a referee for many immunology journals. He is also Editor in Chief of Current Opinion in Allergy and Clinical Immunology. In addition, Professor Canonica is a member of a number of societies, and recently served as President of the World Allergy Organisation (WAO), 2008/09.

He is currently past President of : Interasma - Global Asthma Association and SIAAIC-Italian Society of Allergy Asthma Clinical Immunology.



PROF. M. RECTO, THE PHILIPPINES

Prof. Marysia P. Tiongco-Recto, M.D. FPPS, FPSAAI
Section of Allergy and Immunology, Department of Pediatrics. UP-PGH

Residency:

- University of the Philippines – Philippine General Hospital (UP-PGH)
- Department of Pediatrics (1996)

Fellowship:

- Section of Adult and Pediatric Allergy and Immunology
- U.P.-PGH Medical Center (1998)

Postgraduate Training:

- Section of Pediatric Allergy and Pulmonology, University of Padova Italy (2003)

Current Positions

Associate Professor and Section Head

- Section of Adult and Pediatric Allergy and Immunology
- University of the Philippines
- Philippine General Hospital

Section Head and Active Staff

- Section of Allergy and Immunology
- Department of Pediatrics
- Asian Hospital and Medical Center

Associate Active Staff

- Section of Allergy and Immunology
- Department of Pediatrics
- Makati Medical Center

Vice President and Board Member

- Philippine Society of Allergy Asthma and Immunology

Adviser

- Food Allergy Council
- Philippine Society of Allergy, Asthma and Immunology

Membership

- Fellow, Philippine Pediatric Society
- Fellow, Philippine Society of Allergy, Asthma and Immunology



PROF. NIKKOS PAPADOPOULOS, GREECE

Nikolaos (Nikos) Papadopoulos is Professor of Allergy and Paediatric Allergy at the University of Manchester, UK.

He has also the Chair of Allergy and Pediatric Allergy at the University of Athens (NKUA), Greece.

He has extensive clinical and educational experience in Paediatric Allergy, having headed for many years a unit caring for more than 7000 children with allergic diseases yearly, implementing state-of-the-art interventions and training medical students, resident pediatricians and allergists.

His research focus is the interphase between infection and allergic disease, with emphasis in asthma exacerbations and food allergy.

He is the Co-ordinator of the EU-funded project CURE. He had extensive collaborations in the context of EU Projects, such as PreDicta, GA2LEN, EUROPREVALL, iFAAM and FAST. Prof. Papadopoulos has published over 300 papers (h-index: 69), has received several international awards and is invited to speak at international scientific meetings some 30 times a year.

Moreover, he has/is serving in Boards of EAACI, GA2LEN, WAO, EFA and ARIA.

He was the 2013-2015 President of EAACI and is currently the President of the Respiratory Effectiveness Group (REG).

BILASTINE IN SCHOOL-AGE CHILDREN

As a modern pandemic, allergies place a high burden in western society. Young children receive a high proportion of this burden, taking into account that allergies most often start early in life and persist for long periods of time. The most common of all allergies is allergic rhinitis, affecting up to a third of children and young adults. A wealth of studies has supported the development of guidelines to direct management.

However, studies in children are considerably less than those in adults and certainly less than those that children deserve! Suboptimal practices, such as the use of 1st generation antihistamines, still prevail in many settings. In this regard, the European Medicine's Agency has strongly supported the development of Paediatric Investigational Plans in new medications. Bilastine is the newest 2nd generation antihistamine, with a high and specific affinity for the histamine receptor, rapid onset of action, rapid plasma clearance, very limited interaction with CYP enzymes and 95% intact excretion in faeces.

Bilastine reaches high levels of efficacy in controlling symptoms of allergic rhinitis and urticaria. In head-to-head comparisons with cetirizine in teenagers and adults with allergic rhinitis, bilastine was equally capable of reducing all nasal and ocular symptoms. However, where bilastine excelled was in relation to safety: when 2-11-year-old children were studied, treatment-related adverse events were exactly as for placebo in all age groups (2-6, 6-9, 9-11 years). Most importantly, different measures of somnolence/sedation, including daytime sleepiness and inattention, showed that bilastine does not differ from placebo.

In conclusion, bilastine, the newest 2nd generation antihistamine, is fast acting and effective, while demonstrating a very favorable safety profile in young children.



DR. RALPH MOESGES, GERMANY

University Professor Ralph Mösges, M.D. Ph.D. FAAAAI an otorhinolaryngologist and allergologist, is the chairman of the Institute of Medical Statistics, Informatics and Epidemiology at the University Hospital of the Medical Faculty of the University of Cologne, Germany. His current research fields are allergic and infectious diseases of the upper airways, epidemiology, and clinical pharmacology.

Ralph Mösges is the author and editor of ten books and has published more than 200 articles in major journals. He is in the editorial board of the journal *Rhinology* and several other journals.

He is the chairman of ISCOANA a task force of the European Rhinologic Society (ERS) and serves as a member of the guidelines committee of the German Academy of Otorhinolaryngology for the development of guidelines in rhinosinusitis and in sudden deafness. He chairs the ENT-section of the European Academy of Allergy and serves as vice-president on the board of INTERASMA, the global asthma association.

BILASTINE IN ADULTS WITH ALLERGIC RHINITIS

The nose is an organ which, although it is comparatively small in size, has a multitude of tasks. Many of these functions play an essential role in sustaining an individual's quality of life (QoL). Among these are the climatization of the inspired air in terms of temperature, humidity and absence of irritants and pathogens. The nose is also the central element of the face, in frontal view and in the silhouette. Any disturbance of the normal aspect, like swelling or reddening, may cause embarrassment.

Allergic rhinitis is the most prevalent chronic disorder of the nose. Subjects experiencing allergic rhinitis, especially when it is present in its persistent form, temporarily undergo major QoL impairment. The extent of this suffering is hard to explain to a healthy bystander.

Although a myriad of medications has been developed to treat the multiple symptoms of allergic rhinitis (e.g. sneezing, itching, watery rhinorrhea and nasal blockage), most patients still feel that their disease is uncontrolled when exposure suddenly onsets at the start of the season. Commonly, patients use more than one medication for the suppression of symptoms but surprisingly, the more medications they use, the less controlled they are. In a large-scale observational trial conducted with mobile app-based data collection, it was shown that compliance decreases whenever additional treatment modalities are prescribed. Fixed combinations, as recommended by the latest ARIA update, could be a potential strategy to overcome these limitations.

This presentation will discuss the use of bilastine in adults with allergic rhinitis. Given the limitations in safety and tolerability of some commonly-used antihistamines, bilastine could be the ideal candidate for the treatment of allergic rhinitis.



PROF. MARTIN CHURCH, UK

Martin Church is Honorary Professor of Immunopharmacology, Charité-Universitätsmedizin, Berlin, Germany and Emeritus Professor of Immunopharmacology of the School of Medicine of the University of Southampton, UK. He originally qualified in Pharmacy from the University of Wales in 1964, gained his PhD in 1970 and was awarded a DSc by the University of Southampton in 1990. He was promoted to Professor of Immunopharmacology in 1991.

Professor Church's research has focussed on the mechanisms of allergic disease and their modulation by drugs. He is the author of over 430 research papers and reviews, and has edited ten books, including the textbook "Allergy". He is a fellow of the American Academy of Allergy, Asthma and Immunology, a past secretary of the British Society for Allergy and Clinical Immunology and an honorary member of the Finnish and South African Societies of Allergy.

Honours: In 2013, Professor Church was awarded the Clemens von Pirquet Award by the European Academy of Allergy and Clinical Immunology for improving Clinical Research following which he was elevated to honorary membership of the European Academy of Allergy and Clinical Immunology. In March 2015 he was awarded an honorary Doctorate of Science by D Y Patil University, Mumbai, India.

BILASTINE IN ADULTS WITH URTICARIA AND PRURITIC SKIN DISEASES

Urticaria is a mast cell driven disease in which high local concentrations of histamine are responsible for inducing the primary symptoms of wheal, flare and itch. Consequently, the EAACI/GA2LEN/EDF/WAO urticaria guideline recommends primary treatment with an H1-antihistamine which may be up dosed to four times the initial licensed dose if required. Furthermore, the guideline also states that the goal of treatment is to treat the disease until it is gone. To achieve this objective it is clear that the ideal H1-antihistamine should be very effective in relieving symptoms, should have a rapid onset and long duration of action and should not have unwanted effects or cause drowsiness. How does bilastine meet these criteria?

In histamine-induced wheal and flare studies, bilastine has been shown to have both a rapid onset and a long duration of action. Further, 20 mg bilastine has been shown to have a similar efficacy to 10 mg cetirizine and be more effective than 10 mg rupatadine and 5 mg desloratadine. In cold-induced urticaria, 7 days treatment with 20 mg bilastine was highly effective in reducing the response. Updosing to 40 mg daily significantly enhanced the response while further up dosing to 80 mg produced a smaller increase in effect. Negligible somnolence was seen in these studies. Similar results were seen when treating moderate-to-severe chronic spontaneous urticaria patients ($UAS7 \geq 14$) who had been shown not to be responsive to standard-doses of other H1-antihistamines. Finally a study of a group of patients with pruritus-associated dermatopathies, including chronic spontaneous urticaria, eczema/dermatitis, prurigo and cutaneous pruritus, eight weeks treatment with 20 mg bilastine, which was increased at two weeks to 40 mg in poor responders, was highly effective in reducing pruritus and increasing quality of life.

In conclusion, these studies have shown bilastine to be very effective in relieving the symptoms of urticaria and other pruritic skin conditions, to have a rapid onset and long duration of action and not to cause drowsiness or have unwanted effects.



DR. ERMINIA RIDOLO, ITALY

Undergraduate

- During the period 1986-88 internship in neurophysiology in the Human Physiology Department managed by Prof. Giacomo Rizzolatti.
- From 1989 to 1991 internship in medical semiotics (Prof. Pierpaolo Dall'Aglio and Almerico Novarini)

Degree

- Parma, 1991, "The clinic determination of anti-phospholipids antibodies" (max rank)

Post-degree specialization

- Parma, 1991, Allergic and Immunologic Clinic post graduate
- 1995 post graduate degree with a thesis on "Latex allergy" (max rank)

Doctoral Degrees

- 1997, Genoa, Winner of a place in the PhD in Internal Medicine (13th cycle)
- 1997-2001. Internship in the Medical Pathology Department for a research on intra-cell signals in myeloid leukemia, aimed at PhD thesis
- 2002 Genoa, PhD with a thesis on "Reduction of the blastic proliferation in myeloid leukemia through the MAP kinase ERK inhibition".

Fellowship

- 1996-1997, Parma, Winner of a fellowship for a research on "Biologic rhythm of mites and ITS for respiratory allergy"

Current Academic Position

- From 2002, Parma, Research Fellow in Internal Medicine .
- Teacher of "Clinical Immunology", "Allergology", " Semiotics and Clinical Methodology" and numerous post graduate schools of the University of Parma, secretary of post graduate school in Allergy and Clinical Immunology.
- Researcher c/o Department of Medicine and Surgery , University of Parma , Via Gramsci 14 , Parma
- From 2017 National Academic Qualification as Associate Professor

Research Interests

- She wrote numerous articles published in domestic and international devoted to her research interest on allergy diseases.
- Published articles: 144. H index: 23.
- She participated to different clinic trials in allergy (EASY project, POLISMAIL study, RINOBIT study, ALLIANCE) according to ICH-GCP principles
- From 2006 external coworker of the research group of Prof. Canonica and Prof. Passalacqua in Genoa
- In 2008 she became member of the WAO committee "Impact of Climate Change on Allergy" (Sub-Committee: Allergen Types).
- Since may 2009 she has been managing the Parma GA2LEN (Global Allergy and Asthma European Network) Centre
- Since May 2011 member of Executive Committee of Italian Society of Allergy and Clinical Immunology

BILASTINE IN SENIORHOOD: A MULTI-FACETED ANTIHISTAMINE

Allergy conditions are thought to be “childhood disorders”, but they can persist through all stages of life; furthermore, allergic diseases can appear for the first time in seniorhood. Bilastine is a safe and effective second-generation antihistamine for the treatment of allergic rhinoconjunctivitis and urticaria; up to 10% of the global elderly population may be affected by these conditions. Ageing is characterized by general functional impairments, e.g. decreased renal and hepatic function that reduces drug clearance in the elderly. Moreover, elderly patients usually experience several chronic diseases. Therefore, polymorbidity and polypharmacy result in an increased risk of drug-drug interactions. An accurate evaluation of the efficacy and safety profiles of drugs used in elderly patients is therefore mandatory to ensure appropriate treatments. Bilastine is rapidly absorbed and selective for H1 receptors. Hence, it is not associated with the adverse effects of first-generation H1 antihistamines (e.g. sedation and antimuscarinic effects). The non-sedative effect of bilastine results from its limited penetration across the blood-brain barrier, thus reducing any negative impact on the central nervous system which, for other antihistamines, can include the synergistic effects of alcohol and benzodiazepines.

Cardiac safety is an important issue in the elderly population; bilastine has no effects on cardiac repolarization and QTc interval. Although higher bilastine concentrations, but still within safety margins, are observed in patients with renal impairment, no dose adjustments are required. A low incidence of adverse effects was reported in a recent prospective study of 146 elderly patients receiving bilastine 20 mg once daily, showing that the safety profile in patients aged ≥ 65 years does not differ from that in younger populations.

Due to these features, bilastine is the first choice for the treatment of allergic disease in the elderly.

Beyond its excellent efficacy and safety profile, bilastine improves health-related quality of life (QoL) in patients with rhinitis or chronic urticaria. From the patients' perspective, rhinoconjunctivitis and chronic urticaria have a strong impact on daily life: sleep disorders, daytime drowsiness, altered social life, and impaired occupational activities. In three clinical trials involving 2335 patients, bilastine 20 mg once daily was effective in relieving symptoms of allergic rhinoconjunctivitis, and therefore improving QoL. Similarly, the positive impact of bilastine on chronic urticaria symptoms was demonstrated in a large clinical trial using the Dermatology Life Quality Index (DLQI).

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