

ALK-Abelló sponsored evening symposium at ERS 2005

Sunday the 18th of September,
17.15 - 19.15, Room: Auditorium 12

ABSTRACTS



Tablet based immunotherapy for respiratory allergic diseases – improving treatment for grass allergic patients with or without asthma

Chairmen: *G Walter Canonica and Claus Bachert*

Sublingual immunotherapy - where are we today and where are we going
G Walter Canonica, I

Improved treatment of grass allergy
Claus Bachert, B

Systemic and local immune responses to immunotherapy
Stephen Durham, UK

Update on the clinical development of the grass allergen tablet
Erkka Valovirta, SF

Welcome to the ALK-Abelló sponsored evening symposium!

ALK-Abelló is a dedicated allergy company. For decades we have driven research and development within the allergy field with the aim of improving the efficacy and patient friendliness of immunotherapy products – and we have already come very far.

Our evening symposium at this year's ERS congress will show some of our latest steps along this path, and will reveal how we in the future together with you will be able to offer immunotherapy to an even larger group of patients suffering from allergy.

During the symposium you will be introduced to the largest ever clinical development programme performed for a single compound in the field of immunotherapy. The programme demonstrates how ALK-Abelló's grass tablet in broad allergic populations achieves a protective immune response and provides sustained symptom prevention and is safe for grass allergic patients, with or without allergic asthma.

Thus, by opening the perspective for a convenient future causal therapy, we will take a step towards initiating specific immunotherapy early in the disease process and hence improve the quality of life for the allergic patient.

We look forward to meeting you during ERS 2005.

Yours sincerely

ALK-Abelló A/S

Tablet based immunotherapy for respiratory allergic diseases – improving treatment for grass allergic patients with or without asthma

Sublingual immunotherapy – where are we today and where are we going <i>GW Canonica</i>	5
Improved treatment of grass allergy <i>C Bachert</i>	6
Systemic and local immune responses to immunotherapy <i>SR Durham</i>	7
Update on the clinical development of the grass allergen tablet <i>E Valovirta</i>	8

Sublingual immunotherapy – where are we today and where are we going

GW Canonica

Allergy & Respiratory Diseases, DIMI, University of Genova, Italy

Allergen specific immunotherapy, together with drugs and allergen avoidance, is a cornerstone in the management of respiratory allergy. To further improve safety and convenience of subcutaneous specific immunotherapy, local administration forms have been developed and investigated.

The sublingual form (SLIT) is today the only local administration form with a widespread clinical use, and the amount of clinical data produced in less than 15 years with SLIT is impressive. The clinical efficacy and safety of SLIT in asthma and rhinitis in adults and children is supported by numerous controlled clinical trials including trials showing long-term efficacy and prevention of progression of rhinitis into asthma. In addition, the efficacy of SLIT in rhinitis compared with placebo has recently been confirmed in a meta-analysis.

The safety of SLIT has been documented in clinical trials as well as post-marketing surveillance studies, and SLIT is now accepted by the World Health Organisation as a valid alternative to the subcutaneous route, also in children.

SLIT represents a significant advance in allergy treatment, and the ongoing development of sublingual tablets compared to drops might further add to the convenience of the treatment. However, more studies are needed to clarify the mechanisms of action, optimal dose and duration of treatment as well as adherence to the treatment. Also long-term data and data from prevention studies need to be confirmed.

Improved treatment of grass allergy

C Bachert

Ghent University Hospital, Ghent, Belgium

A number of treatments, such as allergen avoidance, anti-allergic drugs and specific immunotherapy (SIT), can be used to treat the inflammation and symptomatology of grass pollen allergy. Based on international guidelines, symptomatic management of grass allergy is referred to as a basic approach, involving antihistamines and topical corticosteroids, followed by SIT in more severe and persistent disease, if pharmacotherapy fails (ARIA).

Unlike symptomatic medication, SIT induces a protective immune response and treats the cause of the allergic airway disease, providing a global therapy for sustained prevention of all allergic symptoms, rather than addressing individual symptoms.

Conventionally, SIT is used relatively late in the treatment. Nevertheless, according to the ARIA group, SIT should be initiated early in the disease process to provide immediate as well as long-lasting symptomatic relief, to reduce the risk of side effects and to prevent the further development of severe disease (ARIA).

A grass allergen tablet for sublingual use is in clinical development, and the efficacy and safety of the treatment has now been confirmed. As a widely available registered treatment in the future, the grass tablet will have the potential to dramatically increase the number of patients getting access to SIT at an early stage as recommended by ARIA. As an early treatment in grass allergy, the grass tablet is suggested to be used as a baseline treatment, where symptomatic medication can be added when necessary.

Systemic and local immune responses to immunotherapy

SR Durham

Imperial College, London, United Kingdom

Specific allergen immunotherapy (SIT) is the only treatment capable of modifying the natural course of the allergic disease. Injections of high doses of allergen in alum induce changes, IL-12 production among other, in antigen presenting cells leading to a shift in the phenotype of CD4+ T-cells with an accompanying reduction in Th2 and increase in IFN-gamma production. Additionally, SIT has been accompanied by increases in IL-10 producing T-regulatory cells and possibly other subtypes of regulatory T-cells with potential to downregulate Th2 T-lymphocyte responses in an allergen specific fashion. The result of these alterations in T-cell function is a reduction in the occurrence and activation of eosinophils and basophils at mucosal site of inflammation and production of allergen specific IgG antibodies. IgG antibodies in turn enhance the effects of SIT by interfering with allergen IgE complexes having effect on both antigen presentation and mediator release from effector cells.

Only few studies have addressed the mechanisms underlying sublingual immunotherapy (SLIT), but some aspects have been consistently observed. Among these are a reduction in the number of eosinophils and a reduced level of ICAM-1 adhesion molecules in the airway and conjunctival mucosa, which in combination with a clinically observed decrease in the allergic late phase reaction indicate a reduction in mucosal inflammation. Time and dose dependent induction of allergen specific IgG antibodies has been observed in a number of studies including studies with grass allergen tablets, although the increase is not as pronounced as following injections.

The model for the mechanisms of SLIT is more fragmented than the model for mechanisms of injections, but current research targeting the effect of SLIT on T-cells and other effector cells is likely to lead to an increase in our knowledge in the near future.

Update on the clinical development of the grass allergen tablet

E Valovirta

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Specific immunotherapy with sublingual drops (SLIT) is today a widely used treatment for respiratory allergies with the aim to relieve symptoms by treating the cause of the allergic disease. SLIT is a safe and efficacious treatment, and the number of controlled clinical studies documenting the clinical benefits of SLIT is constantly growing.

A fast dissolving grass allergen tablet has now been developed. The clinical development programme for this grass allergen tablet is the largest ever conducted in the field of allergen specific immunotherapy and consists of 6 double-blind, randomised, placebo-controlled trials including more than 1,000 patients treated with grass allergen tablets.

The largest of these trials was conducted during the grass pollen season 2003. 55 centres in 8 countries included 855 adults with grass pollen induced SAR, and subjects were randomised to 2,500, 25,000, 75,000 SQ-T or placebo for sublingual administration once daily with no initial updosing phase. Rhinoconjunctivitis scores showed reductions of both symptom (16%) and medication (28%) for the 75,000 SQ-T group ($p=0.071$ and $p=0.047$). With the recommended pre-seasonal treatment of at least 8 weeks prior to the grass pollen season, the reductions improved to 21% and 29%, respectively ($p=0.002$ and $p=0.012$). Also quality of life was significantly improved, and the tablet was well tolerated with no safety concerns observed.

The clinical efficacy and safety of the 75,000 SQ-T dose has recently been confirmed in subjects with more severe SAR. 114 subjects were randomised 2:1 to grass allergen tablets or placebo and treated 12 weeks before and during the grass pollen season 2004. Rhinoconjunctivitis symptom and medication scores were reduced by 37% ($p=0.004$) and 41% ($p=0.036$), respectively compared to placebo. Also in this trial, the tablet was well tolerated.

The grass allergen tablet is an efficacious and safe treatment for grass pollen allergy, and ongoing clinical trials will further add to the documentation.

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ALK-Abelló is an international group with companies in Austria, China, Denmark, Finland, Germany, Italy, the Netherlands, Norway, Spain, Sweden, the United Kingdom and the USA. ALK-Abelló develops and distributes effective, innovative products for the diagnosis, prevention and potential cure of allergies and the relief of symptoms. The ALK-Abelló products for specific treatment of allergies and in vitro and in vivo diagnostics include Alutarq® SQ, Pangramin® UM, Pangramin® Plus UM, Soluprick® SQ, SLITone® and the ADVIA Centaur® Specific IgE system. The products carry the SQ/UM quality mark - your guarantee of high quality, characterised and standardised allergen extracts.

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Fight The Cause

STAAR Education Programme
Specialists in Allergic Asthma and Rhinitis



We are delighted to announce that the international **Specialists in Allergic Asthma and Rhinitis (STAAR) Education Programme** has been finalised.

How was the STAAR Education Programme developed?

In September 2004, a group of allergy experts from across Europe gathered to develop the STAAR Education Programme. This group included representatives from 9 European countries in order to develop a core international education programme that could be adapted to meet country-specific requirements. The advice and guidance we have received from our specialist advisers has, once again, been essential for the development of this programme.

What is the STAAR Education Programme?

The STAAR Education Programme is a programme on allergic rhinitis and asthma and the role of immunotherapy, including new developments in this field, such as the grass tablet. A slide kit comprising 4 modules has been developed to fit different speciality audiences, with different levels of knowledge of and experience with immunotherapy.

What is the STAAR Education Programme aiming to achieve?

The programme aims to raise awareness of the benefits of immunotherapy in general, in light of novel developments, to a broader group of specialists who are not yet experienced in the use of immunotherapy, but do have experience in treating patients suffering from allergy.

Are you interested in receiving further information about the STAAR Education Programme?

Would you be interested in receiving further information about the STAAR programme? If so, please contact your local ALK-Abelló representative.