



Treating Allergic Inflammation

Zafi3: Therapy Fact Sheet

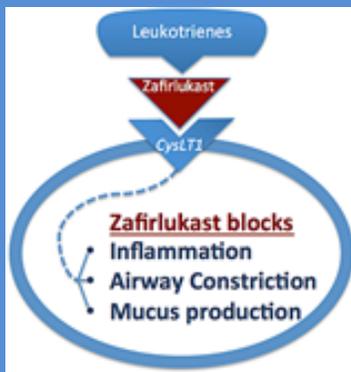
New Topical Intranasal Product for Treating Allergic Rhinitis

About Us

Accolade is a specialty biopharmaceutical company focused on developing a range of products for the treatment of atopic and allergic disorders. Our team is dedicated to re-purposing the use of a known Leukotriene Receptor Antagonist (LTRA), called Zafirlukast (sold as Accolade®). Since our founding in 2012, we have made significant progress in advancing our portfolio based on novel use of Zafirlukast for atopic and allergic disorders, including inflammatory skin and eye disorders.

LTRAs or Anti-leukotrienes

LTRAs are a unique class of non-steroidal, anti-inflammatory drugs. Originally, approved for the treatment of asthma, the anti-inflammatory effects of these drugs has significant potential for the treatment of other inflammatory conditions.



RATIONALE:

Allergic rhinitis is the most common form of atopic disease. It is an inflammation of the nasal mucosa in response to an inhaled allergen. The allergen induces the production of antibody immunoglobulin E, which binds to the mast cells, eosinophils, and basophils of the nasal mucosa and epithelium, causing the release of inflammatory mediators histamines and leukotrienes and resulting in symptoms such as itching, sneezing, nasal secretions and obstruction.

While histamines are a major mediator of allergic rhinitis, they are most strongly associated with neurally mediated responses, i.e. itching, sneezing, and nasal secretions. In contrast, the cysteinyl leukotrienes, act primarily on the vasculature of the nasal passage, and are thus more strongly associated with nasal blockage. Studies by Naciero 1991, Sedgwick 1991, Howarth 2000 and others have demonstrated that cysteinyl leukotrienes may be synthesized in the nasal cavity as both an early response to an inhaled allergen, as well as during the late inflammatory response. Furthermore, cysteinyl leukotrienes have also been shown to induce plasma protein exudation, which contributes to nasal secretions.

In summary, the scientific evidence suggests that the targeting and suppression of the

ABOUT Zafi3: Accolade is investigating a proprietary topical formulation of Zafirlukast (Zafi3) that can be administered intranasally. Target profile includes:

- Non-steroidal treatment alternative to intranasal corticosteroids
- Avoids potential concerns associated with systemic effects of steroids
- Appropriate for long term use — safer for children
- High potential for first line use in allergic rhinitis
- Profile expected to be suitable for OTC use
- Provides faster and superior relief compared to systemic antihistamines
- Longer duration of action compared to NSAIDs and corticosteroids
- Faster onset of action compared mast cell stabilizers

DEVELOPMENT & NEAR-TERM MILESTONES:

- Formulation development activities ongoing
- IND pathway confirmed with FDA
- Supporting non-clinical studies targeted for completion in 2015
- Projected time-to-approval less than 4 years

PARTNERING OPPORTUNITIES: Accolade is seeking licensing and co-development arrangements for Zafi3 for both Rx and OTC use.