THE KAS INHALER

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1. Background Information

Asthma is a chronic, inflammatory disease of the airways that is characterized by a variety of respiratory issues including shortness of breath, chest tightness and excessive coughing. (National Heart, Lung and Blood Institute, *Asthma* 2020). It is caused due to an excessive amount of T helper cell type 2 (Th2) response and the narrowing of the bronchial tubes, which results in patients having a lower rate of airflow. Treatment for diagnosed patients is still quite limited, focusing primarily on relieving daily symptoms and preventing flare-ups. This includes medicated inhalers and corticosteroid inhalation therapy. Untreated asthma can permanently alter the shape of the airways, as the bronchial tube tissue thickens and scars, and the muscles become permanently enlarged. Patients may develop severely reduced lung functionality, which can lead to death or further complications.

2. Proposed Solution

The proposed solution to treat asthma long-term and help alleviate daily symptoms is inhaled stem-cell therapy to recover the damaged tissue within the bronchial tubes of asthmatic patients. The prototype aims to repair damaged tissue within the bronchial tubes as well as correct severe skin damage. Inhaled stem cell therapy also aids in the relief of long-term inflammation of the bronchial tubes and airways. As this is developed and researched further, it will provide a great deal of assistance in the long run, and hopefully prevent acute asthma cases from becoming severe. Present treatment based on inhalation of synthetic glucocorticoids cannot change the immune tolerance of the body to external allergens, as it only controls Th2-driven chronic eosinophilic inflammation. (Zhao & Wang, 2018) This means patients currently undergoing inhaled corticosteroid therapy are unable to overcome asthmatic

flare-ups caused by external allergens and often suffer from damaged bronchial tubes due to the severe inflammation found in the airways.

3. Treatment Process

The treatment begins with the patient inhaling an aqueous solution of Regulatory T Cells. Tregs are potent immunosuppressive cells that are a crucial element of maintaining homeostatic balance during dysregulated immune responses, which is a critical aspect of asthma-related lung inflammation. They play a great role in regulating allergic, autoimmune, graft-versus-host responses, among many others. Tolerance in the lung to inhaled antigens is regulated by Treg cells that can inhibit effector T cells to reduce allergenic flare-ups. Once the cells are introduced into the patient's body, they circulate through the bloodstream until they are drawn to proteins secreted around inflamed or damaged tissue - in this case, damaged bronchial tissue caused by asthma. The cells then rush to the damaged site and start secreting various growth factors including "chemokines", which aid in cell migration, and "adhesion molecules", which regulate cell interactions at the molecular level. This treatment can make use of both autologous and allogeneic stem cells. Along with the series of Treg cells inhaled through the curated inhaler, Vascular Smooth Muscle Cells (SMCs) will be inhaled using the same technique. These cells develop from a variety of progenitor cells. Smooth Muscle contributes to bronchial inflammation by secreting a variety of inflammatory mediators, as well as recruiting and activating inflammatory cells like mast cells or T-lymphocytes. Furthermore, because bronchial smooth muscle mass is significantly increased in asthma, using an inhaler with SMCs will aid in the repair of damaged bronchial tissue in asthmatic patients. The use of various types of stem-cell inhalers will allow asthamtic patients to receive a treatment tailored to their specific lung concerns. Finally, Trachea Basal Cells are the last stem-cell component of the developed stem-cell inhaler prototype. Their main role is within epithelial homeostasis, and these stem cells contribute to disease susceptibility, initiation and progression. Basal cells respond to injury of the

airway and subsequently differentiate to restore a healthy epithelial cell layer. The implementation of these various stem-cell types

4. Prototype Overview

The proposed prototype for stem cell inhalation therapy is an inhaler with a prescribed dose of stem cells that are stored in the canister of the inhaler. There are two types of inhalers, according to a Compound Interest article: relievers and preventers. Relievers are inhalers that contain albuterol, a substance that provides temporary relief during an asthma attack. Preventers, on the other hand, are inhalers that contain a steroid called Budesonide also known as Pulmicort, which is responsible for opening airways and reducing inflammation, providing long-term relief. (Interest et al., 2017). Based on the research developed, the proposed prototype will be designed as a '*preventer'* with the goal of providing long-term relief to patients through consistent, regular use. This inhaler is distinct from others in that it incorporates the use of a variety of stem cells to repair damaged tissue, open the airways and maintain the overall health of the respiratory system.

5. Functionality

The KAS Inhaler, the prototype, is intended to function similarly to a standard inhaler, however, contains our newly developed stem-cell therapy. *The KAS Inhaler's* conceptual design is based on existing soft mist inhalers. *The KAS Inhaler* is different from others because it contains stem cells as a form of medication. Soft Mist Inhalers are a form of inhaler that releases a mist of the medication that has been stored. In order to use this kind of inhaler one needs to follow this procedure; First, the patient holds the inhaler in an upright position. The individual then places the inhaler around their lips, allowing the

medication to enter the airways. Finally, the patient takes a deep breath and inhales the prescribed stem cells.

6. **Cost**

In general, stem cell therapy costs from a range of $5000 to $50,000. The estimated cost for the research and approval of stem cell inhalation therapy is $31,000,000. Currently, the average prescribed inhaler costs between $300 to $400 per dose according to Groen(2021). Taking all costs into account, we estimate that our proposed stem cell inhaler would cost around $500, depending on the dose amount, availability, taxes and other economic factors.

7. **Accessibility**

Stem cell inhalation therapy is a highly accessible treatment option for asthmatic patients. Unlike other treatments, patients can obtain the inhalers as prescribed by their primary health care worker. Furthermore, It serves as a long-term treatment, which reduces the risk of having flare-ups and the need to purchase prescription medication on a regular basis. The costs drawn from research on stem-cell therapy will allow for the procedure of implementing these cells into the patient's body to run smoothly and avoid any further complications. Patients are able to use this treatment with little to no issues of functionality, as the product is easy to maneuver and remains simplistic.

8. **Efficiency**

This prototype will be efficient in that it will eliminate the costs associated with using an inhaler on a continuous basis. With this prototype, healthcare professionals save the time they would have spent monitoring asthmatic patients following an asthmatic attack. Furthermore, the benefits of using The *KAS Inhaler* contribute to a significant decrease in the number of procedures and checkups needed to maintain the patient's overall health. Likewise, the *KAS Inhaler* will make it easier for people to get this treatment.

While the device may be slightly pricey, it is important to note that this treatment option would be less expensive than other stem cell therapies, which can cost thousands of dollars. It also makes a difference when asthmatic patients have a device that can assist them in ways that no other form of stem cell therapy can.

9. Conclusion

The development of a multi-stem cell inhaler for the treatment of bronchial tube damage caused by asthma is an effective treatment procedure which allows patients to have curated stem cells to efficiently repair damaged bronchial tissue due to the severity of asthma. Furthermore, the implementation of inhalation of these essential cells allows for a non-invasive, and diverse approach to curing tissue damage and reducing the frequency of asthmatic flare-ups.

10. Action Plan

Before this product enters the market, extensive research would have to be developed on the efficacy of each stem-cell type outlined in the solution. Before patients are able to use this product, a clinical trial would be conducted with a wide demographic of asthmatic patients. Upon completing the clinical trial, FDA approval is crucial in allowing patients to get prescribed this stem-cell inhalation treatment. Furthermore, after FDA approval, production would start by specialists and researchers who are highly experienced in biomedical engineering. Once this product completes all the phases above, physicians will be informed and can legally prescribe this prototype to clients with suitable concerns and asthmatic conditions.

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