

Edison Explains



Allergy immunotherapy

Can allergy immunotherapy cure chronic allergies?



How large is the market for allergy immunotherapy?

The World Health Organization reports that 300 million people suffer from asthma attacks and about 200 million to 250 million from food allergies worldwide.

Allergy immunotherapy (AIT) retains a small segment of this market, with around 4.7 million patients receiving AIT therapy as of 2017, accounting for \$1.2bn in sales.

This figure has potential for growth, as around 50 million people are eligible for current-generation treatment, not including those suitable for treatments still in clinical trial.

What is AIT?

Nearly all allergens share the same mechanism for generating an allergic reaction. Exposure to an allergen triggers the production of anti-allergen antibodies such as immunoglobulin.

These antibodies release chemicals, commonly in the form of histamine, inflaming the surrounding tissue and prompting an allergic reaction.

Most anti-allergy treatments, like antihistamines, work on inflammatory chemicals but not the antibodies that produce them.

Instead, AIT hopes to address the root cause of the disease. It offers long-term relief by desensitising the patient to allergies by administering a low dose of allergen, then escalating the dose over an extended period (two to five years) to accustom the body to the foreign substance.

Is the prevalence of allergies growing?

Developed countries and dense urban environments tend to produce populations susceptible to allergies.

The World Health Journal traced this trend to environmental factors such as pollution and tobacco smoke in urban areas. This hypothesis is supported by a slight

reduction in western allergy prevalence as new pollution standards start to take effect. At the same time, Asian allergy rates have grown with rising pollution levels.

On the other hand, it is often argued that urban predisposition towards allergens is a product of reduced biodiversity, as young children fail to develop a tolerance to common allergens early in life due to an overly sanitised environment.

A factor some point to as the cause a high rates of autoimmune disease in the western world, alongside a high rate of allergy.

What types of AIT are available?

Established AIT technology takes the form of subcutaneous immunotherapy (SCIT) or sublingual immunotherapy (SLIT).

SCIT works through repeated injections over a long period of time: typically, an initial course of two injections twice a week for up to six months (escalation phase) and then monthly injections for three to five years.

The typical SLIT treatment requires additional doses with daily dosing for at least six months and up to three to five years.

SLIT is often less effective and struggles to provide lifelong immunity, but reduces the chance of a secondary allergic reaction from injections and requires less medical oversight.

Edison's insight:

“Allergies are very common in western markets. Grass pollen allergy results in significant discomfort during the season but almost no deaths.

Others, like peanut allergy, can be fatal.

What links the two is the length and efficacy of the current standard of care. AIT has the promise of having good efficacy in a few doses.”

Andy Smith, Healthcare Analyst

How is AIT affected by regulation?

Historically AIT has suffered from a lack of oversight, resulting in some scepticism about the safety and efficacy of the drugs.

This is especially true in the UK, where many insurers do not reimburse the use of AITs.

In Germany, regulations are more forthcoming as progressive regulatory efforts are made to require fully documented applications for AIT products.

Even so, some products are still being sold as approved, but not commercially

available drugs (NPPs), which must be shipped from overseas at a clinician's request.

However, Germany, along with other European countries, is moving away from NPPs, as regulations begin to tighten over AIT use.

Where are the largest AIT markets?

AIT often struggles with cost efficiency, meaning the largest markets are in Europe and the US where healthcare budgets are consistently high.

In 2017 Allergy Therapeutics estimated the US market was worth \$2bn in potential peak allergy treatment, while Market Research Future predicts a compound annual growth rate of 10.85% until 2023.

In Europe, Germany and France comprise two-thirds of the market, with SCIT therapies accounting for 55% of European sales. Spain and Italy lag behind, with 10% of the European market each.

Which companies are developing immunotherapies?

ALK-Abello, and Stallergene are the world's largest AIT suppliers.

Stallergene's Staloral product for allergic asthma reported 2017 sales of €125.5m on top of its sales of SCIT products worth €70.4m.

ALK-Abello had the rights for its allergic tablet treatment returned in 2017 after weak sales numbers led Merck to pull its partnership in North America.

In the clinical space, the most advanced firms are Allergy Therapeutics and ASIT. Allergy Therapeutics recently announced Phase II trials for G205, potentially followed by a Phase III programme for registration in the US and Europe.

ASIT is soon starting its second Phase III trial aimed at registration of their therapy in Germany. If successful, Germany could act as a reference member state for a marketing authorisation application in other EU countries.