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Allergopharma – Dr. med. Christoph Willers, CEO

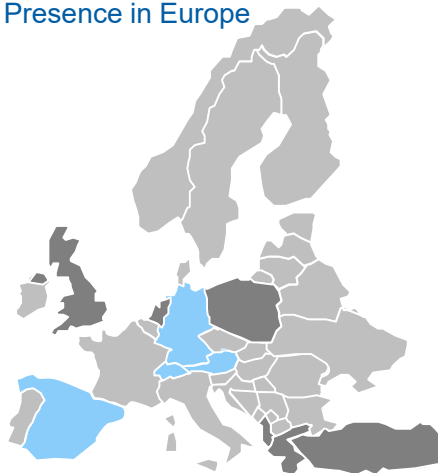


## 2.1 Allergopharma at a glance

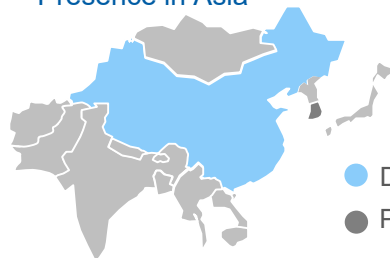
# Allergopharma is a global player with main focus on German market



Presence in Europe



Presence in Asia



- Direct presence
- Partners

Headquarter in Reinbek



# Allergopharma's R&D engagement

Striving new pathways with scientific passion

20%

R&D Investment  
2021

463

Registrations &  
Import licenses in  
9 countries  
2022

42

Clinical trials  
2000-2022

146

Publications  
2000-2022

354

Abstracts  
2000-2022





## 2.2 Products

# Allergopharma's portfolio for diagnostics and AIT<sup>1</sup> including SCIT<sup>2</sup>, skin prick test solutions and provocation test solutions



Allergovit®

42 registered preparations  
in Germany



Acaroid®

6 preparations (TAO<sup>3</sup>)



Novo-Helisen® Depot

9 registered house dust mite preparations and  
preparations for rare allergens in Germany

**SKIN PRICK**  
Test Solution

100 registered preparations  
on the German market



**PROVOCATION**  
Test Solution

50 registered preparations  
on the German market



1 AIT = Allergen Immunotherapy  
2 SCIT = Subcutaneous Immunotherapy  
3 TAO = Therapy Allergen Ordinance



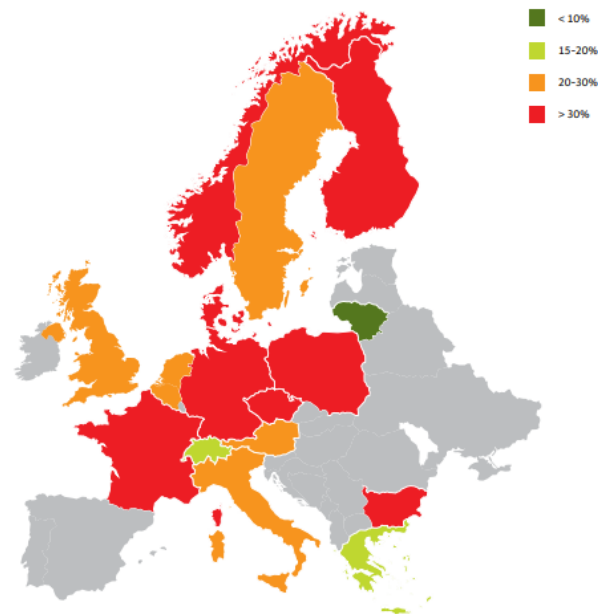
## 2.3 Market environment

# Allergy

## a global burden

- Globally, ca. 20-30% of people suffer from allergy<sup>1</sup>
- The prevalence in industrial countries is increasing<sup>1,2</sup>  
In 2050, up to 4bn people might be affected by allergies<sup>3</sup>
- Allergic rhinitis affects ~500m people globally
- ~200m patients with allergic rhinitis also suffer from asthma
- >80% of asthmatic patients also suffer from rhinitis symptoms<sup>2</sup>
- In Europe, up to 25% of people suffer from allergic rhinitis and 5-12% from asthma<sup>4</sup>
- Up to 90% of these persons are untreated or insufficiently treated
- For the EU, avoidable indirect costs range between €55bn - €151bn per annum due to absenteeism and presenteeism<sup>5</sup>

The prevalence of allergies (not only respiratory allergies) in the countries surveyed<sup>4</sup>



1 Pawankar R, et al., . WAO White Book on Allergy: World Allergy Organization, 2011.

2 Bousquet J, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen), 2008.

3 Akdis CA, Agache A, editors. Global Atlas of Allergy: European Academy of Allergy and Clinical Immunology; 2014.

4 Valovirta e, editor. EFA Book on Respiratory Allergies. Raise awareness, relieve in burden: European Federation of Allergy and Airways Diseases Patients Association (EFA), 2012.

5 Zuberbier, T et al., Economic burden of inadequate management of allergic diseases in the European Union. A GA(2) LEN review. In: Allergy 2014; 69 (10), p. 1275–1279.



# Allergy

the second most chronic disease in Europe

Type of disease	Number of Europeans affected
Hypertension	<ul style="list-style-type: none"><li>▪ &gt;150m (2015)</li></ul>
Allergy	<ul style="list-style-type: none"><li>▪ 100m with allergic rhinitis</li><li>▪ 70m with asthma</li><li>▪ 17m with food allergy</li></ul>
Mental health problems	<ul style="list-style-type: none"><li>▪ 83m</li></ul>
Chronic kidney disease	<ul style="list-style-type: none"><li>▪ 70m with at least some kidney dysfunction</li></ul>
Diabetes	<ul style="list-style-type: none"><li>▪ 58m with diabetes</li><li>▪ 36m are at risk for diabetes</li></ul>
Cardiovascular disease	<ul style="list-style-type: none"><li>▪ 49m (2017)</li></ul>
Respiratory diseases	<ul style="list-style-type: none"><li>▪ 36.6m with COPD (2020)<sup>1</sup></li><li>▪ 600,000 deaths/year (smoke, lung cancer, COPD)</li></ul>
Chronic liver disease	<ul style="list-style-type: none"><li>▪ 29m with chronic liver conditions</li><li>▪ 47,000 deaths/year</li></ul>
Chronic digestive disease	<ul style="list-style-type: none"><li>▪ 3m affected by inflammatory bowel disease</li></ul>
Cancer	<ul style="list-style-type: none"><li>▪ 2.7m diagnosed with cancer<sup>2</sup> (2020)</li><li>▪ 1.3m deaths (2020)<sup>2</sup></li></ul>

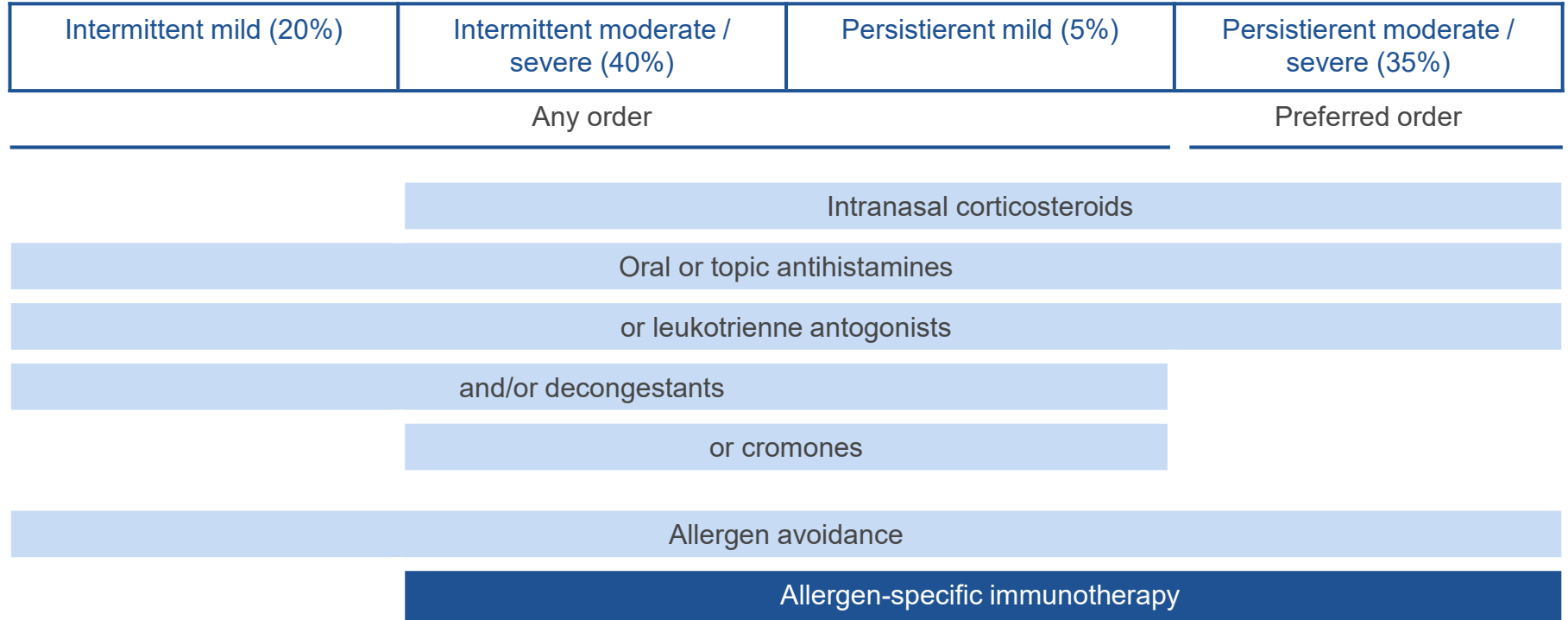


# Symptom-based treatment of allergic rhinitis

Immunotherapy works on all allergic symptoms

Treatment	Symptoms			
	Ocular	Nasopharyngeal itching	Sneezing	Rhinorrhea
Intranasal Corticosteroids	✓	✓	✓	✓
Oral and intranasal antihistamines		✓	✓	✓
Combination intranasal corticosteroid and antihistamine	✓	✓	✓	✓
Oral and intranasal decongestants				✓
Intranasal cromolyn		✓	✓	✓
Intranasal anticholinergics				✓
Leukotriene receptor antagonists	✓		✓	✓
Immunotherapy	✓	✓	✓	✓

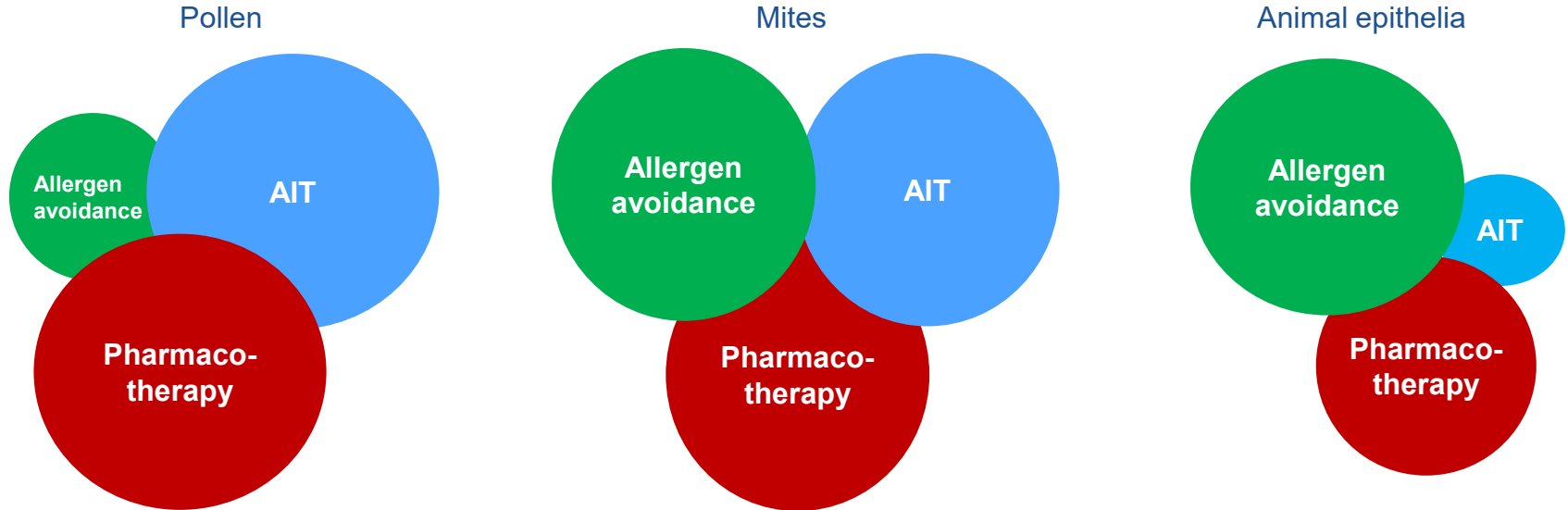
# Treatment scheme of allergic rhinoconjunctivitis



Sublingual allergen immune therapy SLIT

Subcutaneous allergen immune therapy SCIT

Anti-symptomatic treatment

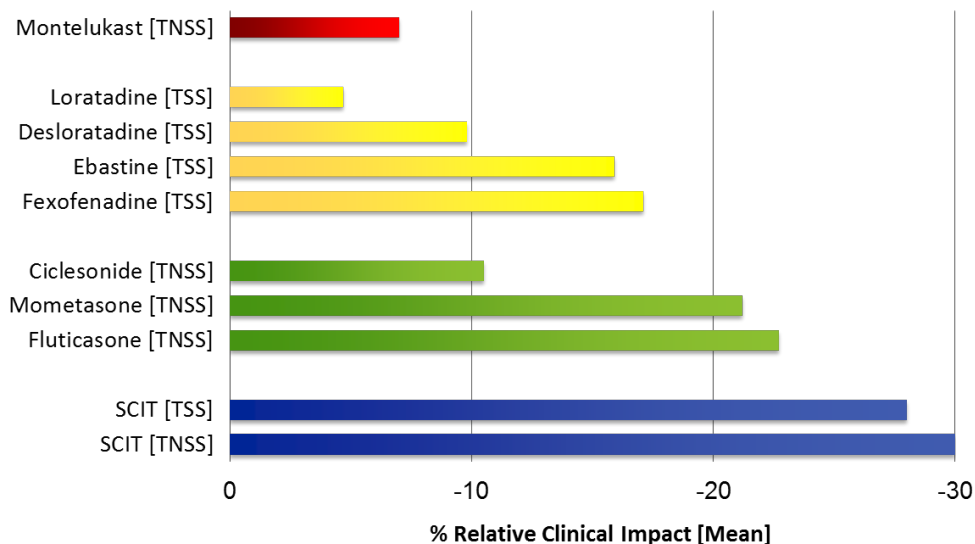


# SCIT in allergic rhinitis

## stronger than antisymptomatics

### Immunomodulation – long-term efficacy

Antisymptomatic effect on total rhinitis symptom score (TSS) and total nasal symptom score (TNSS) of leukotriene antagonists, antihistamines, corticosteroids and subcutaneous immunotherapy (SCIT)<sup>1</sup>



### Additional benefits of AIT in type 1 allergies<sup>2</sup>:

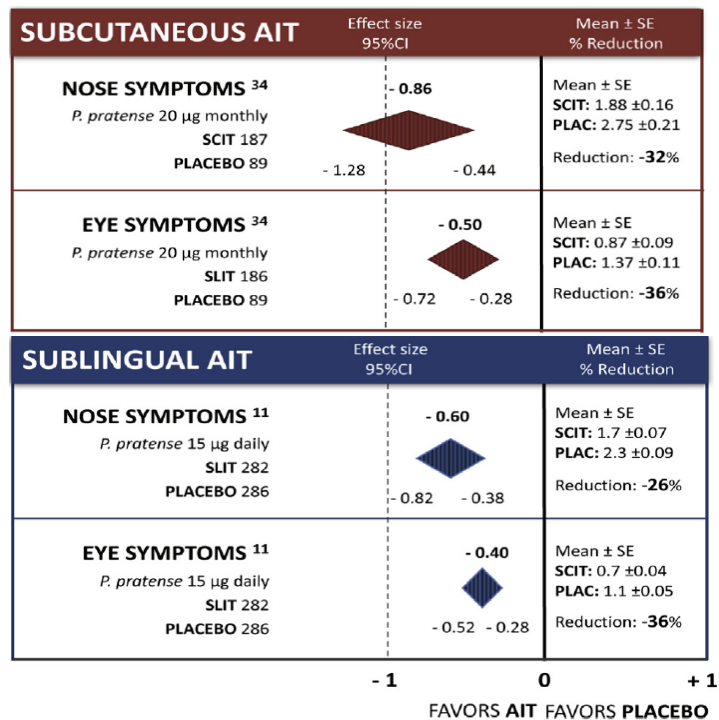
- Reduction of asthma symptoms
- Reduction of antisymptomatic rhinitis and asthma medication
- Prevention of new sensitizations
- Prevention of onset of asthma / prevention of time to onset of asthma
- Increasing efficacy during treatment duration (3 years)
- Long-term efficacy after stop of treatment (disease modification)

<sup>1</sup> mod. acc. to Matricardi PM et al., JACI 2011;128:791-9.

<sup>2</sup> Pfaar O, et al. Guideline on allergen immunotherapy in IgE-mediated allergic diseases. Allergol Select. 2022; 6: 167-232.

# Efficacy of SCIT<sup>1</sup> and SLIT<sup>2</sup> AIT<sup>3</sup> proven

## Both effective – higher effect size on symptoms in SCIT



Efficacy on rhinoconjunctivitis symptoms:

Comparison of two well powered studies of grass pollen AIT of the same manufacturer (similar study design, similar methodology, similar patients)

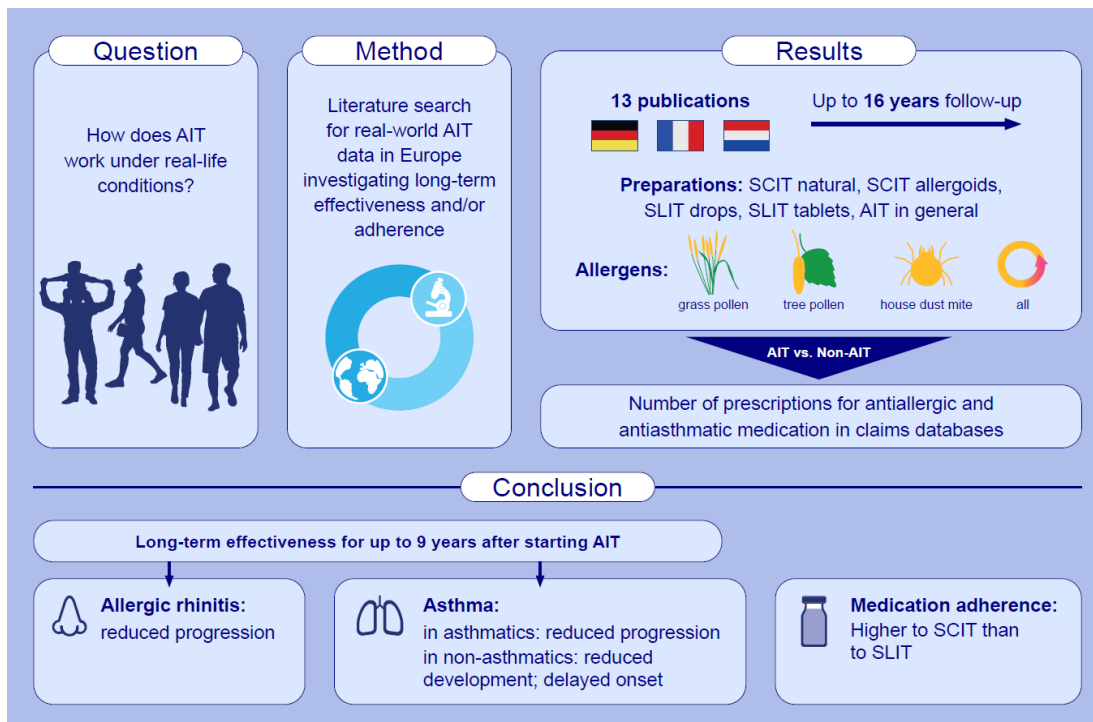
<sup>1</sup> SCIT = Subcutaneous Immunotherapy, Source: Frew AJ, et al. J Allergy Clin Immunol 2006;117:319-25.

<sup>2</sup> SLIT = Sublingual Immunotherapy, Source: Dahl R, et al. J Allergy Clin Immunol 2006;118:434-40.

<sup>3</sup> AIT = Allergen Immunotherapy  
Source: Durham, S. R. and M. Penagos, Journal of Allergy & Clinical Immunology 137.2 (2016): 339-49.

# Allergen Immunotherapy (AIT)

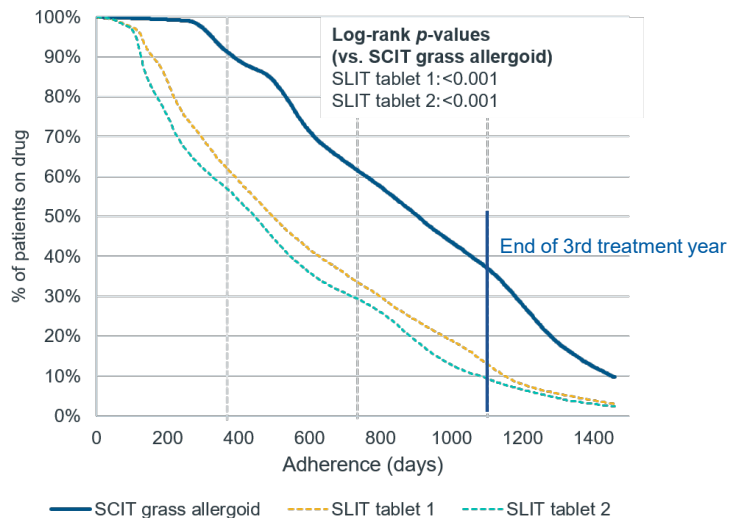
## Real world evidence data prove long-term effectiveness



- Comprehensive overview on methodology, long-term effectiveness outcomes and adherence to AIT derived from 13 retrospective cohort assessments of European prescription databases.
- Compared to Non-AIT control groups, AIT proved long-term effects in allergic rhinitis, while the development and progression of asthma was hampered for most endpoints.
- Medication adherence was mostly higher to SCIT than to SLIT treatment

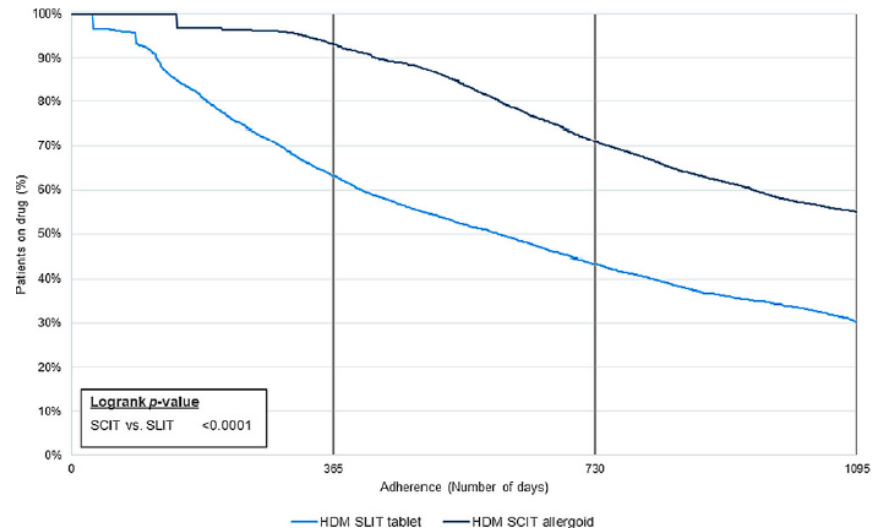
# Data from real world evidence studies

## Different adherence rates in SCIT and SLIT



Grass pollen treatment - 3rd treatment year finished by

SCIT-Allergoid:	37.5% (n= 16,774)
SLIT-Tablet 1:	13.4% (n= 11,705)
SLIT-Tablet 2:	9.6% (n= 17,478)

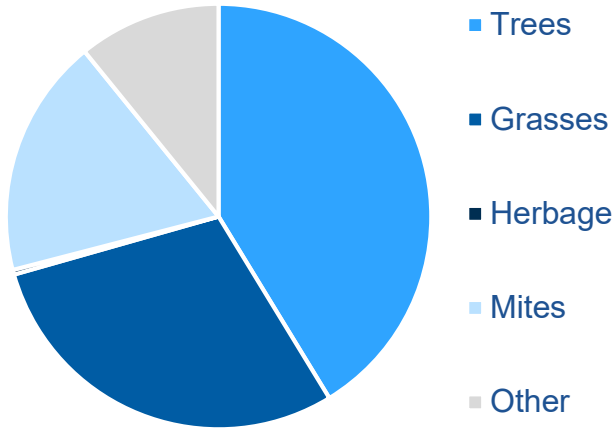


Adherence in patients receiving HDM-SCIT with an allergoid (n= 5677) or SLIT with a tablet (n= 4720)



# Current German AIT market

Allergens: tree and grass pollen and house dust mites are mainly prescribed



Total market turnover: €387m, thereof

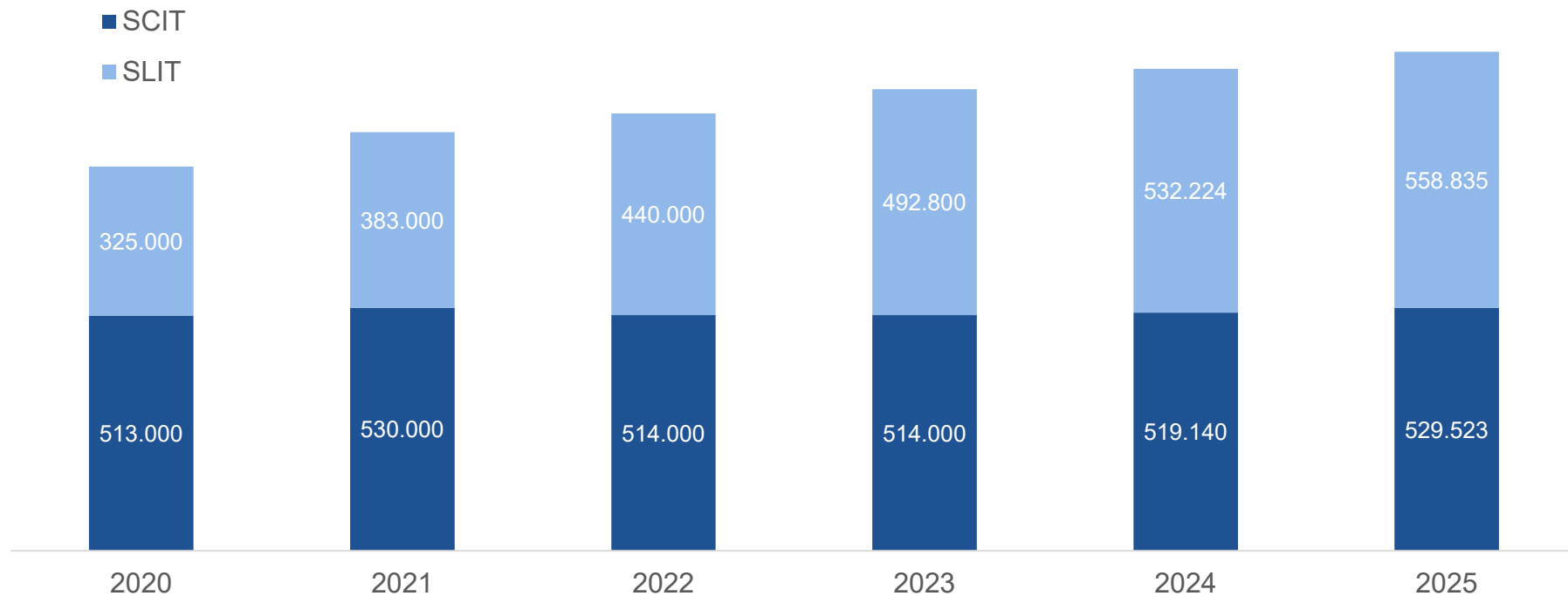
- Subcutaneous immunotherapy (SCIT): €261m
- Sublingual immunotherapy (SLIT): €126m

Estimated number of patients<sup>1</sup>:

- ~640,000 patients in total market, thereof
  - 71% tree, grass and herbage pollen (ca. n=340,000 SCIT; n=120,000 SLIT)
  - 18% house dust mites (ca. n=81,000 SCIT; n=35,000 SLIT)
  - 11% others

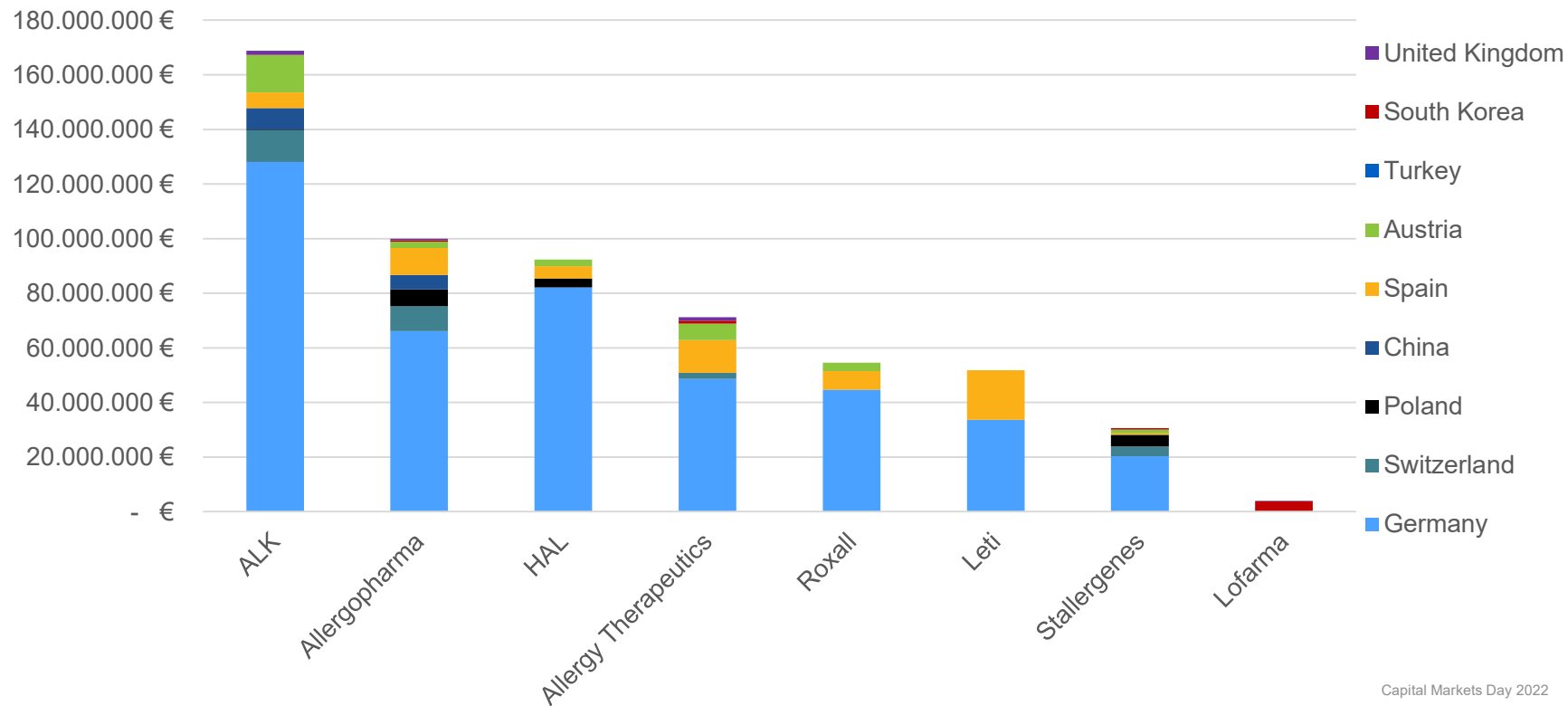
# Development of German AIT market

## Prognosis on units



# Allergopharma is in its markets in second place (2021)

Germany is Allergopharma's biggest market



## Trend towards „convenient“ treatments

- Only one vial  
Allergovit®: Novi Helisen® Depot Mites
- Time saving up dosing (3-6 injections)
- safe

## Trend towards registered AIT products

- payer
- scientific opinion leaders
- allergists' societies
- recent AIT guidelines

## Stagnant SCIT market during covid pandemic

- Less personnel
- Less time (vaccination campaigns)
- Interruption of ongoing therapies

## Treatments with unauthorised preparations

will

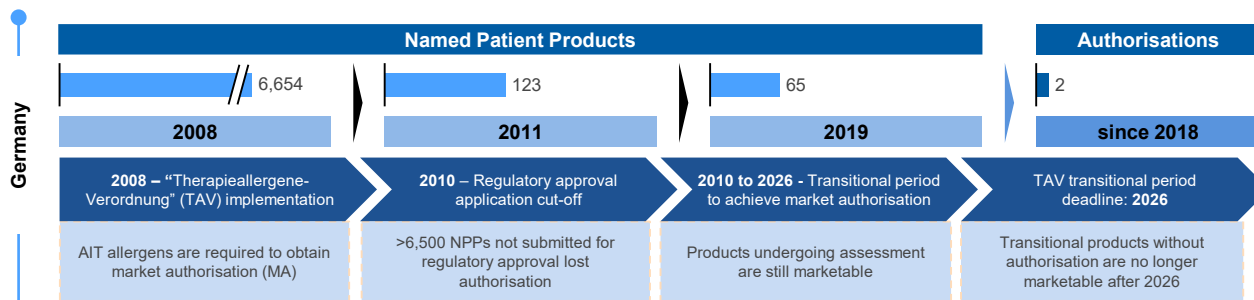
- not be continued (appr. 15%)
- be switched to registered preparations



# Regulatory changes

Changed regulation has led to reduction of many competing products that were unable to demonstrate efficacy

## TAO introduction in Germany: 98% reduction in marketable AITs



## Impact

International allergen regulations reflect a clear shift towards products with proven quality, safety and efficacy

### Opportunities:

- Allergopharma's products have existing market authorisations and Acaroid is currently the only product of Allergopharma being developed and prepared for the TAV process
- Despite varying market authorisation processes across different countries, the obtained TAV data and experiences will provide a valuable support for potential re-admission processes in other core markets

Other Allergopharma markets	Switzerland	China	Spain	Other EU countries
<ul style="list-style-type: none"> <li>Preparations intended for AIT are considered as products requiring marketing approval</li> <li>In 2010, introduction of a simplified authorisation procedure</li> </ul> <p>⇒ Authorisations are more likely for products with existing literature and previous approval in a country with comparable authorisation standards (e.g. Germany), such as Allergopharma's products</p>	<ul style="list-style-type: none"> <li>AIT products treated as biologic medicines require CFDA approval/ import license for commercialisation</li> <li>A tendency for stricter regulations in overall approval process and GMP-compliant manufacturing</li> </ul> <p>⇒ The regulatory environment raises significant entry barriers and offers competitive advantage to existing players with CFDA approval (e.g. Allergopharma)</p>	<ul style="list-style-type: none"> <li>Draft proposal to regulate allergen products pending (timing unknown)</li> <li>Full dossier expected to be required for authorisation of <i>in vivo</i> diagnostics and AIT</li> </ul> <p>⇒ Authorisation process will likely force most NPPs out of the market and create a demand vacuum for clinically-validated products such as those from Allergopharma</p>	<ul style="list-style-type: none"> <li>In the EU (e.g. Austria/Poland), assessment of marketing authorisations is conducted by national competent authorities</li> <li>Simplified procedure allows countries with existing authorisation to act as Reference Member States (RMS) to countries seeking authorisation</li> </ul> <p>⇒ Allergopharma's products can be authorised based on previous approval in another RMS</p>	

# Overview of products

Allergopharma offers innovative SCIT solutions including 3rd generation allergoid products and diagnostics solutions

## Summary of key portfolio assets

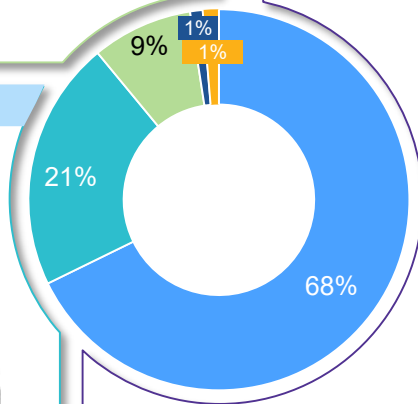
### 3 NHD and Diagnostics

- NHD: 2<sup>nd</sup> generation SCIT with 6 allergens and 15 SKUs
- Diagnostics: Skin prick and provocation test solutions



### 2 Acaroid

- 3rd generation SCIT allergen to foster immunomodulation against house dust mites
- The portfolio comprises 2 allergens and 6 SKUs



### Allergovit 1



- 3rd generation SCIT to foster immunomodulation against pollen
- The portfolio comprises 11 allergens and 38 SKUs

# Allergovit

is a recognised and clinically approved 3rd generation SCIT pollen allergoid

## Description

- Launched in 1985, Allergovit is a fully approved 3rd generation SCIT allergen for immunotherapy and hyposensitisation
- The product consists of depot allergoids absorbed to aluminium hydroxide
- Superior proprietary allergoidisation process
- Used to treat allergic Immunoglobulin E ("IgE") rhinitis and bronchial asthma
- The product is approved for children from 5 years onwards and adults

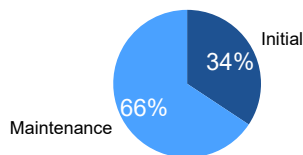
## SKU split



594 SKUs  
(pre APO)



38 SKUs  
(post APO)



## Studies & reimbursement



11  
clinical studies



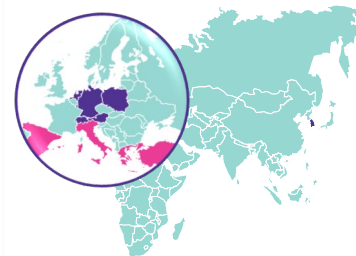
Fully reimbursed



Partially reimbursed



## Regulatory status



- Market authorisation
- Named patient products

## Treatment scheme

Duration: 3 years

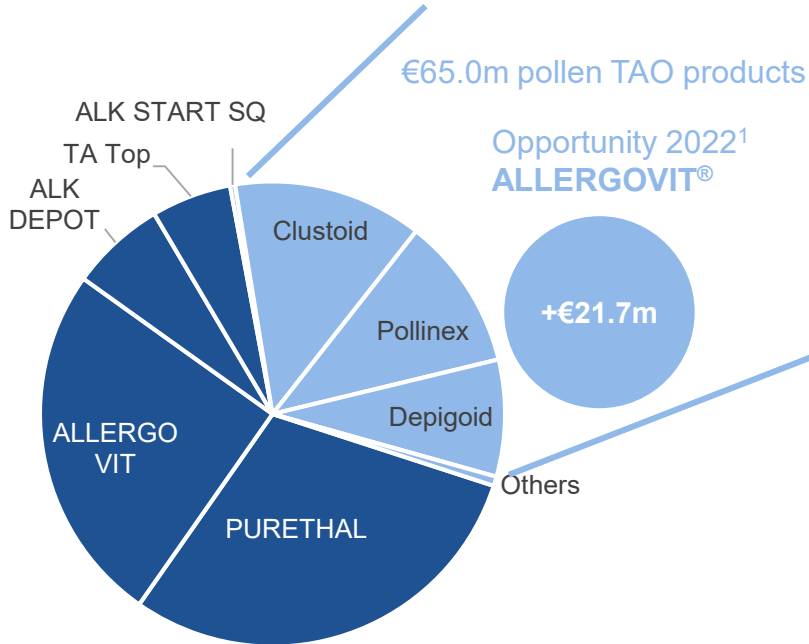
Causal therapy with **long-term effectiveness**

Scheme:

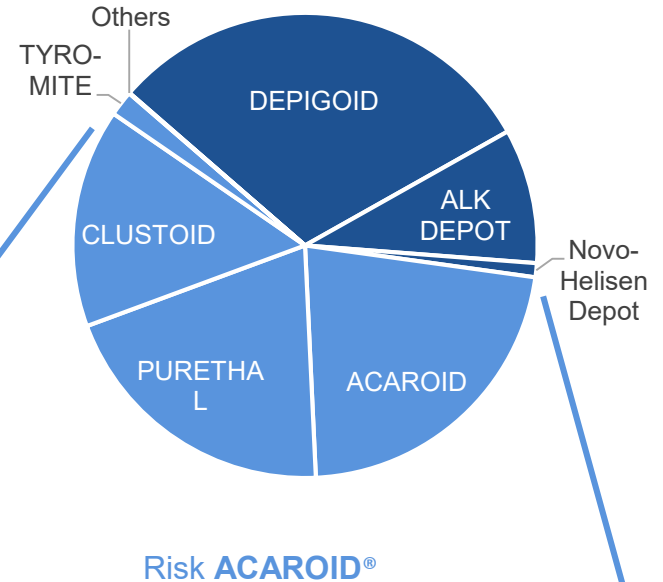
- 4 initial/ 34 maintenance (over 3 years)  
*(fast up dosing for adults for birch and grasses)*
- 7 initial/ 34 maintenance (over 3 years)  
*(standard up dosing for all other patients)*

# Opportunity for Allergopharma's registered products

€134.5m registered SCIT pollen market



€20.9m registered SCIT mite market







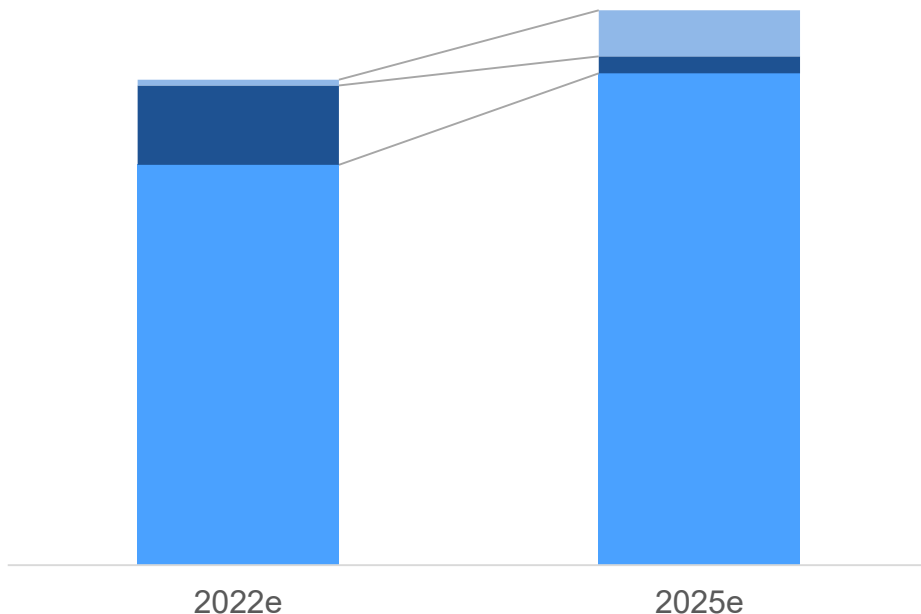
## 2.4 Financials

# Revenues in Germany

with expected revenue increase

Revenue  
€m

■ Allergovit® ■ Acaroid® ■ Novo-Helisen® Depot



Despite stagnant market development in the SCIT segment, Allergopharma will constantly grow – why?

- Payer stakeholders (sickness funds, National Association of Statutory Health Insurance Physicians) set focus on registered AIT products
- Scientific experts, scientific allergists societies set focus on registered AIT products

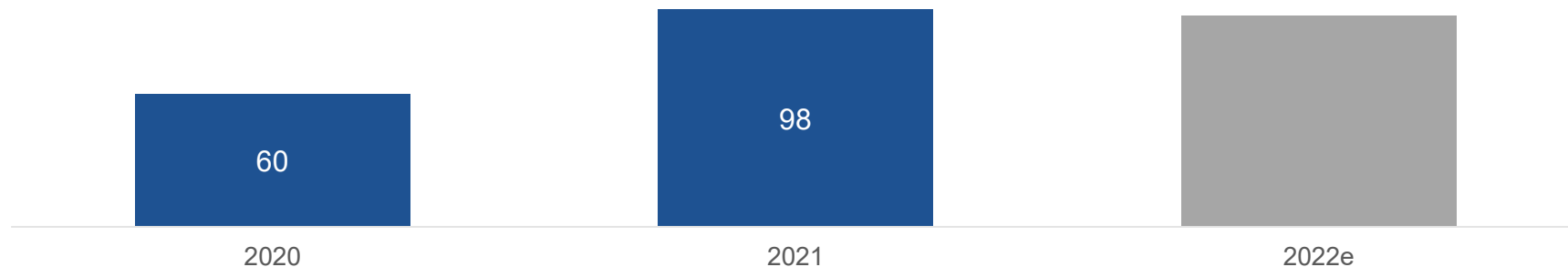
Allergovit® and Novo-Helisen® Depot Mites are registered!

- Allergovit® pollen preparations will win prescriptions from competitors with unauthorised preparations
- Relaunch of Novo-Helisen® Depot Mites in Q3 2023 with one strength up dosing; supported by NIS ,TiME 23'
- Completion of one strength up dosing schemes for Allergovit® by launch of Allergovit® tree pollen in Q4 2024
- Unrestricted availability of Allergovit® mugwort from Q3 2023

# Revenue and EBITDA development since acquisition

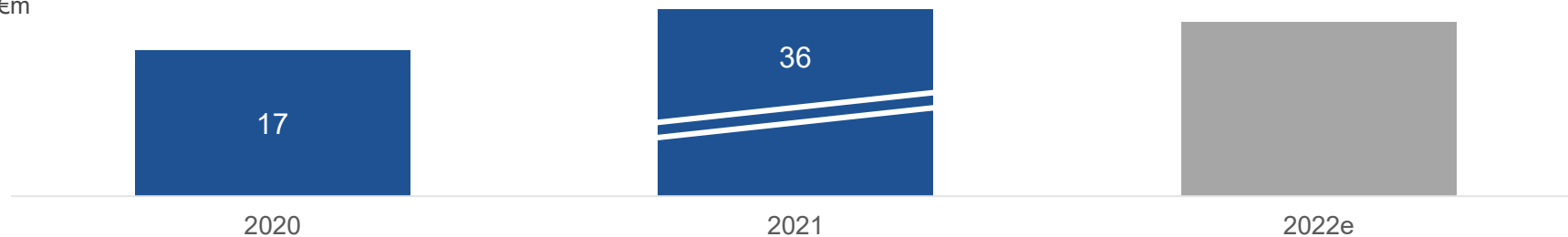
## Total Revenue<sup>1</sup>

€m



## Adj. EBITDA<sup>1</sup>

€m



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