ASIT biotech

Allergen-Specific ImmunoTherapy

INVESTORS PRESENTATION

OPPORTUNITY FOR LEADERSHIP IN ALLERGY IMMUNOTHERAPY (AIT)

GHENT SEPTEMBER 29 2018

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Allergen-Specific ImmunoTherapy

CORPORATE

WHO IS ASIT BIOTECH ?

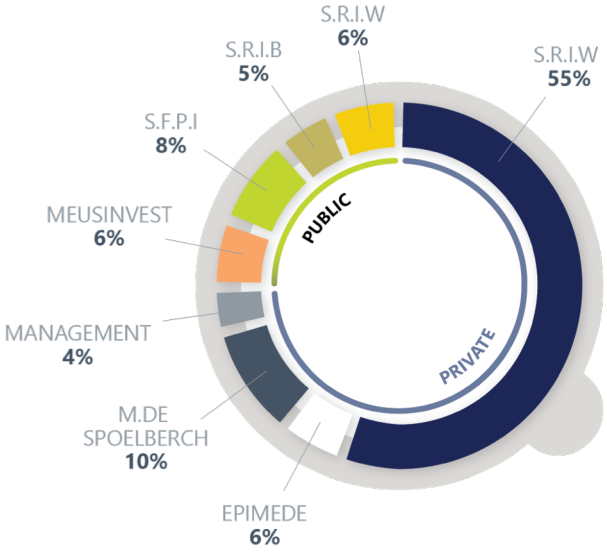
1

ASIT Biotech: Company Overview

ASIT HAS **ROBUST** SCIENTIFIC AND CLINICAL SUPPORT:

26 ACTIVE AND MOTIVATED **COLLABORATORS AND**

A NETWORK OF HIGH CALIBER COLLABORATIVE CENTERS



ASIT
LISTED
EURONEXT

Raised **€86** million since inception

€23.4M IPO (2016)

€15.4M private placement (2018)

€12M convertible bonds (2018)

A CLINICAL STAGE BIOPHARMACEUTICAL COMPANY SPECIALIZED IN ALLERGY IMMUNOTHERAPY QUOTED ON THE **BELGIAN AND FRENCH STOCK EXCHANGES**

(EURONEXT)

ASIT Biotech: Management & Collaborators

MANAGEMENT

- Thierry Legon, Director & CEO
- Everard van Straten, Director & CFO
- Philippe Ghem, Chief Commercial Officer
- Vincent Bille, VP CMC
- Sabine Pirotton, Head of R&D
- Marie-Etienne Pinelli, Chief Medical Officer
- Vincent Theunissen, Head of HR

DIRECTORS

- Gerd Zettlmeissl , Chairman
- Jean Duchateau , Director & Co-Founder
- Francois Meurgey, Director
- Harry Welten, Director
- Meusinvest: Michel Baijot
- Refinance Consulting SA: Yves Désiront
- S.F.P.I.: François Fontaine

COLLABORATORS

KU LEUVEN

Jean Ceupens, MD,
Peter Hellings, MD,
and Team

MRC & Asthma UK Centre in Allergic Mechanisms of Asthma
MRC Medical Research Council | King's College London | Imperial College London | asthma UK

Stephen Durham, MD, FRCP
Mohamed Shamji
and Team

UNIVERSITEIT GENT

Claus Bachert, MD, PhD
and Team

UNIKLINIK KÖLN | Institute for Medical Statistics, Informatics and Epidemiology

Ralph Mösges, MD, PhD
and Team

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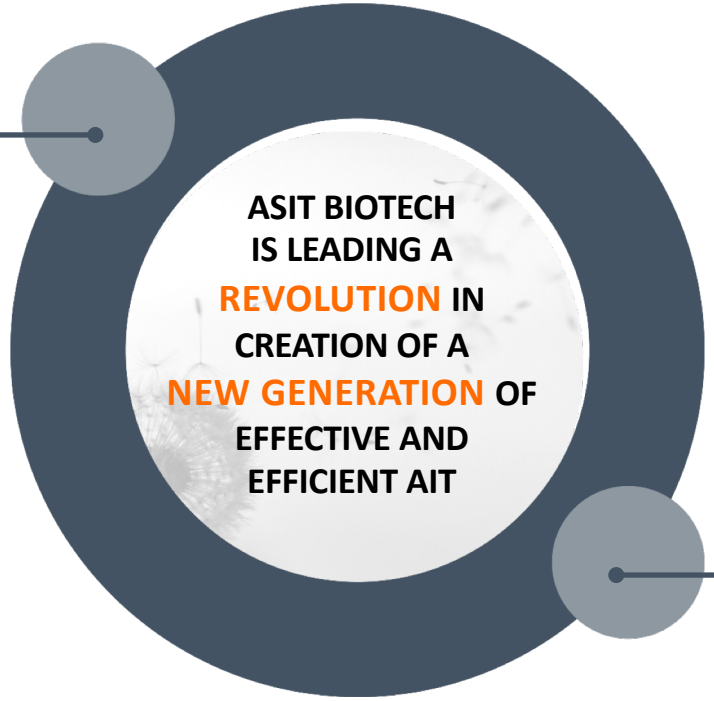
MARKET OPPORTUNITY

2

Opportunity in allergy immunotherapy (AIT) to migrate from old, inefficient therapies to a new generation of preventive treatment

HUGE REMAINING UNMET NEED



CHANGE THE GAME AND BECOME A LEADER IN THE FIELD

The ASIT+ TM platform offers multiple benefits

MANUFACTURING

Allows the production, characterization and QC of its active ingredients, providing **consistent & controllable** product at low COGS and high margins

MECHANISM OF ACTION

Allows the **fast induction** of blocking antibodies while limiting the allergic reaction, resulting in an improved safety profile, a **short course** of treatment* and improved patient acceptance, compliance and efficacy

NOVELTY

ASIT Biotech is the **only company** developing allergy treatments consisting of a unique mixture of highly purified peptides from different selected sizes**, produced from natural sources of allergens, and free of adjuvants

INTELLECTUAL PROPERTY

Patent applications filed in US, EU, Australia, Japan, India, China and Brazil for methods to manufacture and
methods of use of allergy immunotherapy products consisting of short peptide sequences from natural products

ASIT+ : Antigen Specific Immuno-Therapy +

* 3-4 week treatment course as opposed to 40 - 60 doctor's office visits for whole allergen extract subcutaneous administrations and/or 6 to 12 month daily doses of sublingual whole allergen extract treatments which result in low compliance rates, reduced efficacy and increased patient suffering

** 1-10 kDa

The AIT market is <15% of the allergy drug market because of inefficient therapies

HUGE REMAINING UNMET NEED

ONLY **45%** ARE CORRECLTY DIAGNOSED*

1/3 OF PATIENTS WITH MODERATE TO SEVERE AR ARE **NOT ADEQUATELY CONTROLLED** BY PHARMACOTHERAPY

PATIENTS

55% DUE TO **GRASS POLLEN**

50% DUE TO **DUST MITE**

400M PATIENTS SUFFER FROM ALLERGIC RHINITIS (AR)

ALLERGY TREATMENT MARKET IS LARGE AND GROWING

$12B

MANY AR PATIENTS ARE ALSO **ASTHMATICS** AND ARE MORE LIKELY TO BE RECEPTIVE TO A PREVENTIVE APPROACH

MARKET DYNAMICS

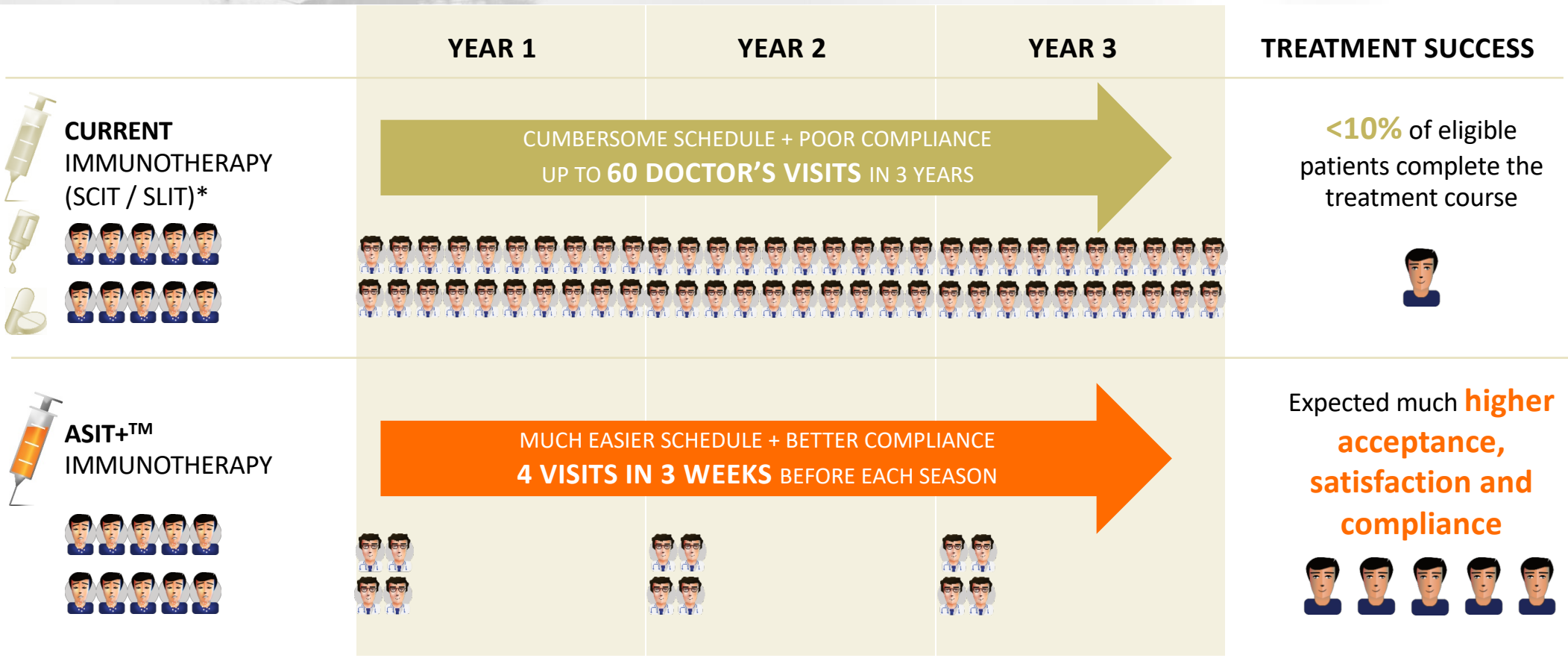
ALLERGY IMMUNOTHERAPY MARKET

$1.8B

ALLERGOLOGISTS ARE EASY TO TARGET
< 100 REPS IN US AND < 100 REPS IN EU

* 7% severe, 58% moderate, 35% mild AR

ASIT's short course immunotherapy is much more efficient than current AIT



Only 4 visits for gp-ASIT+ ™ treatment are expected to provide protection for the entire pollen season

*Subcutaneous immunotherapy treatment / Sublingual immunotherapy treatment

ASIT's short course immunotherapy addresses the unmet needs all key stakeholders

BENEFITS FOR KEY STAKEHOLDERS

HEALTH CARE SYSTEMS

- Registered product with documented **safety and efficacy**
- Reduced direct & indirect costs (4 vs. >10 doctor's visits)

PHYSICIANS

- Truly **innovative solution**
- More patients accepting AIT means more revenue
- Higher **patient satisfaction**
- SC injections handled by the physician

PATIENTS

- Real reduction of symptoms and **improved quality of life**
- Reprogramming of the immune system in a **preventive approach**
- Only 4 doctor visits prior to the pollen season

WE EXPECT FAST UPTAKE OF SHORT COURSE AIT, A NEW CATEGORY OF TREATMENTS THAT ASIT CAN DOMINATE

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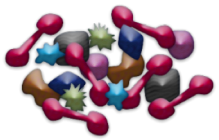
ASIT'S INNOVATIVE SOLUTION FOR AIT

3

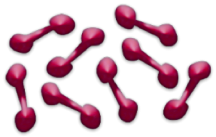
ASIT has developed a versatile platform for allergy immunotherapy

ASIT BIOTECH IS THE ONLY DEVELOPER OF ALLERGY TREATMENTS CONSISTING OF A **UNIQUE MIXTURE OF HIGHLY PURIFIED PEPTIDES FROM DIFFERENT SELECTED SIZES, PRODUCED FROM NATURAL SOURCES OF ALLERGENS**, AND FREE OF ADJUVANTS

HIGH GRADE PURIFICATION OF ALL ALLERGENS FROM NATURAL EXTRACTS



STANDARD ENZYMATIC HYDROLYSIS



SELECTION OF ALLERGEN FRAGMENTS BASED ON SIZE DISTRIBUTION*

HIGHLY PURIFIED ALLERGEN FRAGMENTS WITH OPTIMAL SIZE DISTRIBUTION

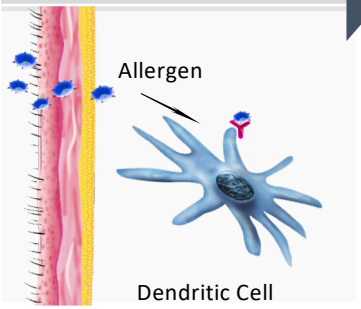
* 1-10 kDa

THE ASIT+™ PLATFORM OFFERS:

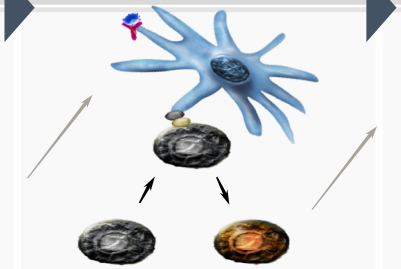
- **A validated production process** at commercial scale
- **Validated QC procedures**
- **A scalable solution that is applicable** to various allergens (e.g., House Dust Mites, Peanuts)
- **Already available** Ex-vivo screening, immunogenicity and therapeutic models

Allergy is an inappropriate immune response against a harmless substance

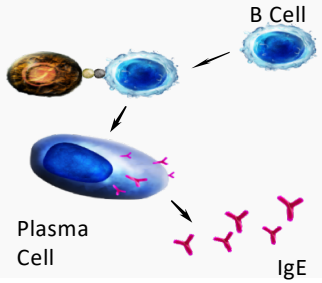
1 **Allergens are captured by active Dendritic Cells**



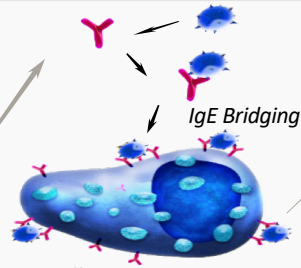
2 Dendritic Cells **activate pro-allergic T Cells**



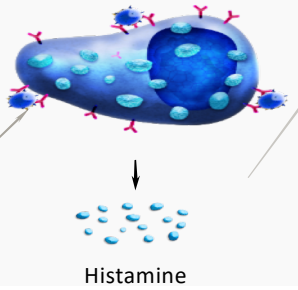
3 T Cells cause B Cells to produce **pro-allergic IgE antibodies**



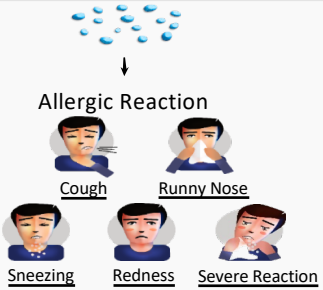
4 IgE bind to allergens and **attach to Mast Cells**



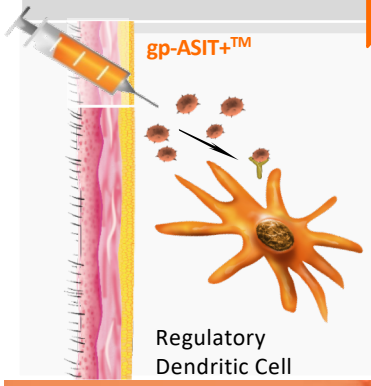
5 Mast Cells **release histamine** and other pro-inflammatory agents



6 These chemicals cause **inflammation** and allergic symptoms

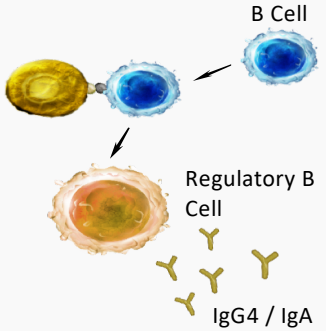


1 ASIT allergen fragments reprogram the immune system and **activate regulatory Dendritic Cells**

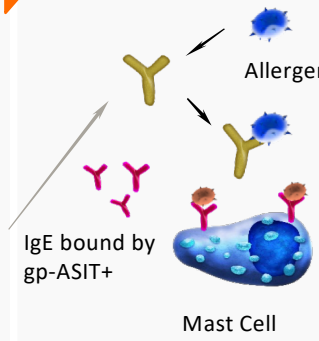


2 Dendritic Cells **activate anti-allergic Regulatory T Cells**

3 Reg. T Cells cause Reg. B Cells to produce **anti-allergic IgA and IgG4 antibodies** + reduction in seasonal IgE

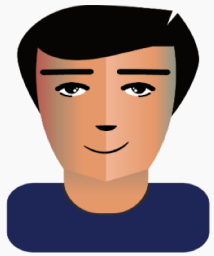


4 IgA / IgG4 blocking antibodies **prevent IgE antibodies from binding allergens**



5 Mast Cells (and Basophils) **remain inactive** and do not release histamine

6 There is **no inflammation** or allergic symptoms



gp-ASIT+™ allergy immunotherapy induces a natural regulation of the immune system in 3 weeks

ASIT biotech

The ASIT+™ platform enables a significantly more efficient therapeutic option

- The mechanism of action allows for the **fast induction** of protective antibodies without the need for an adjuvant, while limiting the allergic reaction, leading to the potential for at least **one-year of efficacy** with a single round of treatment:
  - Lowers the induction of allergen-specific IgE compared to whole allergens during and after treatment
  - Reduces basophil activation and mast cell degranulation
  - Induces regulatory T-cell and B-cell activation
  - Increases IgG4 formation
- Allows for a **faster injection regimen of higher doses**, compared to treatments with whole allergens
- Results in a **reduced course of treatment**, e.g., 4 doctor visits over 3 weeks for gp-ASIT+™

ASIT BELIEVES

THE ABSENCE OF AN ADJUVANT IMPROVES OVERALL LONG TERM SAFETY

ASIT BELIEVES

THE REDUCED COURSE OF TREATMENT WILL IMPROVE PATIENT ACCEPTANCE, COMPLIANCE & AIT EFFICIENCY

ASIT currently has several projects at different stages of the R&D pipeline

GRASS POLLEN:

gp-ASIT+™

PRECLINICAL | PHASE I | PHASE II | PHASE III

2017
POSITIVE SAFETY & EFFICACY

2019
CONFIRMATORY PHASE III PLANNED

PEANUT:

pnt-ASIT+™

PRECLINICAL | PHASE I | PHASE II | PHASE III

CANDIDATE SELECTED 06/2018

2019
PHASE I/II PLANNED

HOUSE DUST MITE:

hdm-ASIT+™

PRECLINICAL | PHASE I | PHASE II | PHASE III

NEW CANDIDATE SELECTED* 06/2018

2019
PHASE I/II PLANNED

OTHER FOOD:

EGG WHITE / COW'S MILK

PRECLINICAL | PHASE I | PHASE II | PHASE III

CANDIDATE SELECTION UNDERWAY

TBD

* Initial candidate for hdm-ASIT+™ showed good safety but insufficient immunogenicity in a PhI/II study

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SUMMARY

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The ASIT opportunity

FOR A POTENTIAL INVESTOR

- A near-term revenue generating opportunity
  - **Phase III, low-risk innovative product** opportunity for grass pollen allergy immunotherapy with **results expected in Q4 2019**
  - **Launch expected in 2-3 years**
- An opportunity to **gain market leadership in a large growing market** with gp-ASIT+™, a novel and efficacious late stage product
- Access to a **pipeline of products** for food and house dust mite allergies, using **NOVEL** small peptide approach with **strong IP,** aiming at changing the game in allergy immunotherapy. Start PhI/II in 2019.

FOR A PARTNER

Partners who will financially support co-development and commercialization of gp-ASIT+™ and/or ASIT's pipeline of potential new products, preferably through equity

* An allergy to grass pollen is the largest cause of allergic rhinitis, impacting millions of patients

ANALYSTS COVERAGE

Analyste	Reco	Objectif *
Gilbert Dupont	Accumuler	4,50 €
KBC Securities	Acheter	5,50 €
Edison	N/A	7,40 €
Bryan Garnier	N/A	5,70 €

** This information does not constitute an offer to sell or subscribe, or the solicitation of an order to buy or subscribe for securities in France, Europe, the US or any other country. ASIT biotech have agreed on a service for the production and distribution of financial analyses with Edison and Bryan Garnier.*

ASIT biotech

Allergen-Specific ImmunoTherapy

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APPENDIX

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gp-ASIT+™
GRASS POLLEN

5

gp-ASIT+™ is the most advanced R&D pipeline project (Phase III)

- Mechanism of action is well understood and characterised
- **Comprehensive preclinical & clinical data set**, including multiple preclinical studies, a Phase I safety study, a Phase II POC efficacy study, and an initial Phase III safety & efficacy study (Data Room available after CDA)
- **A first Phase III study** was completed in 2017:
  - Double blind, placebo-controlled, with four escalating doses of allergen
  - 549 patients across 57 EU centres, with **93% of patients completing the study**
  - **Data for all patients showed significance** and the 20% symptom reduction primary endpoint was nearly achieved despite a poor results in Germany, which heavily weighted the study
  - CPT (Conjunctival Provocation Test) performed after treatment showed a **reduced reactivity** compared to baseline in 177 subjects (60.0%) in the gp-ASIT+™ group and in 56 subjects (37.6%) in the Placebo group*

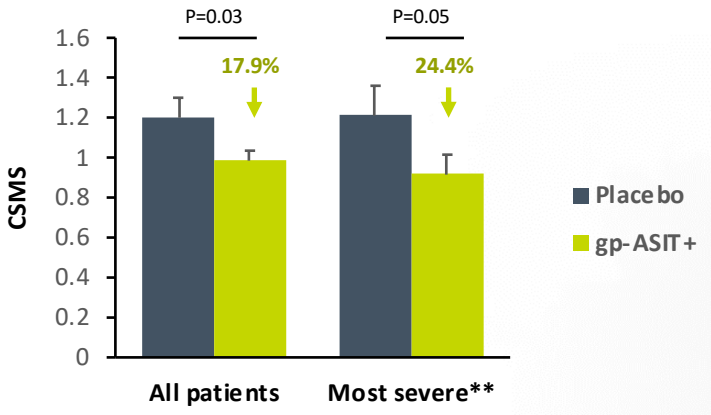
FIRST PHASE III STUDY SHOWED SIGNIFICANT REDUCTION IN ALLERGY SYMPTOMS AND MINIMAL ADVERSE EVENTS

A CONFIRMATORY PHASE III STUDY WITH IMPROVED STUDY DESIGN IS PLANNED FOR 2019

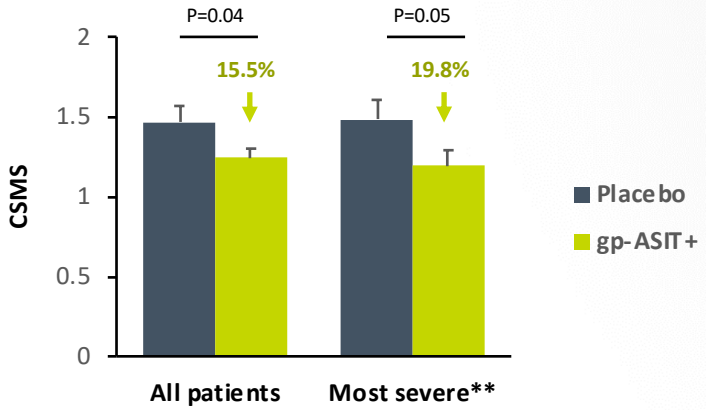
* The difference between the two groups was found to be statistically significant ($p < 0.0001$)

In Phase III, gp-ASIT+^{TM} demonstrated safety and efficacy

CSMS OVER ENTIRE POLLEN SEASON



CSMS: PEAK POLLEN PERIOD



In a Phase III study

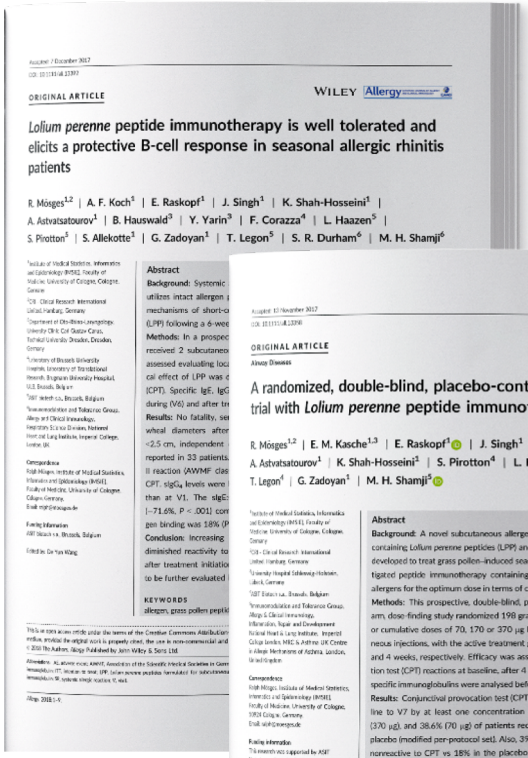
- gp-ASIT+^{TM} resulted in a statistically significant **improvement in CSMS*** during the peak pollen period and the entire pollen season in the whole Phase III patient population
- The predefined absolute average 20% difference in CSMS* between placebo and the treatment group was nearly achieved over the peak season despite a poor results in Germany, which was heavily weighted in the study#
- In a patient subgroup with the highest CPT** reactivity at baseline (more than ½ of patients), **CSMS* improvement** was even higher

Secondary endpoint

- Reactivity to the conjunctival provocation test (CPT) **decreased significantly** in 60.0% of patients treated with gp-ASIT+^{TM} compared with 35.6% in the placebo group

PL: Placebo; LPP: Lolium Perenne Peptides (gp-ASIT+^{TM})
* CSMS : Combined Symptom-Medication Score
** CPT: conjunctival provocation test (score from 1 to 4; most severe patients = CPT 3 & 4)
# ASIT received positive scientific advice from the German regulator, the Paul-Ehrlich Institute, and is now preparing a redesigned confirmatory Phase III study (First patient in planned in Jan 2019)

Clinical data on gp-ASIT+ has been published in top peer-reviewed journals



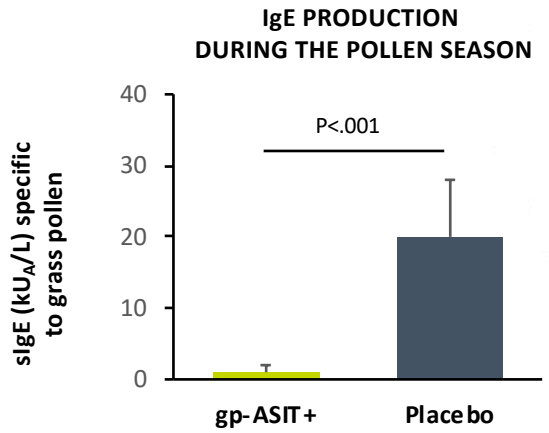
Lolium perenne peptide immunotherapy is well tolerated and elicits a protective B-cell response in seasonal allergic rhinitis patients

A randomized, double-blind, placebo-controlled, dose-finding trial with *Lolium perenne* peptide immunotherapy

Short course of grass allergen peptides immunotherapy over 3 weeks reduces seasonal symptoms in allergic rhinoconjunctivitis with/without asthma: A randomized, multicenter, double-blind, placebo-controlled trial

CLINICAL DATA FROM PHASE II AND PHASE III HAS BEEN PUBLISHED BY WORLD-CLASS SCIENTIFIC PARTNERS IN PEER-REVIEWED JOURNALS

Reliable immunological data correlates with strong efficacy data in a Belgian sub-population*



- The production of sIgE due to exposure to natural allergens during the pollen season was **blunted** in a sub-group of Belgian patients* receiving gp-ASIT+™ compared to those receiving placebo

BELGIUM

- Data from 33 patients in Belgium showed a **35% reduction in CSMS****
during the peak pollen period and **>50% reduction** for the entire pollen season (both highly significant)

* Blood samples from a representative sub-group of Phase III patients in Belgium (n=33) were compared from V8 (after the grass pollen season) vs. V6 (after treatment before the pollen season)
** CSMS : Combined Symptom-Medication Score

ASIT is now preparing a confirmatory Phase III study designed to maximise probability of success

Learnings implemented in the upcoming study:

- A **higher number of clinical centres*** spread over **6 countries** to avoid recruitment issues and weighting of a single center or country
- Each study site will be restricted in the number of patients that can be enrolled
- Sites will be selected in **regions with a history of high pollen rates** and high quality pollen counts
- The study will seek to enroll the **most allergic patients**
- Electronic diaries instead of paper diaries will be used to engage with patients and ensure better data collection
- The study will be subcontracted to a **single CRO** experienced in allergy studies

WE WILL START TREATING PATIENTS BEFORE THE POLLEN SEASON: Q1 2019

TOP-LINE DATA EXPECTED BY THE END OF 2019

FILING MAA IN GERMANY EXPECTED IN 1ST HALF 2020

Lessons from the first Phase III are helping not only to optimize the confirmatory study but also discussions with the FDA to finalize a US development plan for gp-ASIT+™**

* 80 centres vs. 57 centres in the first Phase III study
** Planned for Q4 2018

The ASIT+ TM platform is protected by several routes of intellectual property

Pharmaceutical formulation for allergen preparation

Expiration date: 28/06/2027

Patent Numbers: PCT/EP2008/068366

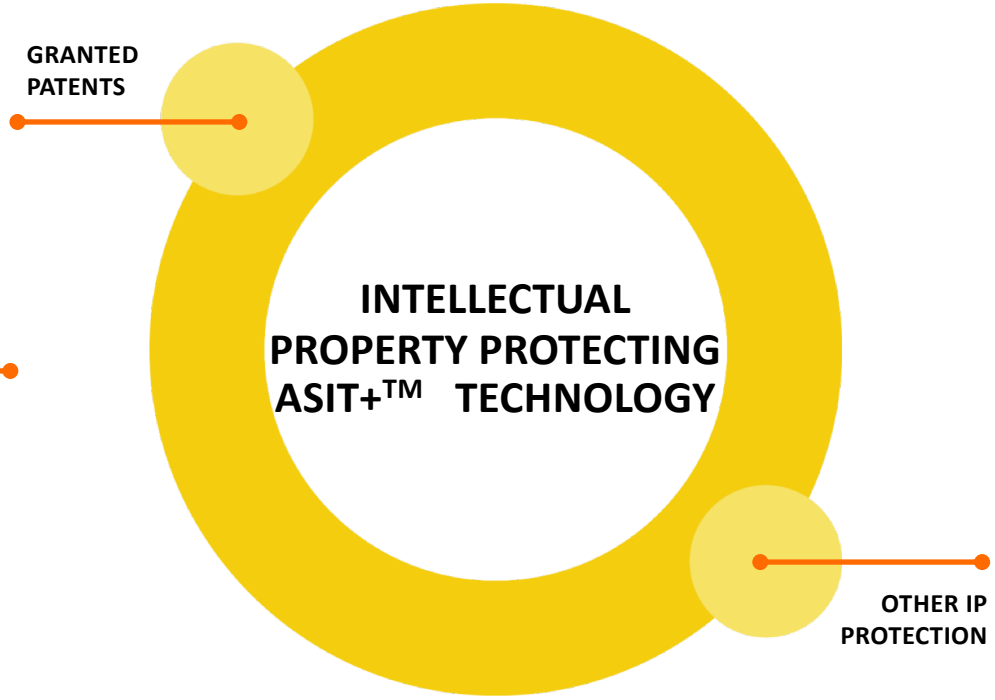
The patent family is directed to a special way of purifying and denaturing extracts of natural allergens and a special way of hydrolysing allergens, their formulation and use as pharmaceutical product to treat allergy.

A method for the production of hydrolyzed allergens

Expiration date: 15/06/2032

Patent Numbers: PCT/EP2012/061404

The patent family covers an improved method for the production of hydrolysed allergens, especially applicable to peanut allergens



5 YEAR
PATENT TERM EXTENSION FOR BIOLOGICS

12 YEAR
DOCUMENT PROTECTION FROM THE REGISTRATION DATE OF EACH PRODUCT IN EU AND US