

INNOVATION IN ALLERGY IMMUNOTHERAPY

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CFO

ASIT biotech 
Allergen-Specific ImmunoTherapy



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Welcome, let's get to know each other

How many of you are suffering from allergy or have a family member suffering from allergy?

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M
P
A
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Eye symptoms



Reduced work productivity



Asthma



Angiodema



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Nasal symptoms



Reduced school performance



Sleep deprivation



Anaphylactic reaction

ASIT biotech: An Innovative Allergy Platform Company with Phase 3 Data in Dec 2019

Investment Highlights

A biopharmaceutical company with a proprietary technological platform developing products based on a unique mixture of natural allergen peptides targeting respiratory and food allergies

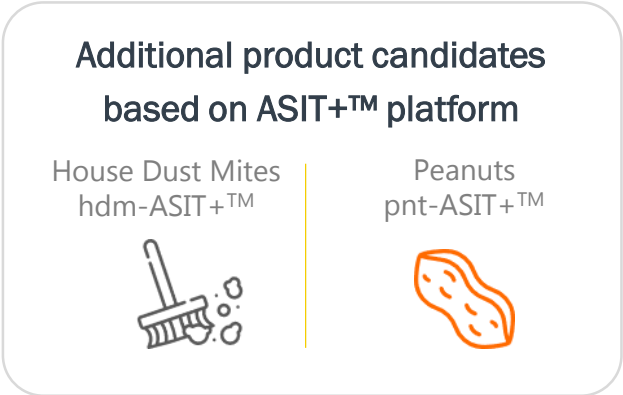


Financials end Q2 2019:			
Financing instruments available			
Cash € 2,5 million	Convertible notes 2019 € 9.2 million	Convertible notes 2018 € 5.8 million outstanding out of € 12,0 million	Warrants 2 € 4.2 million outstanding








LEAD COMPOUND in Phase III:

gp-ASIT+™, a 3-week pre-seasonal treatment for grass pollen allergic Rhinitis

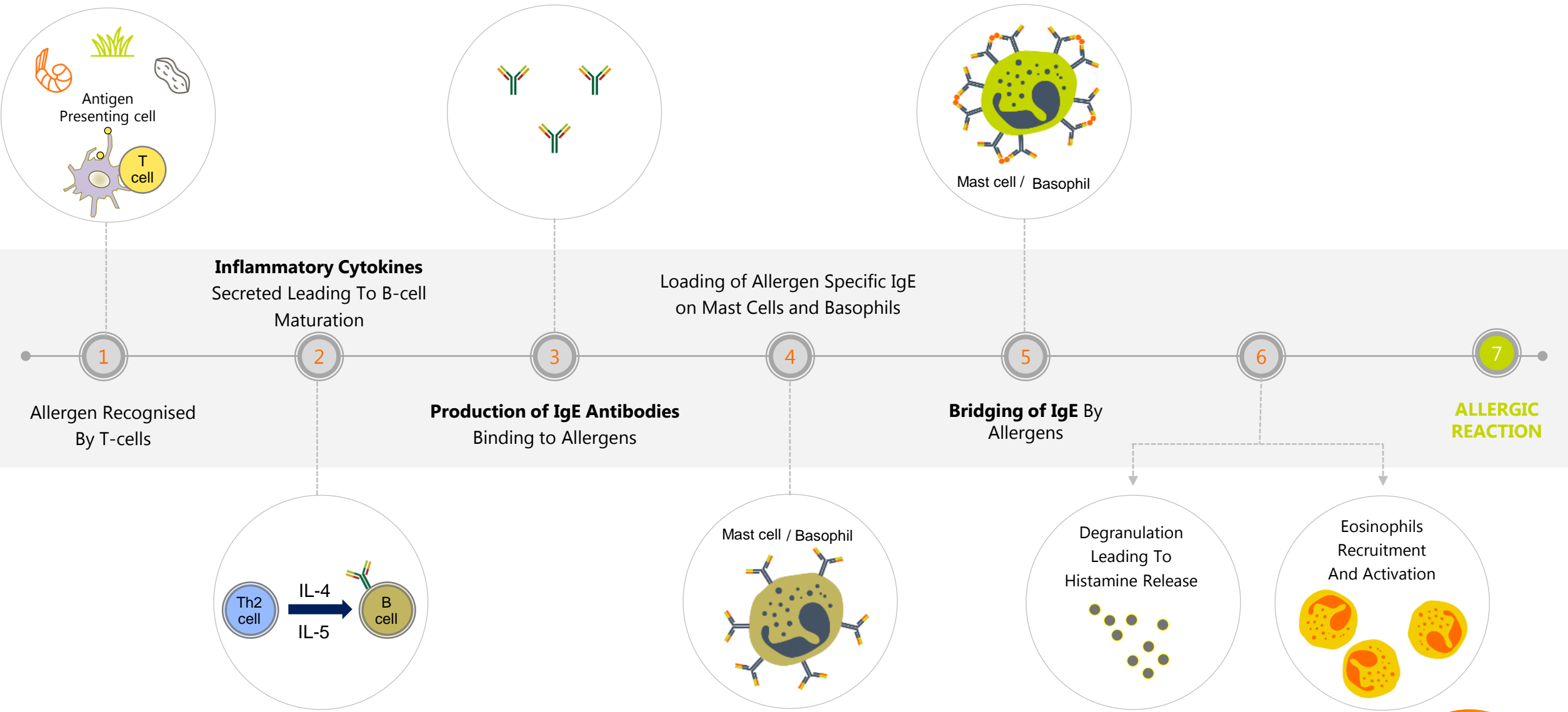
- Phase III data expected in December 2019
- Good safety profile demonstrated in nearly 1000 patients
- Commercial launch expected by 2021 with potential €500m peak sales



ASIT biotech pipeline & expected milestones

		Pre-clinical	Phase I	Phase II	Phase III	Reg/Market	Comments	
	Grass pollen gp-ASIT+™						<ul style="list-style-type: none"> • Ph III readout Dec 2019 • 2nd year treatment study planned for 2020 • Pre-IND H2 2020 	Proprietary or partnered
	Peanut pnt-ASIT+™						Pre-clinical package expected by Q4 2019	
	House dust mite hdm-ASIT+™						Pre-clinical package expected by Q1 2020	
	Other protein-based allergens: ragweed, Jap cedar, birch, milk, egg white						Candidate selection in 2020	

From Allergens to Allergic Reaction: Steps of the Inappropriate Immune Response



Symptomatic drugs for allergy leaves 33% of treated patients unsatisfied

Allergic rhinitis

>95% of the market daily intake during allergen exposure

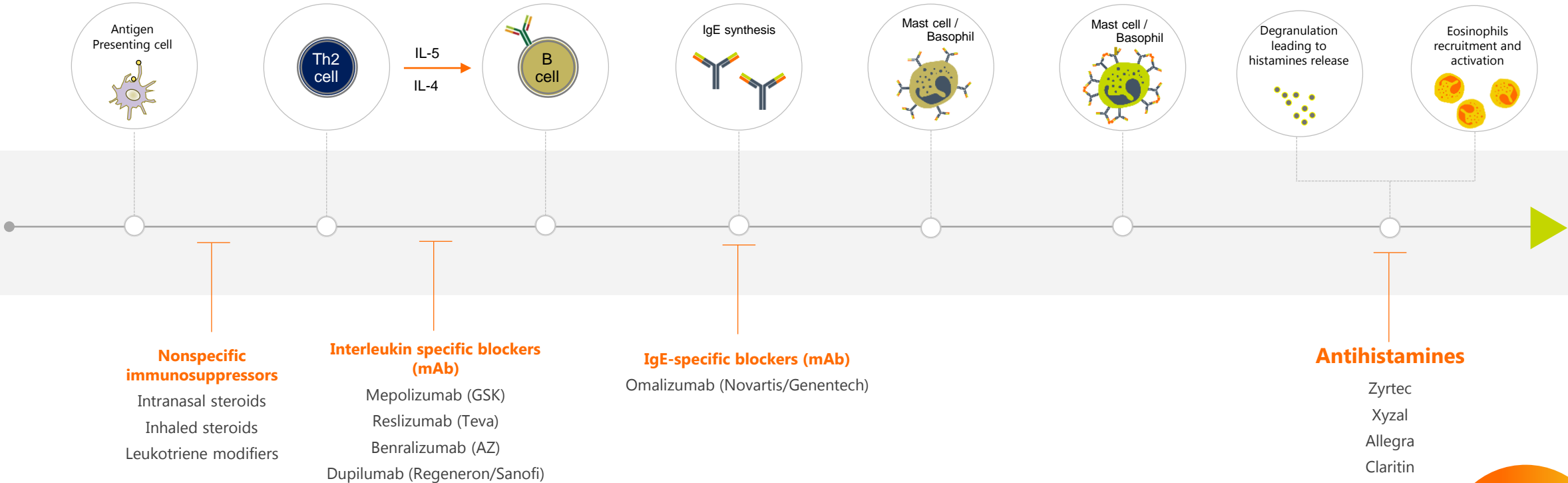
No long-term effect, poor effectiveness in case of low compliance

Food allergy

No registered drugs available

Food avoidance

Epinephrine injection



Current AIT provides long-term benefits but still has limitations

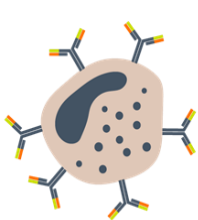
Induces natural regulation of the immune system and dramatically improved long-term symptom reduction

Induction of regulatory T and B cells	Prevention of the seasonal increase of IgE	Induction of IgG4-associated blocking antibodies leading to clinical benefit during the pollen season	Suppression of grass pollen-induced basophil activation responsible for immediate allergic response
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Whole allergen extract (current AIT standard) have limitations: time to get the benefits & low compliance

SAFETY CONCERNS: INDUCTION OF HISTAMINE AND PROINFLAMMATORY SUBSTANCES

MAST CELL /
BASOPHIL



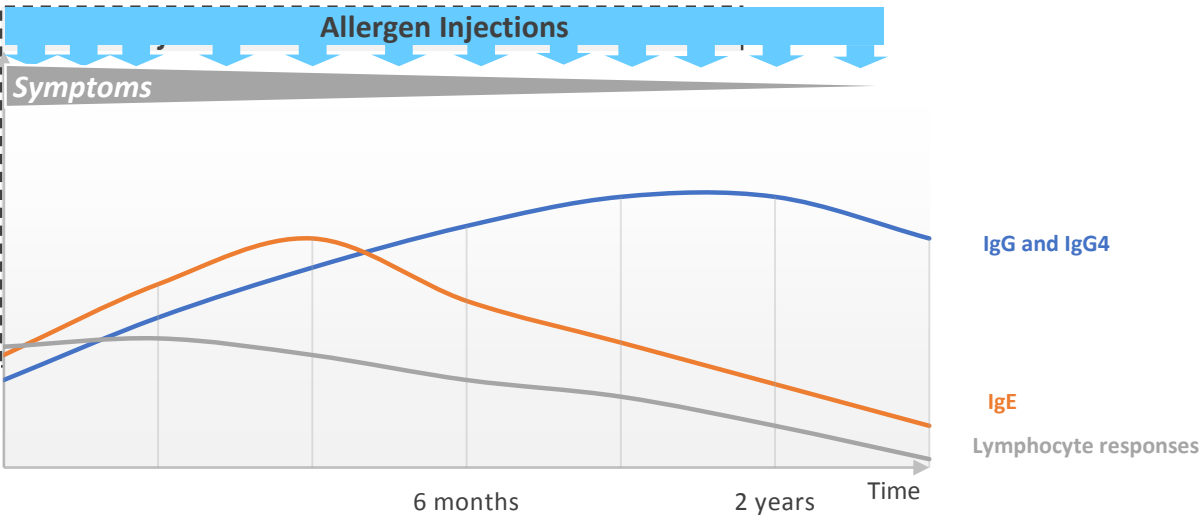
Exposure to
allergens

ACTIVATED STATE

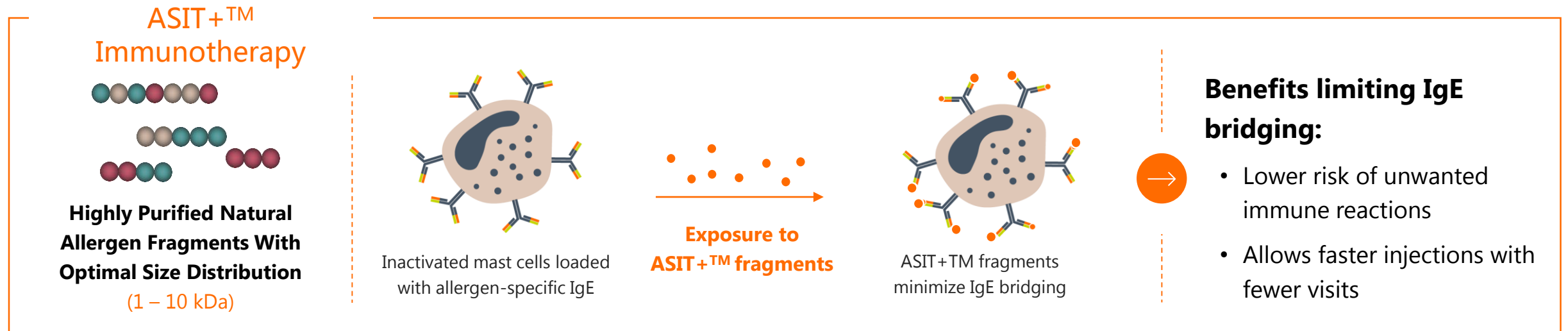
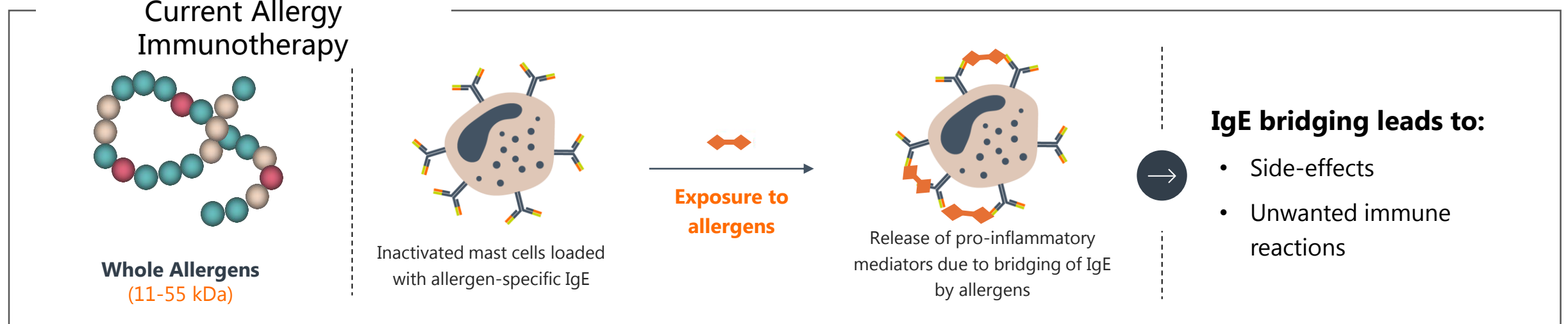


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- RELEASE OF
HISTAMINE AND
PRO-INFLAMMATORY
CYTOKINES

EFFICACY CONCERNS: DELAY IN REACHING THE OPTIMAL BALANCE BETWEEN IGG4 AND IGE

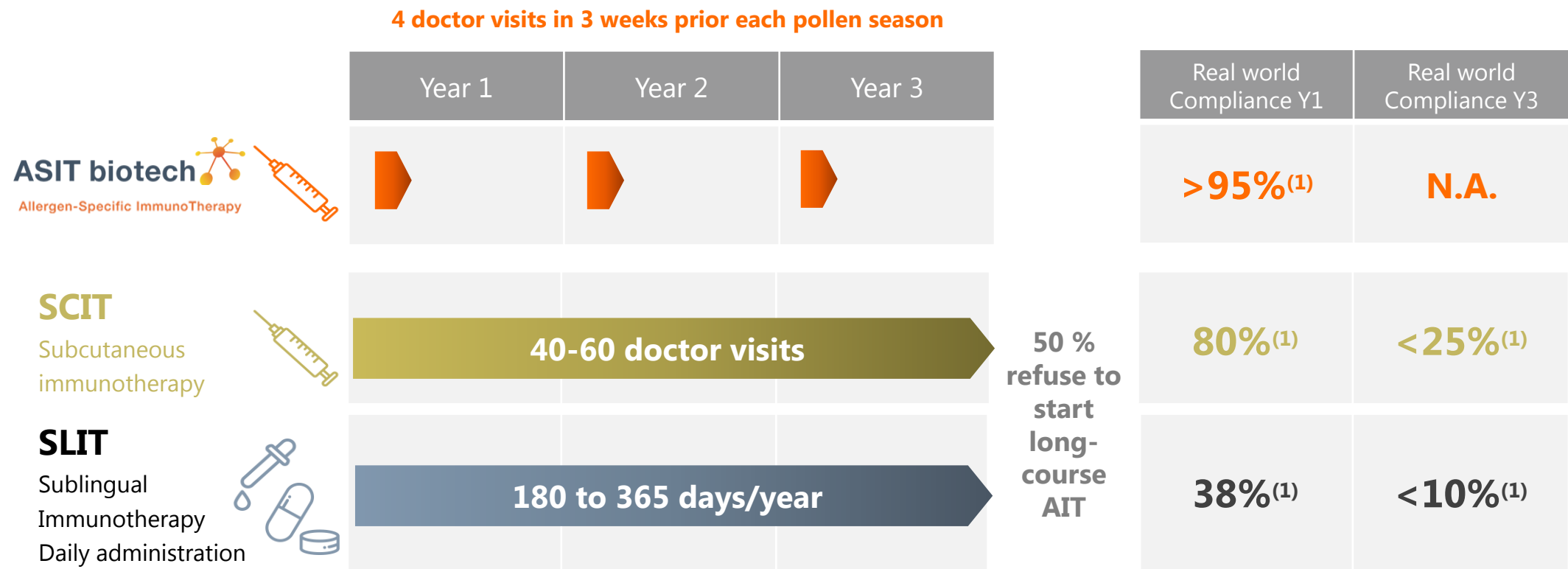


ASIT+™ technology platform is limiting IgE bridging vs Current AIT



The unique Mode of Action of gp-ASIT+™ has been published in **JACI** (Sharif et al, 2019)

The ASIT+ Platform Aims to Transform Allergy Immunotherapy



1) Kiel et al., J Allergy Clin Immunol 2013;132:353-60

GP-ASIT+™ SHORT SCHEDULE IS MORE ACCEPTABLE AND EASIER TO COMPLY FOR HIGHER TREATMENT EFFICIENCY, PATIENTS' AND PAYER'S SATISFACTION

ASIT biotech is uniquely positioned in the AIT market

Short-Course (weeks)	Mid-Course (months)	Long-Course (years)	
Adjuvant free	With adjuvant	Adjuvant free	With adjuvant
<div>New</div> <div> Allergen-Specific ImmunoTherapy</div> <div>(Respi & Food: SCIT)</div>	<div> (Respi: SCIT)</div> <div> Allergien in besten Händen (Respi: SCIT)</div>	<div>New</div> <div> (Food: Patch)</div> <div> (Food: oral-Powder)</div>	<div> (Respi: SCIT)</div> <div> (Respi: SLIT/SCIT)</div> <div> (Respi: SLIT/SCIT)</div> <div> (Respi: SLIT/SCIT)</div>

SCIT: Sub-Cutaneous ImmunoTherapy; SLIT: Sub-Lingual ImmunoTherapy (Tablets or Drops)

gp-ASIT+™ : Comprehensive Clinical Studies >900 Patients to Date

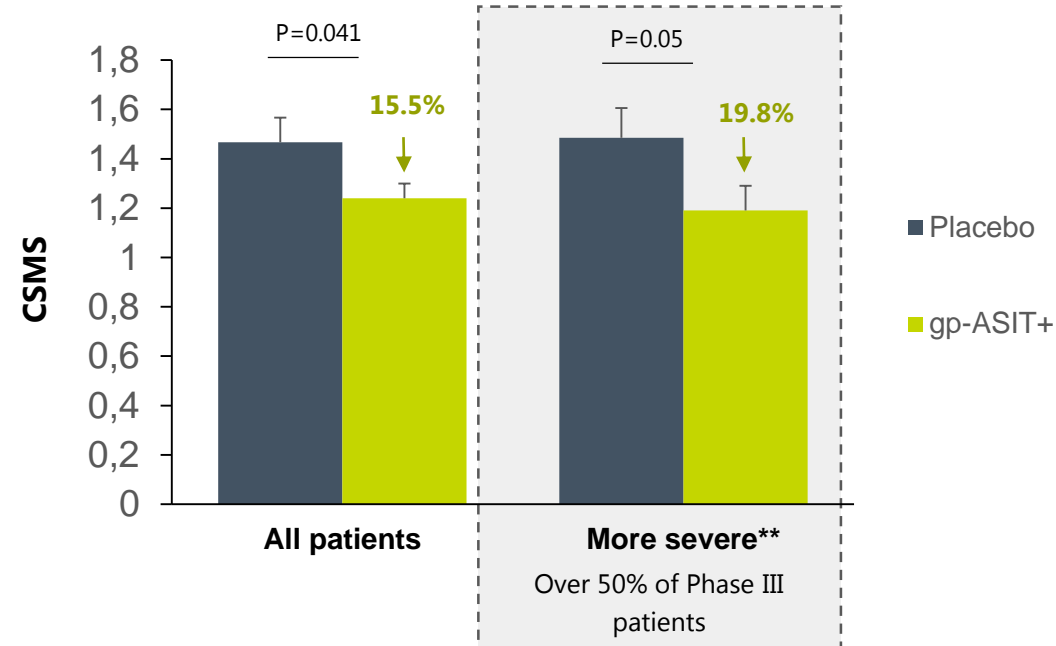
Trial	# patients	Aim	Timing	Design	Status	Publication
Phase I BTT004	27	Safety and clinical tolerability Immunogenicity	2010	Double-blind - placebo controlled Dose-escalation Single center in Belgium	✓	
Phase IIa BTT006	24	Safety and clinical tolerability Immunogenicity	2012	Double-blind - placebo controlled Dose-escalation Single center in Belgium	✓	
Phase IIa BTT007	65	Safety and clinical tolerability Immunogenicity Clinical efficacy assessed by CPT	2013	Open-label Dose-escalation Single center in Germany	✓	Data published in the journal ALLERGY
Phase IIb BTT008	200	Dose-finding assessed by CPT Immunogenicity Safety and clinical tolerability	2014	Double-blind - placebo controlled Dose-escalation Multiple centers in Germany	✓	Data published in the journal ALLERGY
1st Ph III BTT009	549	Clinical efficacy assessed by CSMS Safety and clinical tolerability	2017	Double-blind – placebo controlled 57 centers in Germany, Belgium, France, Italy, Spain, Czech Republic	✓	Data published in the journal ALLERGY Mode of action of gp-ASIT+™ published in JACI
2nd Ph III ABT011	651	Clinical efficacy assessed by CSMS Safety and clinical tolerability	2019	Double-blind – placebo controlled 70 centers in Germany, Poland, Belgium, France, Czech Republic and Hungary	Ongoing LPO Sept 2019	Primary end point results in Dec 2019

Note: CPT = conjunctival provocation test / CSMS = combined symptom and medication score

BTT009 - gp-ASIT+™ Demonstrated Efficacy

PRIMARY ENDPOINT

CSMS: PEAK POLLEN PERIOD



- gp-ASIT+™ 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 in the whole Phase III patient population and achieved in the more severe patients (55% of the study population)

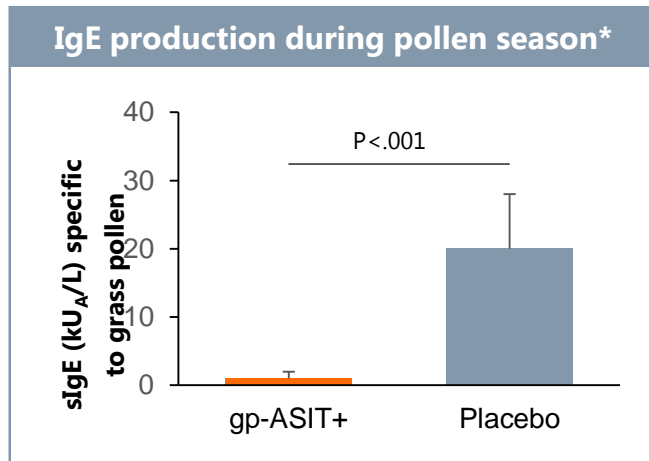
* CSMS : Combined Symptom-Medication Score

** CPT: conjunctival provocation test at baseline (score from 1 to 4; more severe patients = CPT 3 & 4)). Data obtained by post-hoc analysis.

gp-ASIT+™ - Key Elements of Successful Phase III

Learnings from BTT009 Phase III

- **Well tolerated**
- **Good safety profile**
- **Efficacy demonstrated clinically and immunologically**



- **Sub-optimal patient selection and data collection diluted the results**

Impact on ABT011 confirmatory Phase III Design



Patient Recruitment

- Recruit only **moderate to severe patients** with moderate to severe AR during the 2017-2018 seasons based on
 - ARIA criteria
 - And significant sIgE level
 - And minimum Skin Prick Test wheal diameter
- **Clinical centres selected** based on high pollen count and high-quality data recording history

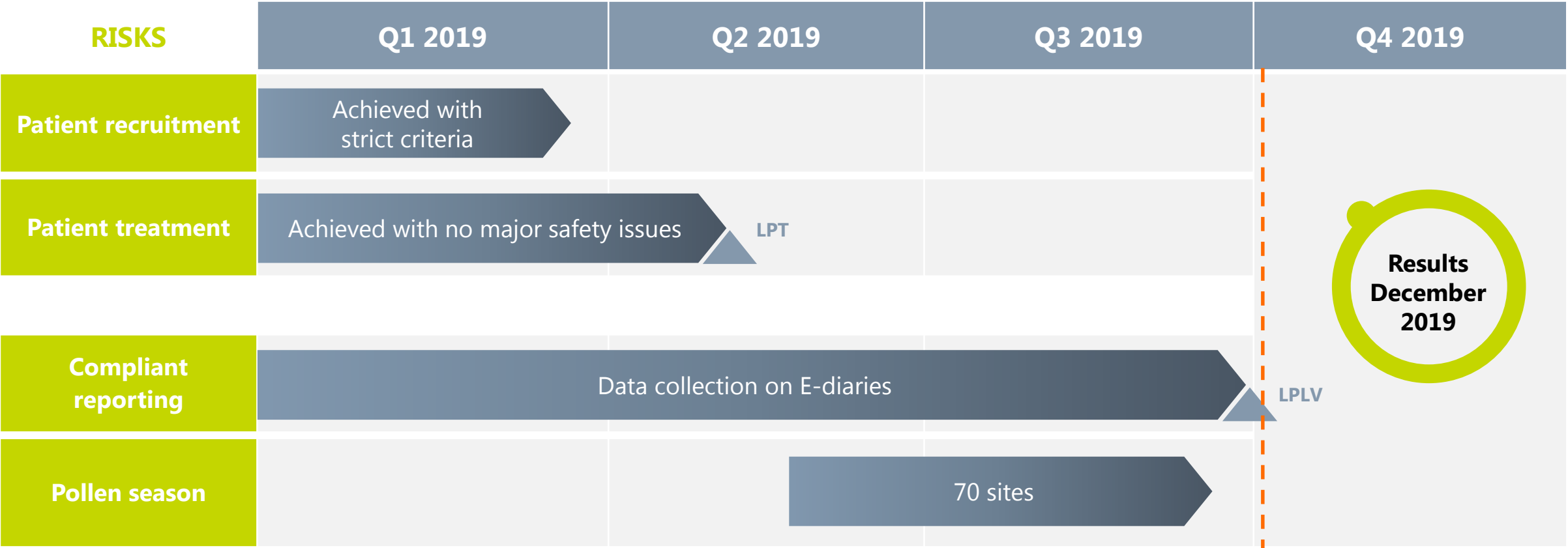


Data Collection

- **One single Top Ten CRO** experienced in allergy studies is in charge (ICON)
- **Electronic diaries used** to optimize data collection quality and reliability
- **Pollen count monitoring is centralized** by the European Aeroallergen Network from the University of Vienna

*Subpopulation of BTT009- JACI, Sharif et al, 2019 ; achieved 35% reduction in CSMS during the peak period and >50% reduction for the entire pollen season (both highly significant)

gp-ASIT Ph III (ABT011) - Ready to deliver in December 2019



All patients are treated with no major safety issues

Phase III well on track to deliver pivotal readout in December 2019

LPT: Last Patient Last Treatment - LPLV: Last Patient Last Visit

Likelihood of positive Phase III results is 71,4 % in allergy studies*

GP-ASIT+™ FOR ALLERGIC RHINITIS SHOULD EVEN BE HIGHER:

ONGOING PH III (ABT011) INCLUDES LEARNING FROM THE FIRST PH III (BTT009)

gp-ASIT+™
likelihood of
approval
should be
>70%

Phase Success	Phase I to Phase II		Phase II to Phase III		Phase III to NDA/BLA		NDA/BLA to Approval	
	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success
Hematology	86	73.3%	83	56.6%	64	75.0%	50	84.0%
Infectious disease	347	69.5%	286	42.7%	150	72.7%	133	88.7%
Ophthalmology	66	84.8%	101	44.6%	60	58.3%	40	77.5%
Other	96	66.7%	116	39.7%	46	69.6%	43	88.4%
Metabolic	95	61.1%	84	45.2%	35	71.4%	27	77.8%
Gastroenterology*	41	75.6%	56	35.7%	33	60.6%	26	92.3%
Allergy	37	67.6%	40	32.5%	14	71.4%	16	93.8%
Endocrine	299	58.9%	242	40.1%	143	65.0%	107	86.0%
Respiratory	150	65.3%	196	29.1%	45	71.1%	37	94.6%
Urology	21	57.1%	52	32.7%	21	71.4%	14	85.7%
Autoimmune	297	65.7%	319	31.7%	135	62.2%	86	86.0%
All Indications	3582	63.2%	3862	30.7%	1491	58.1%	1050	85.3%
Neurology	462	59.1%	465	29.7%	216	57.4%	161	83.2%
Cardiovascular	209	58.9%	237	24.1%	110	55.5%	76	84.2%
Psychiatry	154	53.9%	169	23.7%	70	55.7%	58	87.9%
Oncology	1222	62.8%	1416	24.6%	349	40.1%	176	82.4%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematology	283	26.1%	197	35.7%	114	63.0%	50	84.0%
Infectious disease	916	19.1%	569	27.5%	283	64.5%	133	88.7%
Ophthalmology	267	17.1%	201	20.1%	100	45.2%	40	77.5%
Other	301	16.3%	205	24.4%	89	61.5%	43	88.4%
Metabolic	241	15.3%	146	25.1%	62	55.6%	27	77.8%
Gastroenterology*	156	15.1%	115	20.0%	59	55.8%	26	92.3%
Allergy	107	14.7%	70	21.8%	30	67.0%	16	93.8%
Endocrine	791	13.2%	492	22.4%	250	55.9%	107	86.0%
Respiratory	428	12.8%	278	19.6%	82	67.3%	37	94.6%
Urology	108	11.4%	87	20.0%	35	61.2%	14	85.7%
Autoimmune	837	11.1%	540	17.0%	221	53.5%	86	86.0%
All Indications	9985	9.6%	6403	15.3%	2541	49.6%	1050	85.3%
Neurology	1304	8.4%	842	14.2%	377	47.8%	161	83.2%
Cardiovascular	632	6.6%	423	11.2%	186	46.7%	76	84.2%
Psychiatry	451	6.2%	297	11.6%	128	49.0%	58	87.9%
Oncology	3163	5.1%	1941	8.1%	525	33.0%	176	82.4%

*Biomedtracker LOA
(Likelihood of Approval)

AIT market is attractive and has significant growth opportunity with better products

ATTRACTIVE MARKET DYNAMICS

- **Large & growing allergy market¹ (\$12B)**
 - 33% of patients are not satisfied with 1st line pharmacological treatments³ (addressable market for Allergy immunotherapy (AIT))
 - AIT market²: \$1.3B , only ~10% of overall market because current therapies are inefficient (long treatment = low acceptance & compliance)
- **Favorable pricing & regulatory environment**
 - €500 to €1200/year of AIT (EU), up to \$5000/year (US), no generics
 - Push for approved products (stop NPPs)
- **Limited sales & marketing infrastructure required:** <200 reps in U.S. & EU combined

EU5 + US	Grass Pollen ⁴	House Dust Mite ⁴	Peanut ⁵
Prevalent cases	42m	38m	3.1m
Diagnosed & treated	23m	20m	2.2m
Addressable market	7.7m	6.8m	2.2m
Patients treated with AIT	1.5m	1.4m	0

1. Visiongain, Global Allergic Rhinitis Drugs Market 2018-2028, Aug. 2018 - 2. Stallergenes annual report 2018 - 3. Droessaert et al., Rhinology 54: 0-0, 2016- 4. Global Data, 2019 Allergic Rhinitis report - 5. Aimmune presentation

Commercial potential of ASIT pipeline could reach € 2 billion

large
unmet
need

favorable
pricing

long
exclusivity
(no generics)

Analysts peak sales estimates (EU+US)*

Peak sales per project	Date	Gp-ASIT (M€)	hdm-ASIT (M€)	Pnt-ASIT (M€)
Kepler Cheuvreux	Nov 2018	360	300	860
Gilbert Dupont	Nov 2018	384	325	N.A.
KBC Securities	June 2016	280	240	N.A.
Bryan Garnier	Sept 2018	500	430	N.A.
Edison	May 2018	403	373	1448

** 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. Corporate: ASIT biotech has agreed on a service for the production and distribution of financial analyses with Edison and Bryan Garnier.*

In control of manufacturing & IP

MANUFACTURING

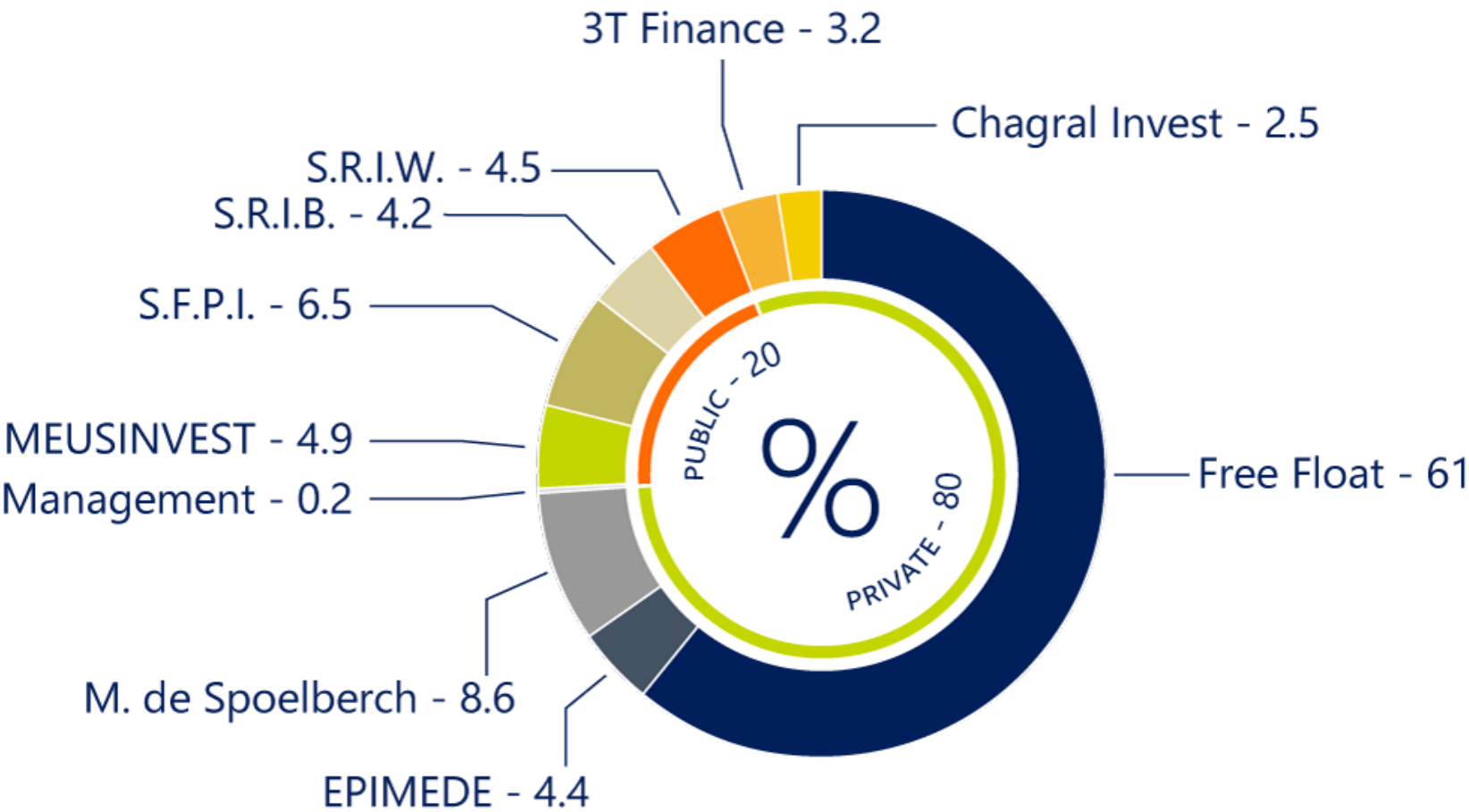
- The Company continues to make steady progress towards internalizing manufacturing capabilities for clinical and commercial capacity
- Allows the production, characterization and QC of its active ingredients, providing consistent & controllable product at low COGS and high margins

IP

- Fully owned
- The ASIT+ TM platform is protected by several routes of intellectual property up to 2032 and additional patents are being filed.

Shareholder Base

Shareholders status 1 August 2019



Cash position and financing instruments

- The company has cash of €2.5M at 30/06/2019
- The company has financing instruments available for up to €19.2M under certain conditions

Financial instrument	Amount	Condition
Convertible notes 2019	€9.2M	Tranche A of €5.0M is paid in July 2019 Tranche B of €4.2M can be triggered by the Company in case of positive phase 3 data
Convertible notes 2018 (Equity Line)	€5.8M	Can be triggered by the Company in case of a share price above €1,1368
Warrants 2	€4.2M	At the discretion of the holders; strike price €3.83

- The company has the intention to seek additional funding in H1 2020 after the pivotal phase III results

Expected news flow

- **Q4/2019:** The Company intends to start a **follow-up study with gp-ASIT+™** to evaluate the long-term benefits of gp-ASIT+™ and build a strategy to achieve a regulatory indication for efficacy beyond a single pollen season.
- **Dec 2019: top-line results of gp-ASIT+™ pivotal Phase III study**
- **Dec 2019:** The Company expects the **preclinical package of the pnt-ASIT+™** drug candidate for peanut allergy to be ready.
- **H1/2020:** The **preclinical package of the hdm-ASIT+™** drug candidate for house dust mite allergy is expected, subject to testing results at the Imperial College of London.
- The Company intends to be ready to clinically develop, co-develop or partner these assets when and if needed.

Seasoned Leadership Team

Michel Baijot

Director & Chief Executive Officer

Expertise: building biologicals businesses (strategy, licensing, M&A and technology transfer)

Education: Bioengineer and PhD in Molecular Biology



Rémy von Frenckell

Head of Clinical Development

Expertise: drug development in academia and in the pharmaceutical industry; >150 publications in peer reviewed journals

Education: Civil Engineer in Chemistry and PhD in Experimental Biomedical Sciences



Frank Hazevoets

Chief Financial Officer

Expertise: strategy development, M&A and financing

Education: Master of Engineering and Master of Business Economics



Vincent Bille

Head of Operations

Expertise: leadership of technical operations, CMC, quality control and manufacturing processes

Education: PhD in Biochemistry and Master in Business Administration

Lonza



Beatrice De Vos

Chief Medical Officer

Expertise: medical affairs, regulatory and launch preparedness

Education: Medical Doctor



Philippe Ghem

Head of Commercial Operations & Licensing

Expertise: commercial expertise in the pharmaceutical industry, market access and business development

Education: Commercial Engineer and Master in Business and Marketing

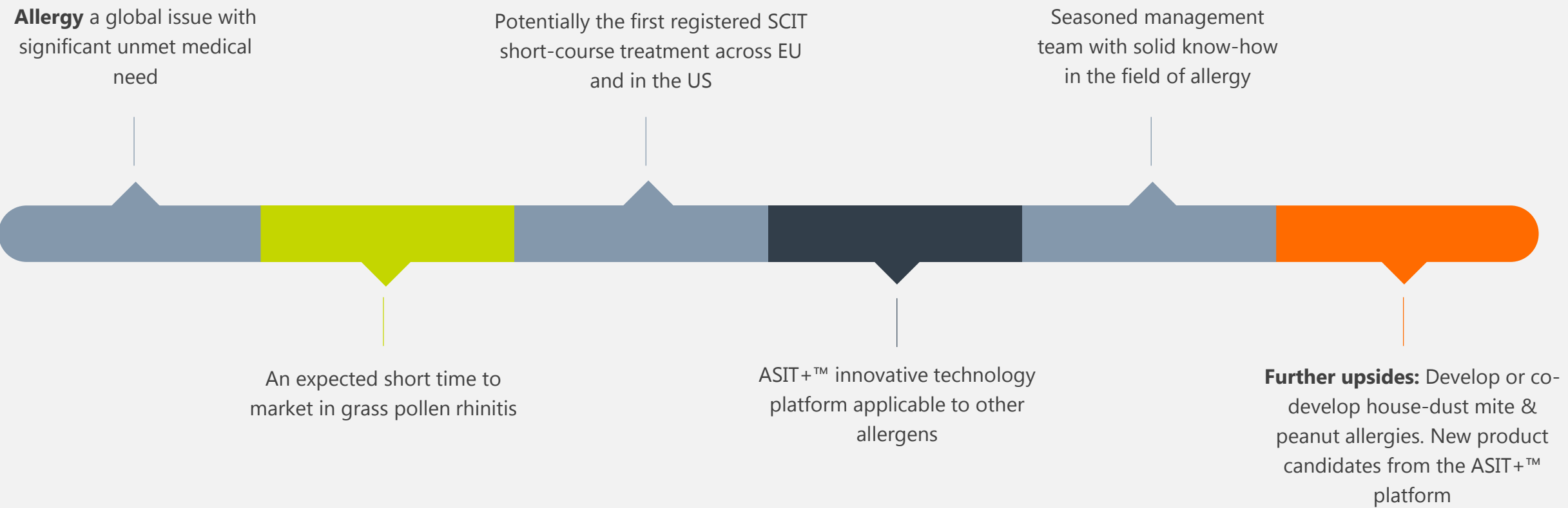


NOVARTIS



ASIT biotech: innovation in allergy immunotherapy

A unique investment opportunity on the cusp of pivotal phase III results in grass pollen AR



THANK YOU

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