### REVOLO BIOTHERAPEUTICS

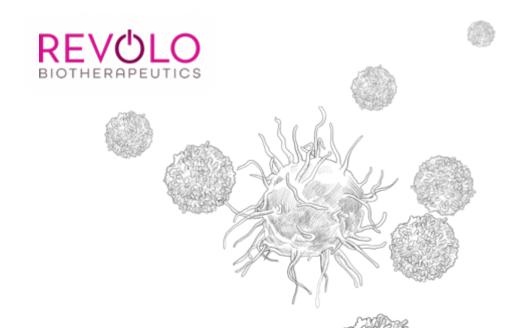
Analyze Reset Revolutionize



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### Our Mission

# *Revolutionize* Autoimmune and Allergic Disease treatment by *Resetting* the Immune System for *Superior* long-term disease *Remission*



Short-term, partial disease remission Current biologics e.g., anti-TNFs

> Disease modification Immunosuppressants

Treat symptoms only Steroids

#### Chronic Suppression of immune system:

- Low remission rates
- Patients at risk of serious infections and lifethreatening side effects



Superior, long-term disease remission without immune suppression

### Resetting the immune system with:

- Short PK but prolonged PD effect (weeks to months)
- Superior disease Remission
- No immunosuppression



# Revolutionary Company with Revolutionary Therapies









Developing two therapies that *Reset* the immune system for *long-term* remission

### Demonstrated *Efficacy and Safety*

- '1805 Phase 2 study achieved remission in Rheumatoid Arthritis
- '1104 Phase 1 study (94 healthies and asthmatics) safe and tolerable and shown to be a key regulator for Allergic Disease
- '1104 MAD study 18 healthies safe and tolerable no SAE's

#### Multiple *Near-Term* milestones:

- Initiating four Phase 2 clinical programs in RA, Allergic Disease, EoE and Uveitis
- Seven near-team clinical readouts
- Multiple autoimmune and allergic disease indication targets

#### **Strong** cash position

- \$54M Series B September 2020
- In process of S1 drafting
- Discussions Initiated: Crossover to IPO
- Discussions Initiated: PIPE/ SPAC



### → Revolutionizers



**Jonathan Rigby**Group CEO

As employee #1 in the US, Jonathan Rigby has led the company through rapid and substantial strategic and operational growth. He brings three decades of experience creating value through multiple private financings and IPOs and public to public mergers in the pharma and biotech industry.



**Woody Bryan** CBO Ph.D.

Jones (Woody) Bryan, Ph.D., brings almost 30 years of experience in the healthcare industry to the team, having led successful business development operations in both private and public pharma and biotech companies.



Perry Calias, Ph.D., brings over 25 years of experience in pre-clinical and clinical development, CMC and global regulatory submissions across the drug and device sectors of healthcare. He has held numerous executive positions leading clinical and non-clinical operations.



Jeff Myers M.D. Ph.D. CMO

Jeff Myers, M.D., Ph.D., has 20 years of experience in medical affairs, regulatory and clinical development within the biopharmaceutical industry, with focuses on cardiovascular, pulmonary, oncology, and inflammatory diseases.



Nancy Vinh brings over 20 years of experience in managing early and late phase, international clinical trials for drugs, biologics, cell therapy and combination products across a wide range of therapeutic areas to the team.



**Roly Foulkes Ph.D.** 

Dr. Roly Foulkes has 25 years of experience building and delivering innovative therapeutic portfolios within the immunology and inflammatory disease space. He has a strong record advising small and medium sized immunology biopharma companies in developing competitive therapeutic strategies.



Marylyn Rigby VP Marketing, IR, PR

Marylyn Rigby is an experienced pharmaceutical, biotech, and drug delivery professional. In addition to her expertise in marketing, public and investor relations, she has a successful track record with business development, licensing, public and private equity financing, and business strategy.



**Dora Rau** SVP Quality

Dora Rau brings 25 years of experience in development and commercial operations for drugs, biologics, devices and combination products to the team. She has held numerous executive-level quality positions, with expertise in building quality systems and in leading teams to attain successful regulatory authority inspection outcomes and product approvals.



Jonathan Gold

Over the last 25 years, Jonathan Gold has been an institutional venture capitalist, a public fund manager, a founder, an operating executive, and a board member for companies across sectors including life sciences. In those roles, he was active in the development, financing and mergers and acquisitions for numerous public and private companies.



### '1805 Our Revolutionary Protein Drug to Treat Autoimmune Diseases



#### '1805 Lead indications

**Uveitis** 

RA

Select Additional Indications

Celiac disease

Ulcerative colitis (UC)

Crohn's disease

Multiple sclerosis

ANCA Positive Vasculitis

Autoimmune Hepatitis

Many others



Phase 2 trial complete showing disease remission with single dose out to 12 weeks



Upcoming: Phase 2 trial in patients with moderate-to-severe RA to further assess clinical response duration and disease remission

Upcoming: Phase 2 trial in patients with *non-infectious uveitis* 



Performed a systematic review of >150 autoimmune diseases, identified *pipeline expansion* into additional indications



### • '1104 Our Revolutionary Peptide Drug to Treat Allergic Diseases



#### '1104 Lead indications

Eosinophilic Esophagitis (EoE)

Allergic Disease

Select additional indications

Food Allergy

Allergic Asthma

Allergic Bronchopulmonary Aspergillosis

Eosinophilic Gastritis and Duodenitis

Contact Dermatitis

Pet Allergy

Many others



Placebo-controlled, Phase 1 study in 94 healthy and mild asthmatics shows '1104 safe at clinical doses

Placebo controlled phase 1 MAD study no SAE's

'1104 shown to increase levels of A20, a key regulator of the inflammatory response



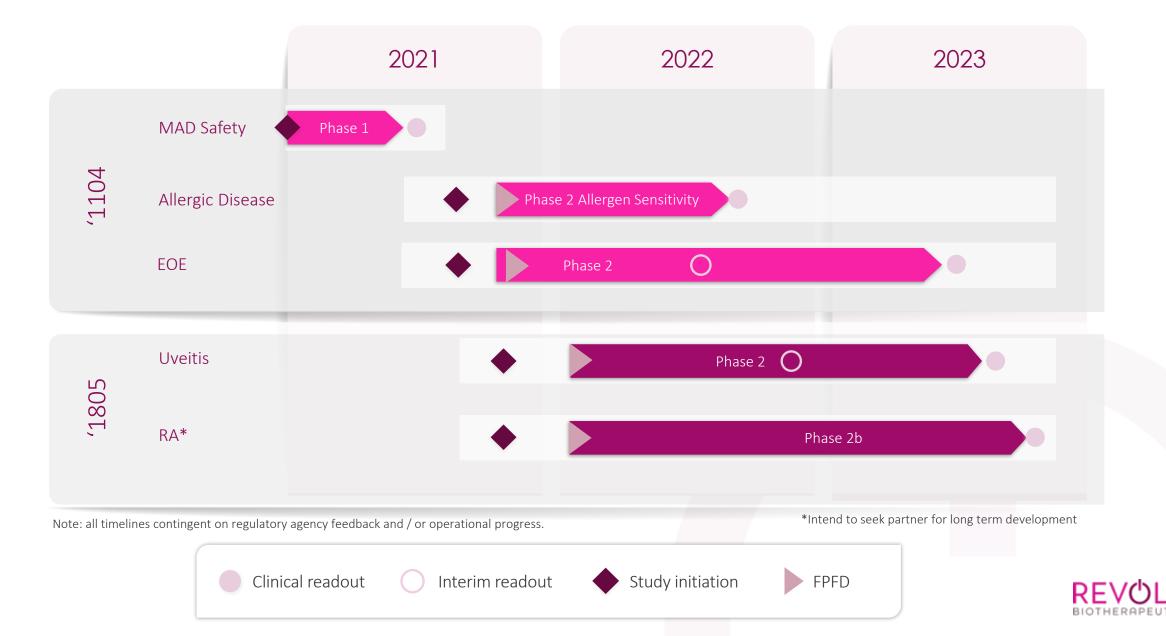
Upcoming: Phase 2 trial in patients with EoE and Phase 2 Allergen Sensitivity Study



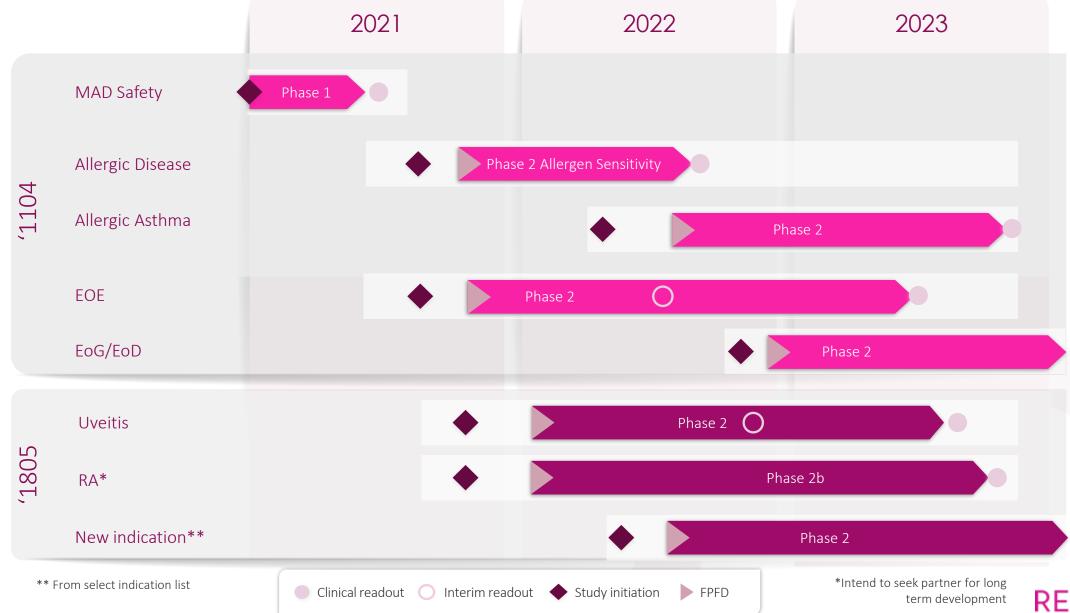
Performed a systematic review of >150 autoimmune diseases, identified *pipeline expansion* into additional indications



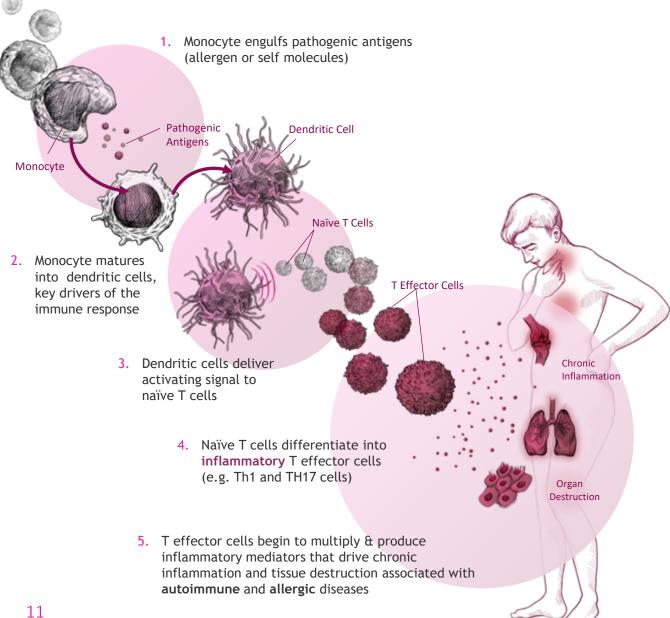
### Cascade of Clinical Readouts to Drive Value



# • IPO to Drive Value With Additional Indications

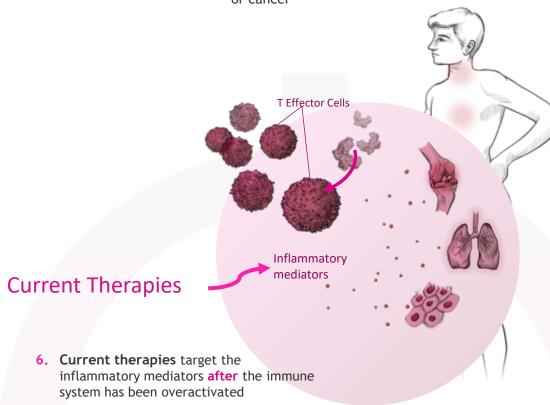


### MOA; Current Therapies Treat Downstream After Inflammatory Mediators Released

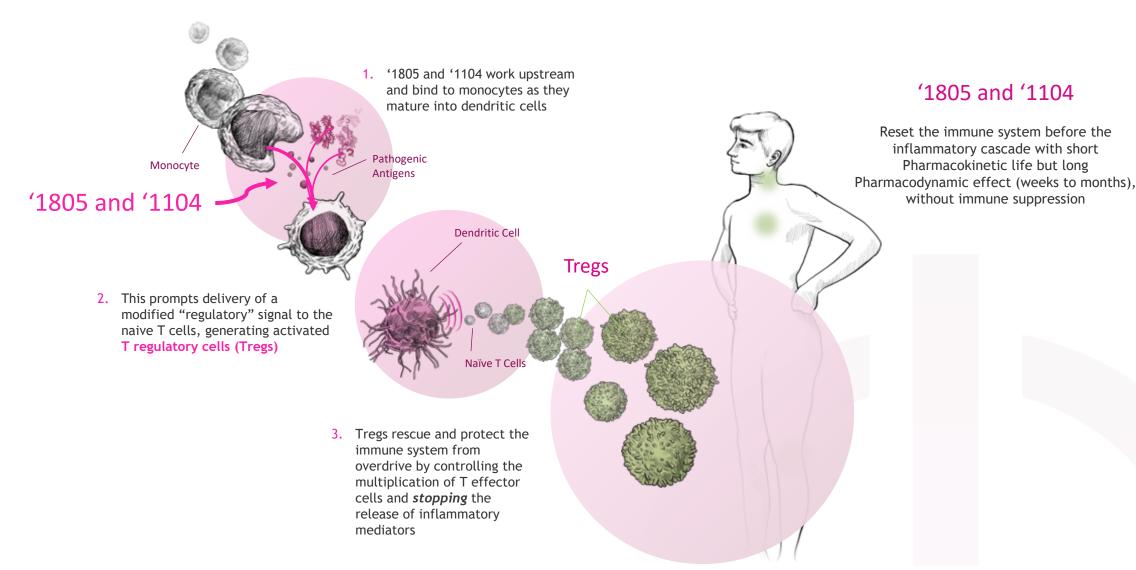


### Current Therapy Treatment

Require frequent dosing, provide short-term disease remission in a limited number of patients and suppress the immune system making patients susceptible to serious infection or cancer



### → MOA; '1805 and '1104 **Reset** the Immune System *Upstream* to Prevent Inflammatory Mediator Release



4. Since Tregs live for a long time, '1805 and '1104 may lead to long-term disease remission by resetting the immune system to its normal regulatory state without immune suppression

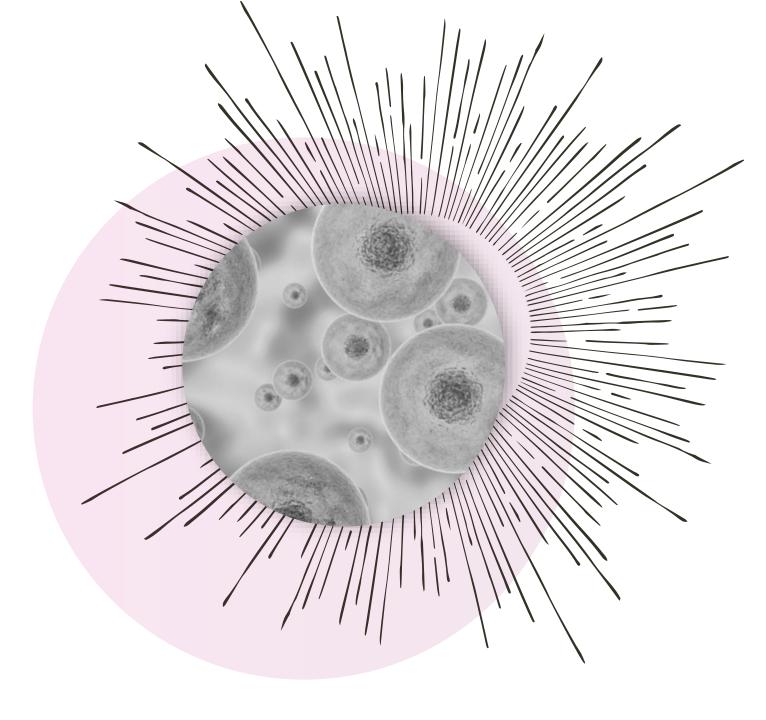




# 1805

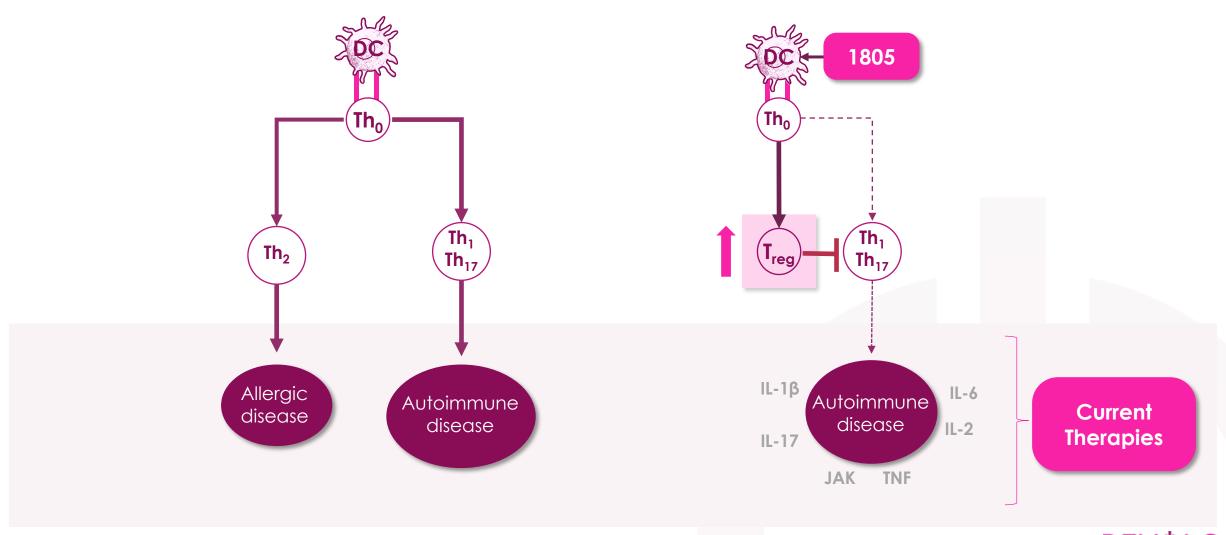
First-in-class modified analogue of the endogenous Binding Immunoglobulin Protein, BiP.

Reset the Immune System for longterm autoimmune disease remission.



# Revolutionary Upstream Targeting to Avoid Overactive Immune Response

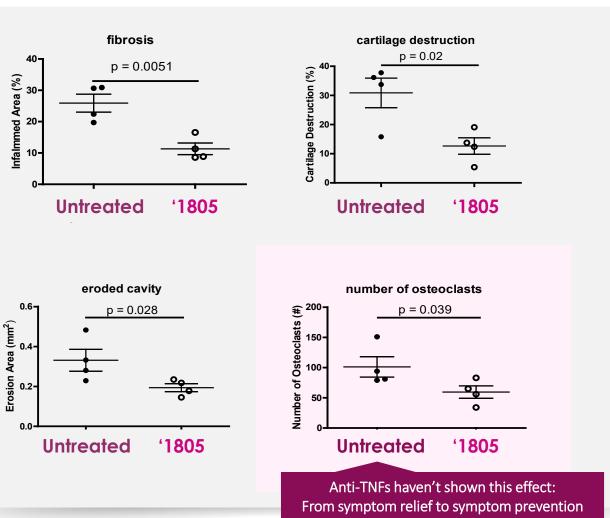
Our therapeutics increase T-regulatory cells that control inflammatory T-effector cells

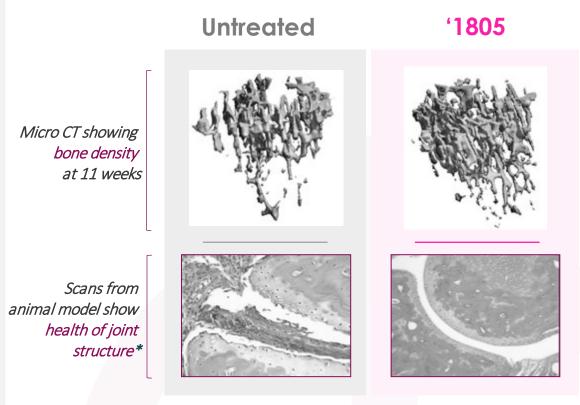




# Strong Pre-clinical Profile – We Have a Wealth of Data

In a gold-standard mouse model, a single administration of '1805 positively reduced fibrosis, cartilage destruction and cavity erosion and decreased osteoclast numbers while achieving long-term disease remission.







# O Short PK, Long PD, Disease Remission in Phase 2 Trial From a Single Dose

'1805 shows remission in some refractory patients in Rheumatoid Arthritis

	Low Disease Activity Week 3 DAS28	Remissions <b>Week 12</b> DAS28	Inflammatory Biomarker Change*	T <sub>reg</sub> cells Change
Placebo <i>n=6</i>	0	0	$\uparrow$	-
1 mg <i>n=6</i>	0	0	-	-
5 mg <i>n=6</i>	3	1	$\downarrow \downarrow$	$\uparrow \uparrow$
15 mg <i>n=6</i>	2	2	$\downarrow \downarrow$	个个

<sup>\*</sup>Includes CRP, VEGF, TNFα, INFγ, IL-1β, IL-6, IL-8

Most patients had *failed multiple DMARD therapies*, and remained on a DMARD during the study

*Four patients* had failed up to eight biologic therapies

*No* safety and tolerability *signals* 

- AE and SAE distributed equally across groups
- No infusion related reactions

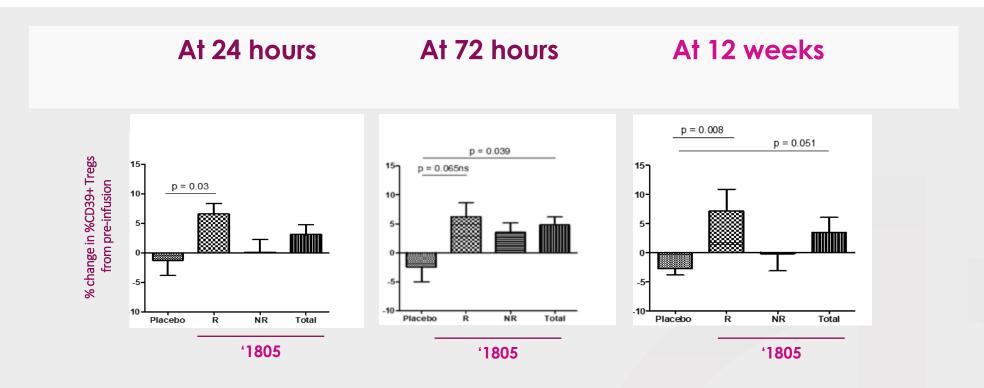
**Reduced** bone loss not seen with current standard of care like DMARDs and anti-TNFs (e.g. Humira) was also achieved.

We believe 15mg is on the low end of the therapeutic range and plan to *evaluate* a range of higher doses in our upcoming *phase 2* clinical study



Phase 2 Clinical Response Correlates with Increased Activated Treg Cells and is Durable to 12 Weeks After a Single Dose





CD4+ CD25hi CD127lo CD39+



# Superior Long-Term Remission Without Ongoing Drug Exposure

Short PK and long PD for '1805 offers multiple potential advantages vs current biologics



Current Biologic Therapies: Long PK and Long PD

Suppresses the immune system

Safety

Humira in RA:

• 64% of patients discontinue at 1 year, and only ~90% at year 12

Durability of Effect and

Adherence

• Crohns: annual risk of loss of response is ~18%

> Less frequent drug exposure with short PK

Drug Exposure

Chronic drug exposure

off-target Aes eg

heightens potential for

infections and cancer

Exploring multiple RoAs

- Symptom relief
- Anti-drug antibodies are associated with *loss of effect*

Efficacy

'1805: Short PK and Long PD

(No suppression of the immune system)

Well tolerated and *no AEs* from phase 2 study

- Reducing exposure may reduce loss of effect due to ADA response and other escape mechanisms
- Longevity of action dependent on generation of T<sub>reg</sub> response

- Symptom prevention
- Points to a novel and unique MoA



<sup>1</sup> Pappas "Long-Term Effectiveness of Adalimumab in RA" Rheumotl Ther 2017

<sup>2</sup> Chaparro et al, "Long-term durability of response to adalimumab in Crohn's Disease," IBD, 2012

<sup>3</sup> Bartelds et al, "Development of antidrug antibodies against adalimumab and association with disease activity and treatment failure during long-term follow up, JAMA 2011

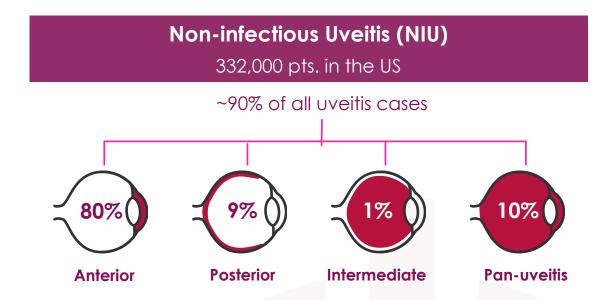
# Preparing for Phase 2 Study - Non-infectious Uveitis

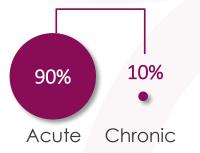
1805

- Non-infectious uveitis (NIU) or inflammation of the inside of the eye is leading cause of blindness (~10-20% of cases)
- Most severe and difficult to treat presentation (~310k cases)
- Untreated, NIU can cause vision loss in up to 40% of patients
- Even if temporary, vision loss interferes with productivity and negatively impacts quality of life
- ~87,000 patients treated annually
  - ~50% non-responsive to adalimumab (Humira), the only approved biologic
  - Steroids are mainstay of therapy despite well-known ocular and systemic adverse effects.

"We don't have great steroid-sparing treatment for refractory disease."

-KOL interview





~80% are anterior, but posterior, intermediate, and pan-uveitis subtypes more severe and sight-threatening. Chronic anterior cases treated more aggressively.

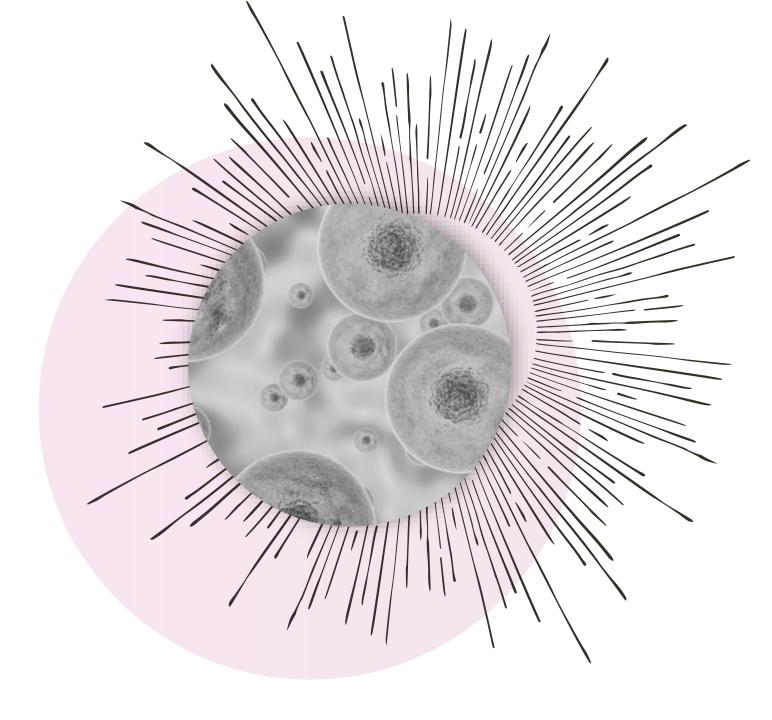




# 11104

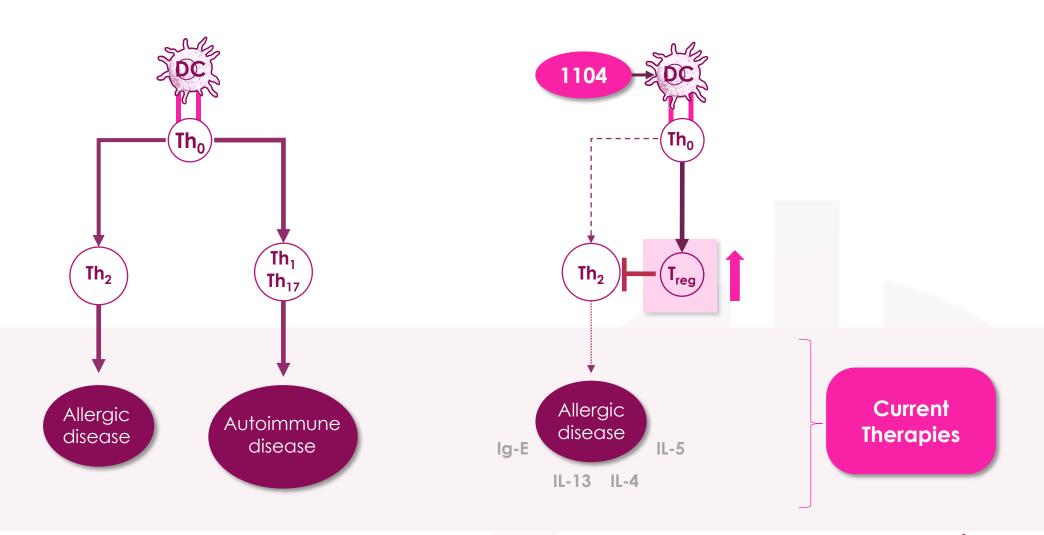
First-in-class peptide derived from immuno-regulatory protein (mTB chaperonin 60.1).

Reset the Immune System for long term allergic disease remission.



# Revolutionary Upstream Targeting to Avoid Overactive Immune Response

Our therapeutics increase T-regulatory cells that control inflammatory T-effector cells





### • '1104 is a Druggable Fragment of Chaperonin 60.1

### Demonstrates the Same Immune Resetting Properties

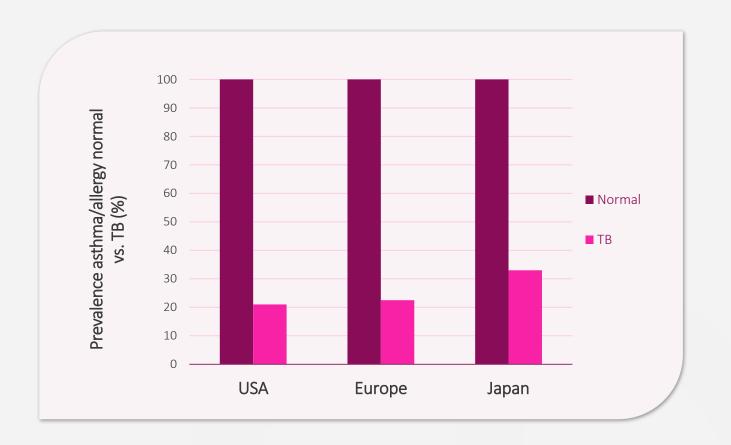


Meta-analysis of >260K humans exposed to tuberculosis (TB) are found to be 75% less likely to develop allergy/asthma\*

Studies identified a key bacterial protein responsible (Cpn 60.1)

'1104 was derived from Cpn 60.1

- It has the same immune *resetting* properties of Cpn 60.1 but is easier to manufacture
- It does not compromise safety or suppress the immune system



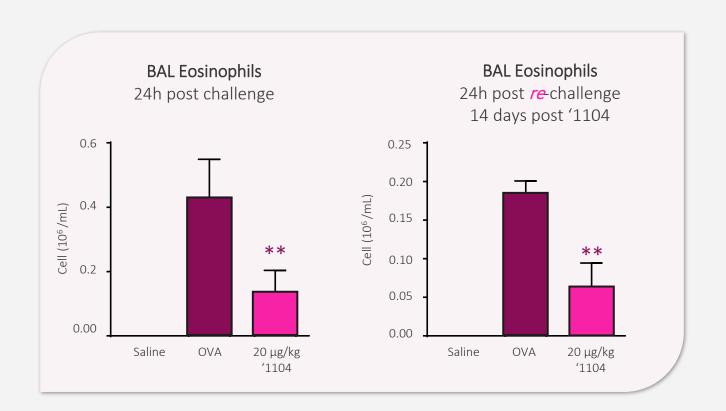


#### 1104

# Pre-Clinical Data of Long-term Reduced Cellular Inflammation

on 🥼

Prevents response to allergen re-challenge 14-days post treatment



Short PK but long PD points to *profound longevit*y of action

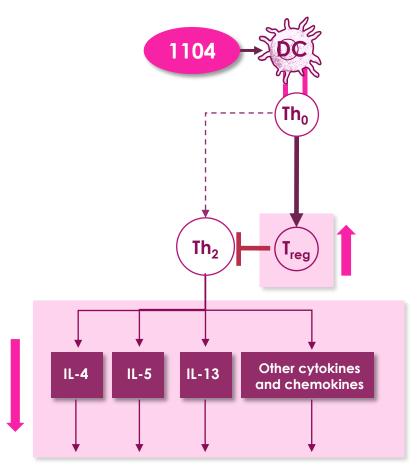
'1104 prevents eosinophil recruitment to the lung following ovalbumin (OVA) challenge and re-challenge at 14 days

'1104 is allergen-agnostic and *reduces* the cellular *inflammation* to a wide range of allergens

No immunosuppression observed



# Preclinical Data Shows That Single Dose Resets Allergic Response

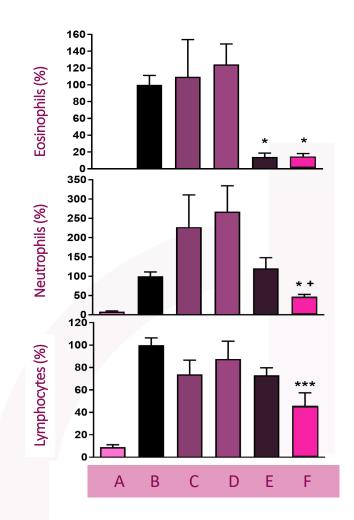


Barrier disruption, tissue remodeling and fibrosis, eosinophil trafficking

• 20 ug/kg translates to  $^{\sim}$ 2mg in human – a dose lower than our EoE clinical study (8 mg)

### 14 days after single dose of '1104 with HDM re-challenge at day 14:

- '1104 resets allergic response of all 3 key inflammatory cells
- '1104 reduces key Th2 cytokines



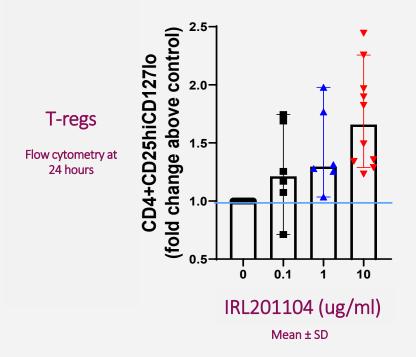
- A; Saline
- B; Saline / HDM
- C: Fluticasone
- D; Montelukast
- E; IL-5 mAb
- F; '1104

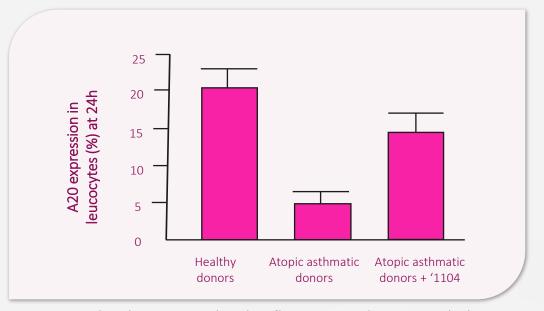


### Ex-vivo Studies Show Increase of Tregs and Restoration of A20 in Blood

'1104 increases the expression of A20, a key regulator of the inflammatory response

### '1104 increases the number of Treg cells





- Low A20 levels associated with inflammatory diseases including asthma°
- A20 is a key negative regulator of the family of nuclear factor-κB transcription factors (NF-κB), which control a broad range of cellular activities including cell activation and inflammatory pathways
- In blood cells from severe asthmatics, '1104 shown to restore levels of A20 to those seen in healthy donors



# Demonstrated Safety and Tolerability in Two Phase 1 Studies





Two placebo-controlled Phase 1 studies included healthy volunteers and mild asthmatics and demonstrated that '1104 is safe at clinically relevant doses



#### Single Ascending Dose:

94 participants dosed with '1104 intravenously or subcutaneously

- 62 healthy volunteers and patients with mild asthma received at least one dose of '1104
- 32 received placebo



18 healthy volunteers, dosed with '1104 intravenously once daily for up to 7 days

- 4mg arm (n=8; 6 active, 2 placebo) QD for 5 days and 8mg (n=10, 8 active, 2 placebo) QD for 7 days
- Further supportive of 8mg dose EoE trial
- No serious adverse events
- No severe AEs
- No AEs leading to withdrawal





# Target Indication: Eosinophilic Esophagitis

1104

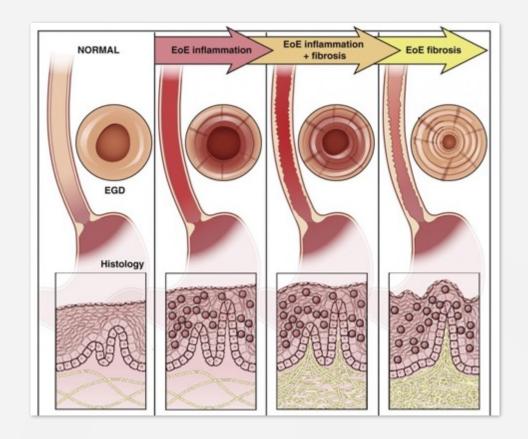
EoE is a progressive disease characterized by food impaction, reflux and difficulty swallowing that affects children and adults.

~180,000 people in the U.S. and up to 80% of patients have secondary allergic conditions.

Early disease control is *critical* to avoid fibrosis.

Standard of care includes chronic proton pump inhibitors, steroids and dietary restriction, which lead to *unwanted side effects* and poor compliance.

There are *no FDA approved* drug products, and 50,000 patients are unresponsive to current treatments, including long-term steroids







# '1104 Upstream Resetting of Immune Cells to Treat EoE Rather Than Downstream Blocking of Select Cytokines



Biologic	$T_{reg}$	IL-4	IL-5	IL-13	A20*	Reduce Eosinophils?	Symptomatic EoE success?
Mepolizumab			<b>\</b>			✓	
Reslizumab			$\downarrow$			✓	
QAX576				$\downarrow$		✓	
Cendakimab				$\downarrow$		✓	?
Dupixent		$\downarrow$		$\downarrow$		✓	✓
′1104	<b>↑</b>		$\downarrow$		<b>↑</b>	<b>√</b>	Phase 2 trial Q3 2021

- '1104 reduces relevant Th2 cytokines (IL-4, IL-5, IL-13)
- '1104 preventing not just cytokines but the inflammatory cells themselves
- \* A20 is a negative regulator of NF-kB, which controls a broad range of cellular activities including cell activation and inflammatory pathways



# Revolutionary Company with Revolutionary Therapies









Developing two therapies that *Reset* the immune system for *long-term* remission

#### Demonstrated Efficacy and Safety

- '1805 Phase 2 study achieved remission in Rheumatoid Arthritis
- '1104 Phase 1 study (94 healthies and asthmatics) safe and tolerable and shown to be a key regulator for Allergic Disease
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#### Multiple *Near-Term* milestones:

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#### **Strong** cash position

- \$54M Series B September 2020
- In process of S1 drafting
- Exploring Crossover to IPO
- Exploring PIPE to SPAC





Lagniappe



### <del>-</del>

### Board Members and Investors

#### Peter Greenleaf, Chairman

Peter Greenleaf currently serves as the Chief Executive Officer and member of the Board of Directors of Aurinia. From March 2018 to April 2019, Peter served as the Chief Executive Officer of Cerecor, Inc. From March 2014 to February 2018, CEO and Chairman of Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP). sold in February 2018 to UK pharmaceutical company Mallinckrodt PLC. From June 2013 to March 2014, Peter served as CEO and a member of the Board of Directors of Histogenics Corporation,. From 2006 to 2013, he was employed by Medlmmune LLC, the global biologics arm of AstraZeneca, where he most recently served as President. From January 2010 to June 2013, Peter also served as President of Medlmmune Ventures, a wholly owned venture capital fund within the AstraZeneca Group. Prior to serving as President of Medlmmune, Peter was Senior Vice President, Commercial Operations of the company. He has also held senior commercial roles at Centocor, Inc. (now Jansen Biotechnology, Johnson & Johnson) from 1998 to 2006 and at Boehringer Mannheim (now Roche Holdings) from 1996 to 1998. Peter currently chairs the Maryland Venture Fund Authority, whose vision is to oversee implementation of Invest Maryland, a public-private partnership to spur venture capital investment in the state. He is also currently a member of the Board of Directors of Antares Pharmaceuticals, Inc. (NASDAQ: ATRS) and Chairman of the Board of Directors of Biodelivery Sciences International, Inc. (NASDAQ: BDSI). Peter earned an MBA from St. Joseph's University and a B.S. from Western Connecticut State University. Peter's significant executive management, leadership, corporate development, and commercial operations experience in the biopharmaceutical industry enables him to provide valuable insight to our Board of Directors.

#### Jonathan Rigby, Chief Executive Officer & Board Director

Experienced CEO with three productive decades of pharmaceutical, biotech and drug delivery technology value creating achievements. In 2011 he became the CEO of SteadyMed Therapeutics Inc. and focused the company on the development of drug device combination products to treat Pulmonary Hypertension. He led the company through a Nasdaq listing in 2015 (Nasdaq: STDY) and a public-to-public company sale to United Therapeutics (Nasdaq: UTHR) in late 2018. In 2006 he cofounded Zogenix, Inc. (Nasdaq: ZGNX) a specialty pharmaceutical company now focused on the development and commercialization of drug products to treat rare diseases and was instrumental in its listing on Nasdaq in 2010.

#### Isaac Cheng, MD, Board Director

Dr. Cheng joined Morningside in 2006 and focuses on biopharmaceutical and healthcare investments. He has served on numerous public and private company boards, including NuCana (NASDAQ: NCNA), Advanced Cell Diagnostics (sold to Bio-Techne), Liquidia Technologies, Meissa Vaccines, Amylyx Pharmaceuticals, Cognoa, Artugen Therapeutics, Cognito Therapeutics, Big Health, and Tallac Therapeutics. Prior to joining Morningside, Dr. Cheng was Director of Research and Development at Serica Technologies, a Morningside portfolio company which was sold to Allergan. In addition, Dr. Cheng was previously an Associate Director at Novartis Pharmaceuticals in Clinical Development and Medical Affairs. Dr. Cheng received his M.D. from Tufts University School of Medicine.

#### Michael Albisser, Board Director

Michael is a partner of Metellus, a Zurich and London-based venture capital firm investing in technology and life sciences with ground-breaking potential. Having more than 25 years of experience in the finance area he is responsible for finance, tax, and deal structures. He serves on the board of various venture-backed companies







24 Haymarket (U.K.)



Metellus AG (Switzerland)



NCL Technology Ventures (U.K.)



Dara Capital (Switzerland)



Wellcome Trust (U.K.)











King's College London (U.K.) Greenwood Way Capital (U.K.)

CVC (Australia)

Suntrust Investment (Switzerland)

Gunderson Dettmer (U.S.A.)

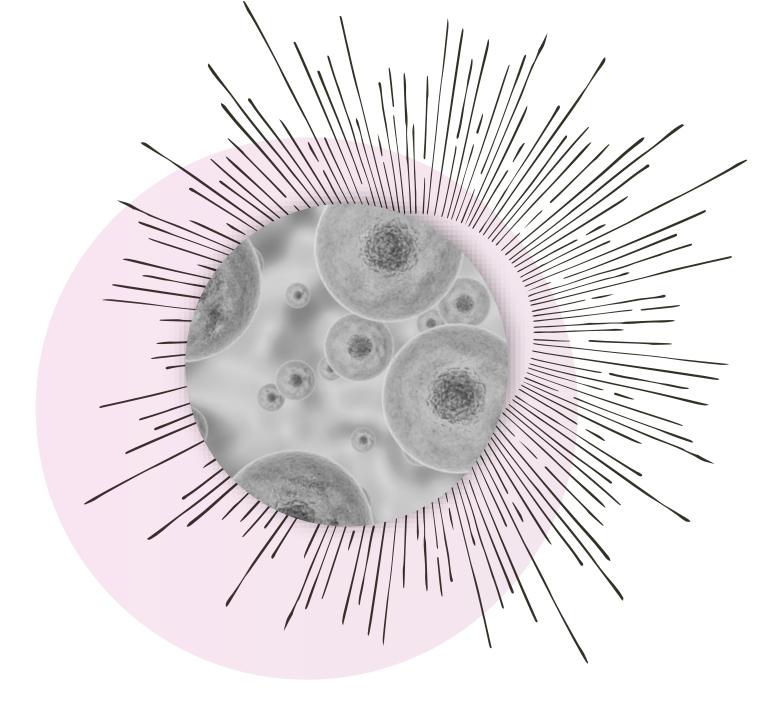




# 1805

First-in-class modified analogue of the endogenous Binding Immunoglobulin Protein, BiP.

Reset the Immune System for longterm autoimmune disease remission.



# Rheumatoid Arthritis (RA): Existing Unmet Need





RA is a chronic inflammatory disease that can be *disabling* for patients



It represents one of *the largest therapeutic areas* worldwide, affecting roughly *1.3 million* people in the United States (U.S.).\*



#### Though treatment options exist:

- 60-70% of patients *do not achieve r*emission with current options
- ~20% of patients are *refractory* to current options with risk serious infection and cancer



Pfizer's big blockbuster Xeljanz flunks its post-marketing safety study, renewing harsh questions for JAK class

January 2021



### Current options *induce immune suppression* and other *risks*:

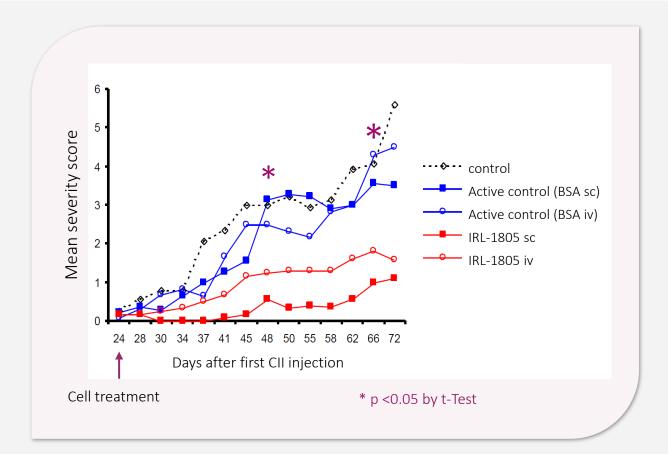
- Filgotinib: Discontinued due to safety concerns
- Baricitinib: High (and more efficacious) 4mg dose not approved by FDA; only approved 2mg dose due to safety
- Tofacitinib: Failed non-inferiority safety trial vs. TNF inhibitors on both MACE and cancer endpoints
- Janus kinase inhibitors (JAKs): Black box warnings for



Market opportunity is *\$20B* in the U.S. and \$40B globally



### Adoptive Transfer of Reset Cells From CIA Mice Treated with Single Dose of '1805 Prevents Arthritis in Naïve Sensitized Recipients (IV And SC)



Transfer of splenocyte and lymph node cells from mice given '1805 can *reset the immune system* to suppress active CIA (collagen-induced arthritis)

Spleens and lymph nodes were removed from groups of DBA-1 mice 12 days after they had been treated s.c., with 200mg '1805 or the control protein, BSA, or i.v., with 10mg '1805 or BSA

Cell cultures were set up with  $20\mu g/ml$  of the respective protein ('1805 or BSA) and then administered i.p. into DBA-1 mice that had been injected with CII/CFA 24 days previously (n=6/7 per group)

Data shown represents the *mean severity score* 

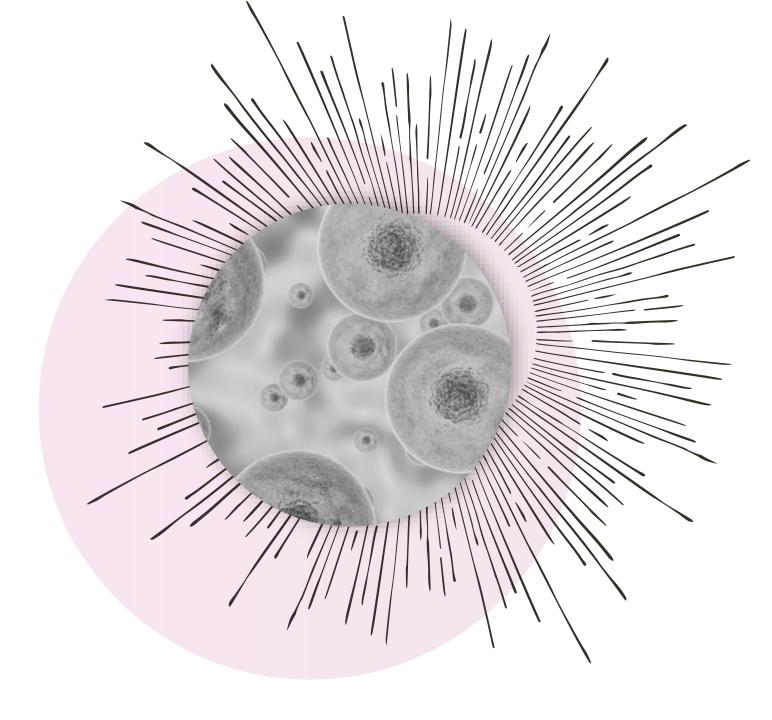




# 11104

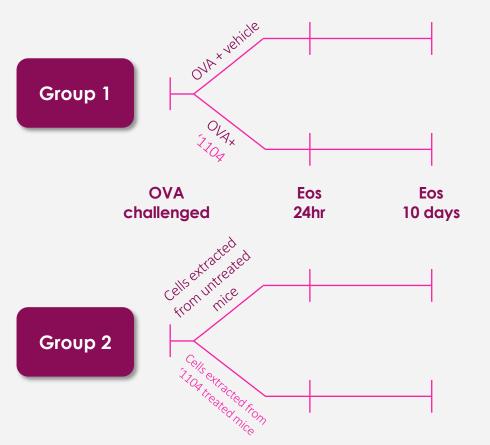
First-in-class peptide derived from immuno-regulatory protein (mTB chaperonin 60.1).

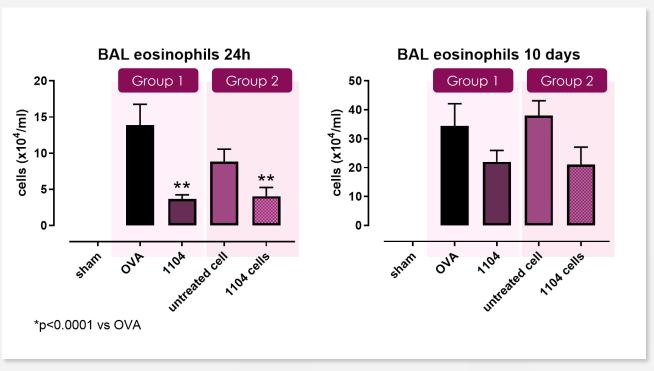
Reset the Immune System for long term allergic disease remission.



## An '1104- Reset Immune System can be Adoptively Transferred to Show an Effect in Mice Never Exposed Directly to '1104

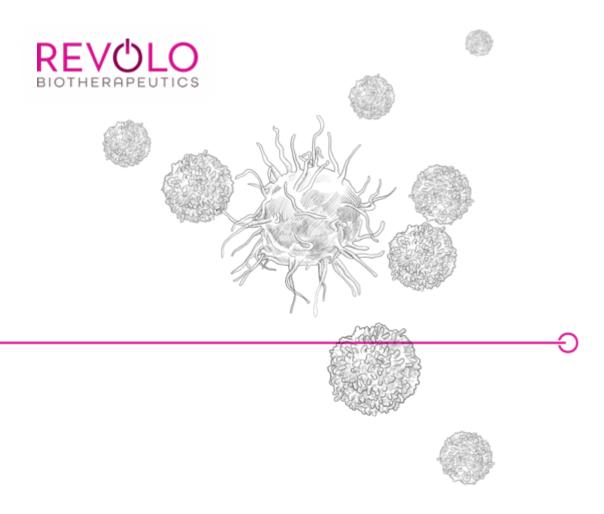






Immunity induced by '1104 in the donor mice is transferred for an anti-inflammatory effect in recipient mice





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