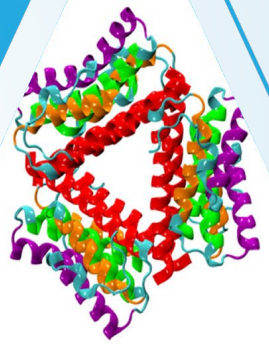
Amilo-5MER

Amilo-5MER, Specific, Targeted Immune - Modulator for the Treatment of Chronic Inflammatory Diseases



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Important Disclaimer

Research of Amilo-5Mer is currently being conducted under a research and option agreement with Yissum, the tech transfer company of the Hebrew University. Under the agreement, Galmed has been granted an exclusive option to negotiate and enter into a definitive license agreement with Yissum for Amilo-5Mer upon certain pre-agreed upon terms and such other terms to be agreed upon. Galmed plans to exercise its option if the planned Phase 1a first-in-human study is successful, however there can be no assurance that Galmed will enter into a definitive license agreement or that it will be on terms favorable to Galmed. If Galmed does not enter into a definitive license agreement, then Galmed will not have the ability to continue the development and potential commercialization of Amilo-5Mer.

Amilo-5MER Highlights

Amilo-5MER is a Differentiated, Specific and Selective Immune-Modulator

- Amilo-5MER is a penta-peptide that prevents Serum Amyloid A (SAA) polymerization and aggregation
- Prevention of SAA polymerization and aggregation results in shut down of chronic inflammation

SAA is a validated target for the treatment of chronic inflammation

- SAA concentration in serum rise rapidly in response to acute stimuli such as infection and trauma
- Elevation of SAA is a common bio - marker as well as main cause of inflammation
- SAA is effective in enhancing chronic inflammation only in it's aggregated form

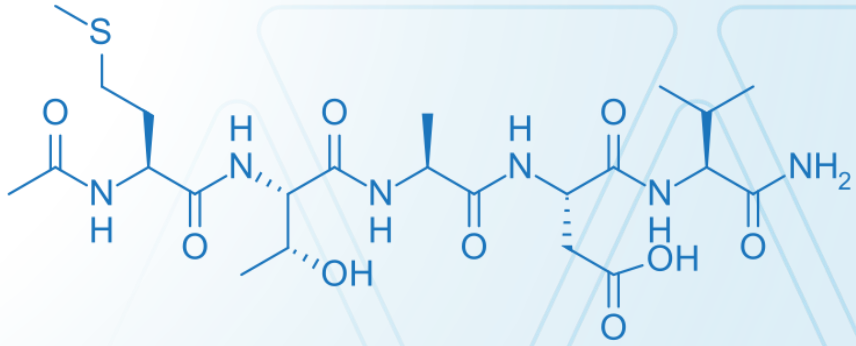
Pursuing multiple large indications

- Inflammatory Bowel Disease (IBD)
- Rheumatoid Arthritis (RA)
- Potential for COVID-19 - Acute Respiratory Distress Syndrome (ARDS)

Main anticipated short-term milestones

- First-in-human Phase 1a topline data expected in Q1 2021
- Phase 1b/2a Study in IBD patients – Inc. biomarkers (SAA in serum) expected in H2 21

Established manufacturing process and IP protection beyond 2034



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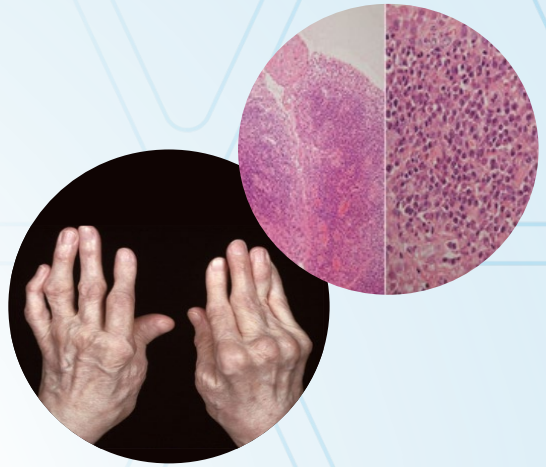
How Was Amilo-5MER Discovered?



Isolation of joint inflammatory cells

↓

Identification of the MTADV (Methionine, Threonine, Alanine, Aspartic acid, & Valine) sequence in the human CD44 variant

↓

Searching in the protein data bank reveals two proteins that contains the complete sequence MTADV

↓

Production of synthetic MTADV peptide Amilo-5MER

↓

Identification of pathological proteins targeted by Amilo-5MER

Amilo-5MER is a Pentapeptide Specifically Sequenced to Interfere with SAA Aggregation to Prevent Inflammation

SAA - a validated biomarker and target for acute and chronic inflammatory disease

- SAA has pro-inflammatory properties only in it's aggregated forms
- Aggregated SAA is a key player in the destructive autocrine, self-amplifying cytokine loop leading to chronic inflammation and tissue destruction
- SAA is elevated by over 1000 fold in multiple autoimmune diseases

Amilo-5MER – potential to be specific and selective immune-modulator[1]

- Amilo-5MER is a specific amino acid sequence, homologue to the human CD44 variant which displays an efficient anti-inflammatory effects
- Amilo-5MER interferes significantly with SAA aggregation, a key player in the vicious cycle of inflammation
- Significant reduction in chronic inflammation in animal models of RA, IBD and MS

Amilo-5MER – Highly Potent Drug Candidate

- Prominent improvement of clinical symptoms, histological features and reduction of pro-inflammatory cytokine secretion in animal models
- Addresses downregulation of chronic inflammation with complete preservation of immune surveillance
- Strong preclinical package: very good PD effects and excellent safety profile

Amilo-5MER – key upcoming milestones

- Phase 1a - single and multiple dose in healthy volunteers – topline data expected in Q1 2021
- Phase 1b/2a Study for IBD Inc. biomarkers (SAA in serum) planned for H2 2021

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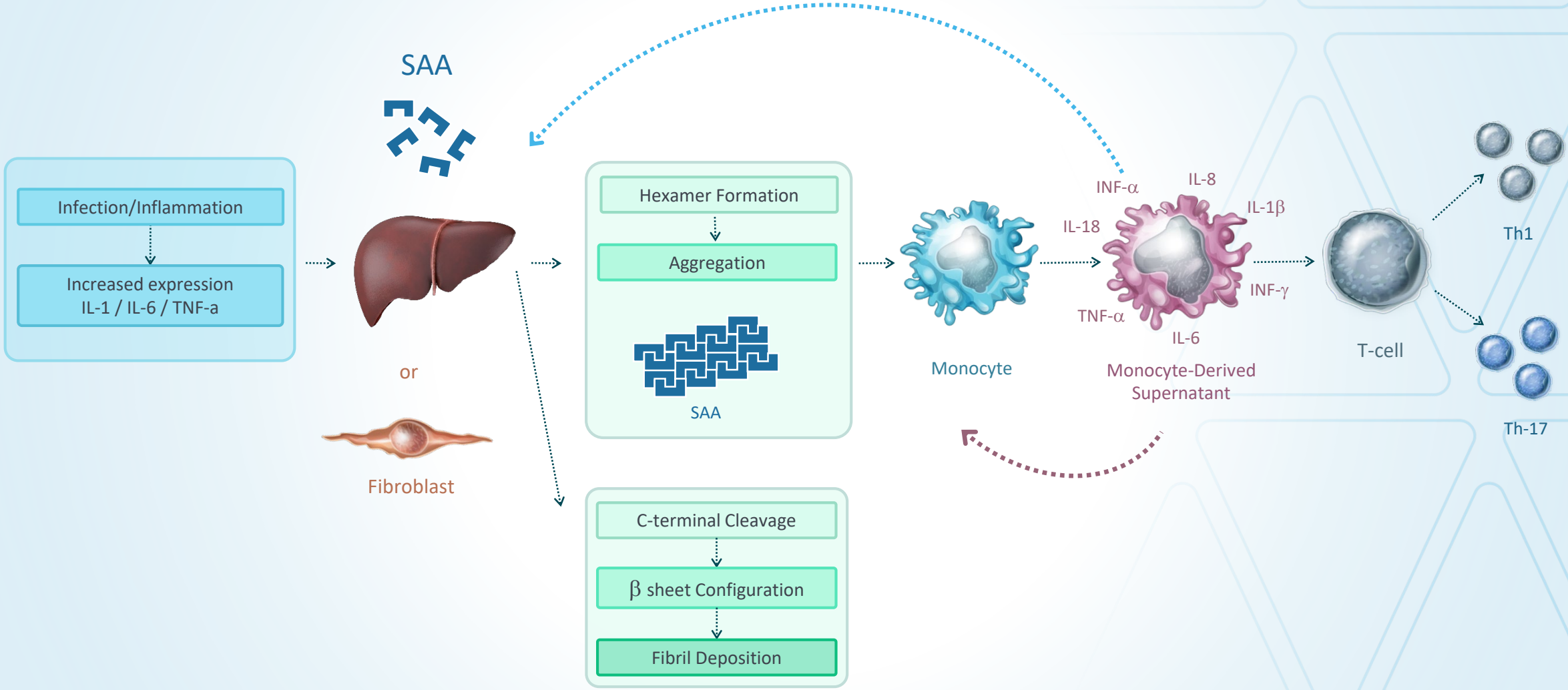
[1] David Naor, et al., A HUMAN-DERIVED 5-MER PEPTIDE (MTADV), WHICH RESTRICTIVELY ALLEVIATES THE PRO-INFLAMMATORY ACTIVITY OF SERUM AMYLOID A (SAA), SUBSTANTIALLY AMELIORATES IBD PATHOLOGY: NEW POTENTIAL DRUG (MTADV) AND THERAPEUTIC TARGET CANDIDATE (SAA) FOR IBD, *Inflammatory Bowel Diseases*, Volume 26, Issue Supplement_1, January 2020, Pages S3–S4,

SAA – an Inducer and Biomarker of Chronic Inflammation



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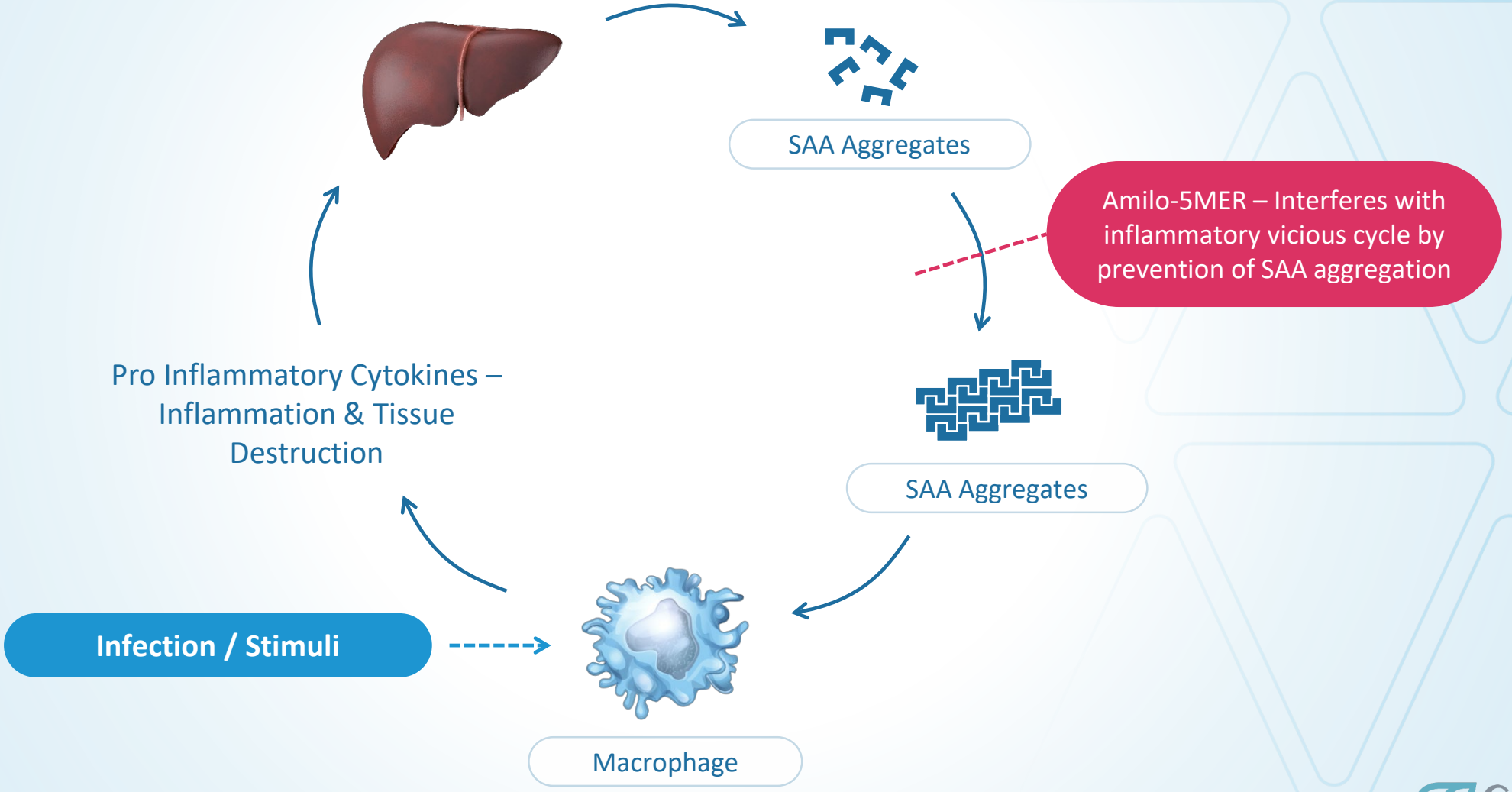
Amilo-5MER Interferes with SAA Aggregation to Inhibit Chronic Inflammation



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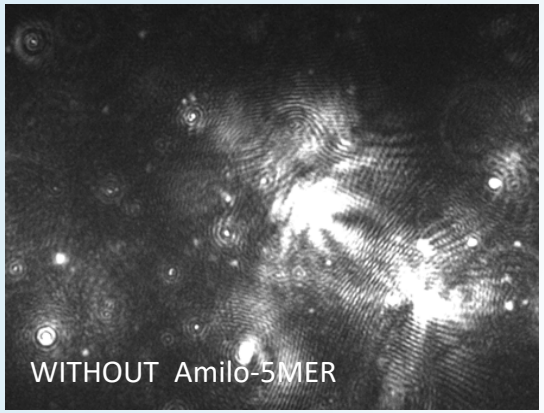
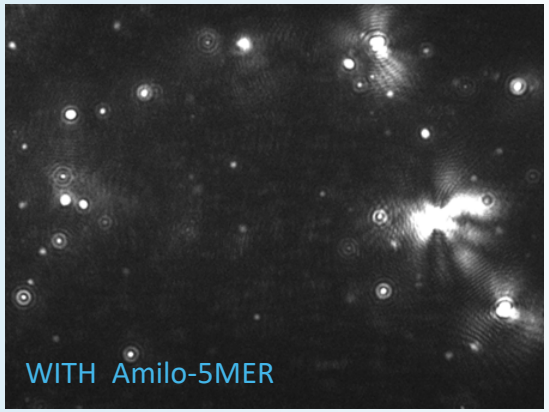
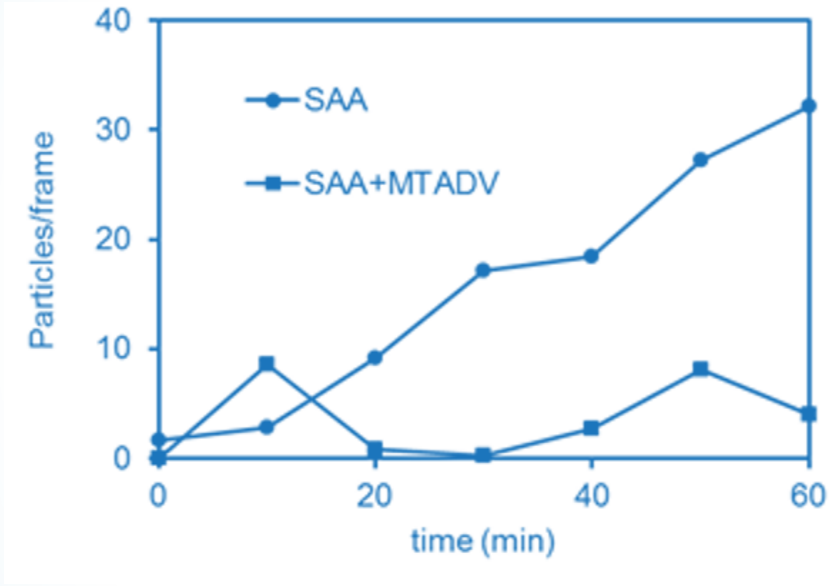
Amilo-5MER Prevents SAA Aggregation





Video recording of Nanoparticle tracking analysis of SAA*



Number of SAA aggregates above a certain size counted in defined frame as function of time

* Research work performed in collaboration with Prof. Mary Cowman from New York University

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Amilo-5MER, an Opportunity in Acute and Chronic Inflammatory Conditions: IBD, RA and COVID-19

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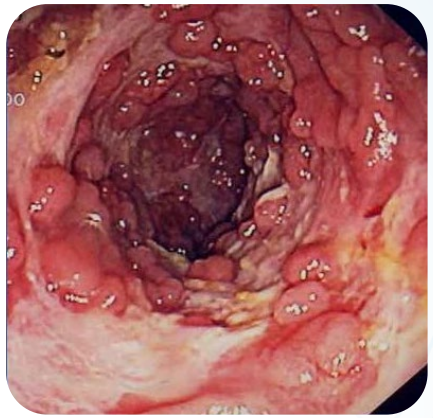
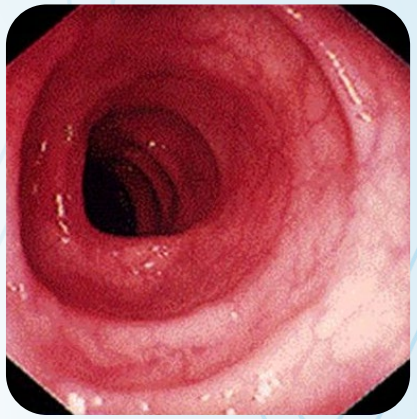
Inflammatory Bowel Disease (IBD)

- IBD (ulcerative colitis and Crohn's disease) is a chronic lifelong disease
- IBD results from the interaction between genetic, microbial and environmental factors
- The treatment goal in IBD is to induce and maintain remission



Colon with Crohn's Disease



Normal Colon

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Current IBD Therapies are Modestly Successful due to Undesired Side Effects

Unmet need in the treatment of patients with mild to moderate IBD

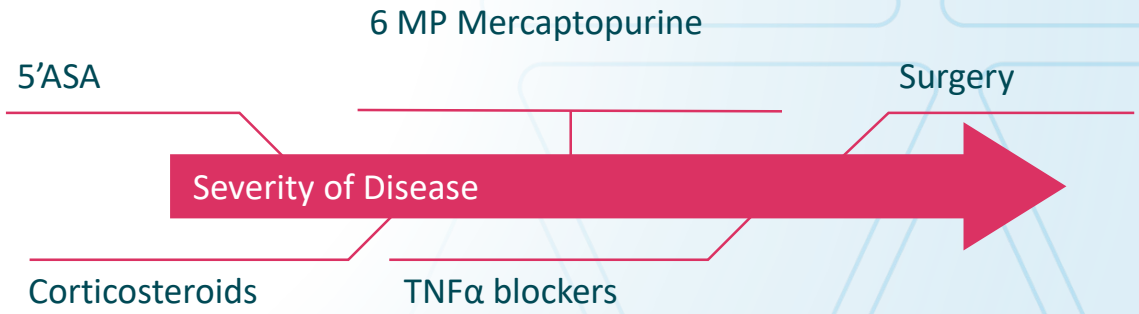
- Treatment of IBD aims to control symptoms sustain remission and reduce complications
- Low risk patient – Step Up approach - less potent drug with good safety profile
- High risk patient- moderate-severe disease - biologic or immunomodulator therapy Top Down approach

The choice of therapy in patients with IBD is dependent upon:

- The anatomic location of disease/ disease distribution
- The severity of disease
- Clinician / patient preferences
- Treatment goal (induce or maintain remission)
- Insurance coverage/cost.

Medical therapies that are used for IBD include

- Oral 5-aminosalicylates (e.g., sulfasalazine, mesalamine) – 5'ASA
- Glucocorticoids (e.g., prednisone, budesonide)
- Immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate)
- Biologic therapies (e.g., TNFα blockers)



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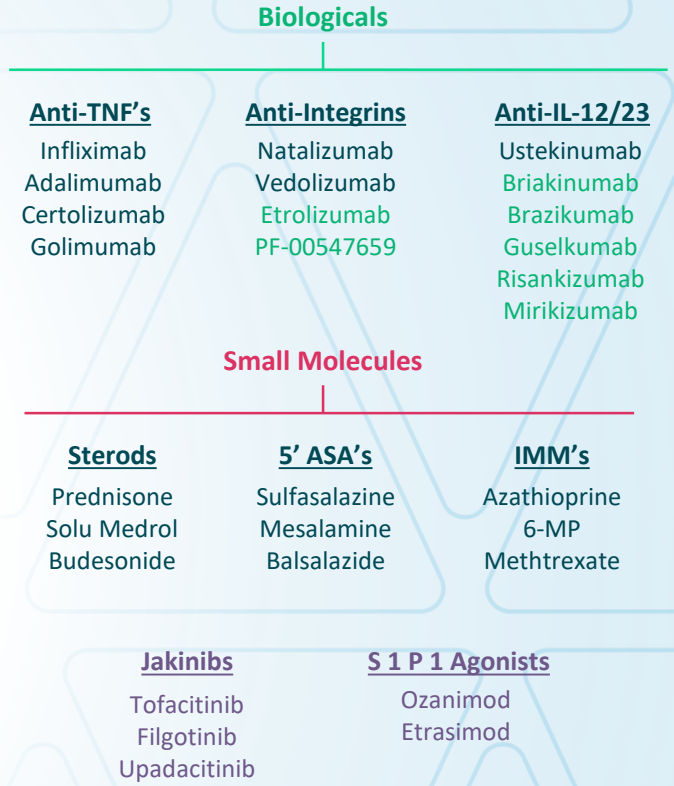
IBD, Current and Future Therapy Directions

- **Current IBD market consists of low-cost generics as well as expensive biologics**
- **Anti-TNFs are essentially effective drugs however, several issues limit their long-term use limitation [1] :**
  - Systemic Immune-Suppression with associated side effects such as an increased risk of infections and lymphoma (rare)
  - Product label – boxed warning due to increased risk of TB and opportunistic infections;
  - High price.
- **Other recently approved biologics include Entyvio (integrin α4β7 Ab for CD and UC) and Stelara (IL12/IL23 Ab for CD); Tofacitinib is an oral, small molecule JAK3 inhibitor that was recently approved for UC, RA and Psoriasis [2].**
- **Amilo-5MER has the potential to be a backbone treatment of IBD**



[1] Overview of the medical management of mild (low risk) Crohn disease in adults Authors: Miguel Regueiro, MD, AGAF, FACG, FACP Jana Al Hashash, MD, MSc Section Editor: Paul Rutgeerts, MD, PhD, FRCP Deputy Editor: Kristen M Robson, MD, MBA, FACG This topic last updated: Nov 25, 2019) .

[2] Use of biologics and unmet medical need Gordon et al. European Journal of Gastroenterology & Hepatology 2015, Volume 27, Number 7

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Amilo-5MER Significantly Affects Clinical Symptoms in IBD animal model (TNBS)

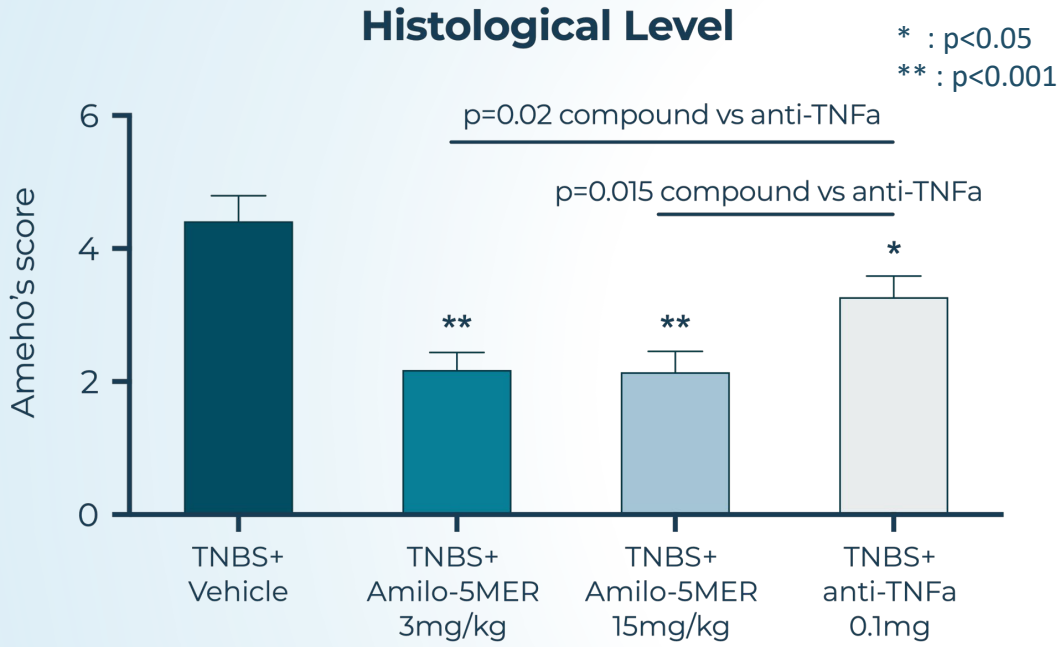
STUDY Description:

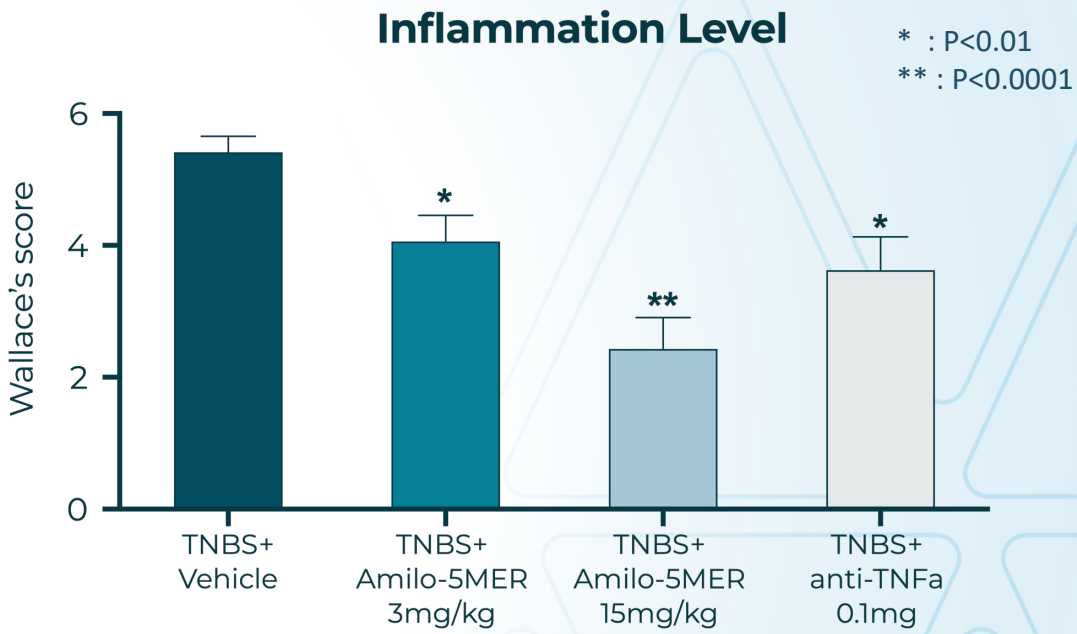
- Evaluation of Amilo-5MER's anti-inflammatory properties was demonstrated in the IBD's Gold standard model of colitis induced by TNBS in C57bl6 mice.
- TNBS model is well-characterized, reliable, reproducible and admitted by regulatory authorities in IBD
- 80 C57bl6 mice TNBS induced were randomized in 4 groups
- Amilo-5MER was administered once a day by subcutaneous injection at 3 and 15mg/kg in a preventive treatment starting 5 days before colitis induction and until euthanasia at day +2. Inflammatory effects were evaluated at the macroscopic level using the validated score of Wallace (0 no inflammation, 5=2 or more ulcerative and inflammatory sites with an extent > 1cm, 6= Ulcerative or inflammatory site > 2cm) and at the histological level (Ameho's score 4= Large inflammatory infiltrate with ulceration area through all the colonic wall, >50% of the section).
- Study performed by: Intestinal Biotech Development, Lille , France

STUDY Results:

Amilo-5MER demonstrated strong, dose-dependent, anti-inflammatory properties at the macroscopic and histological levels. Moreover, Amilo-5MER exerts stronger anti-inflammatory effects at the histological level compared to the positive control, the anti-TNF antibody considered as a benchmark in the treatment of colitis.

Amilo-5MER Significantly Affects Clinical Symptoms in IBD animal model (TNBS)





Amilo-5MER (15mg/kg) exerts stronger anti-inflammatory effects at the macroscopic and histological levels compared to anti-TNF antibody considered benchmark in the treatment of colitis.

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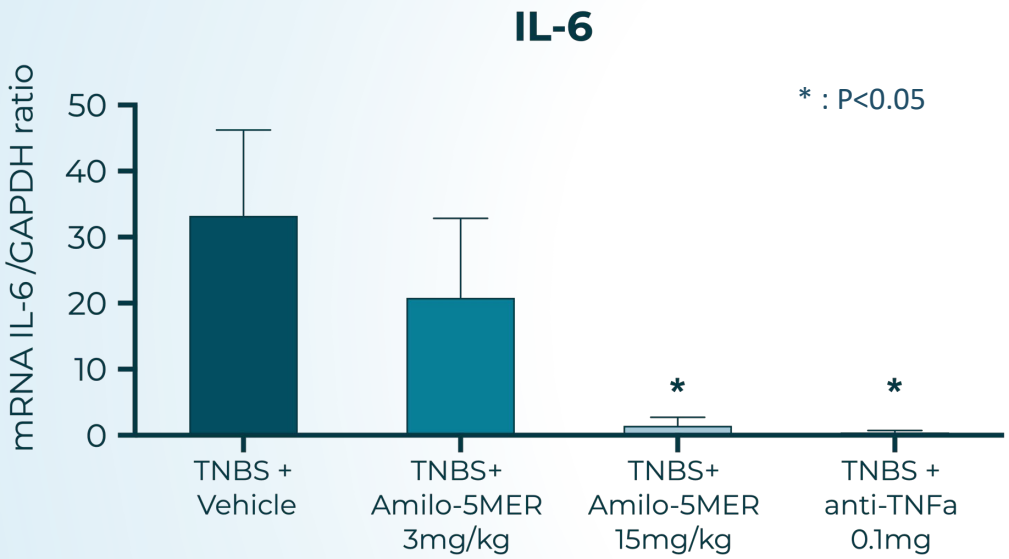
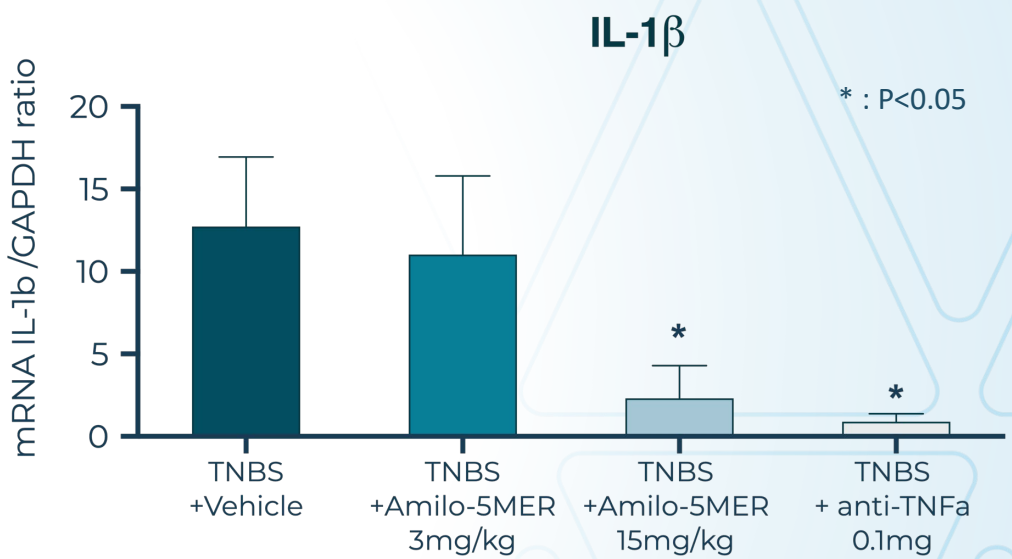
Amilo-5MER Reduces Pro-Inflammatory Cytokines in Animal Model for IBD (TNBS)

Evaluation of the Colonic mRNA levels in TNBS-induced Colitis in Mice





Amilo-5MER (15mg/kg) Significantly Decreases IL-1β and IL-6 gene expression

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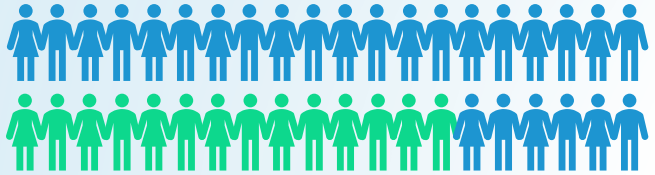
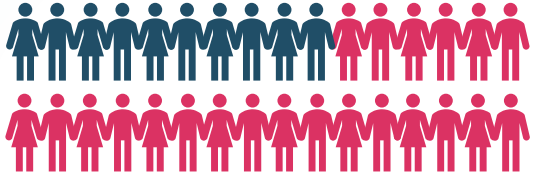
IBD Market Potential [1]

4M people afflicted



1.4M in US

700,000 Crohn's

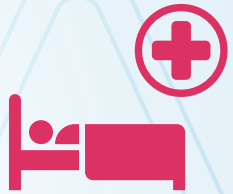


70% require surgery

Physicians visits

700K

Hospitalizations



100K

Global sales forecast (by 2026)

Crohn's Disease

$13.8B

Ulcerative colitis

$6.8B

[1] Global Drug Forecast and Market Analysis to 2026

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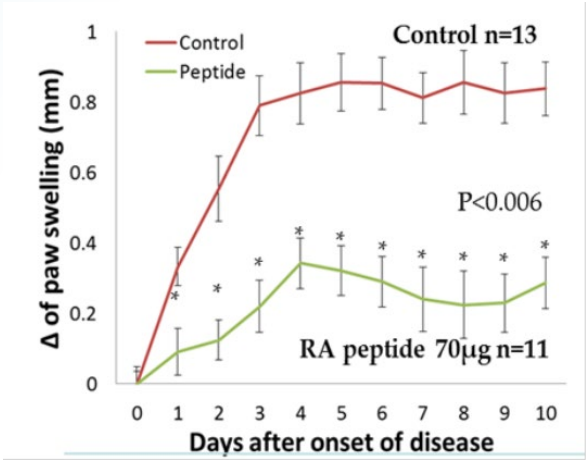
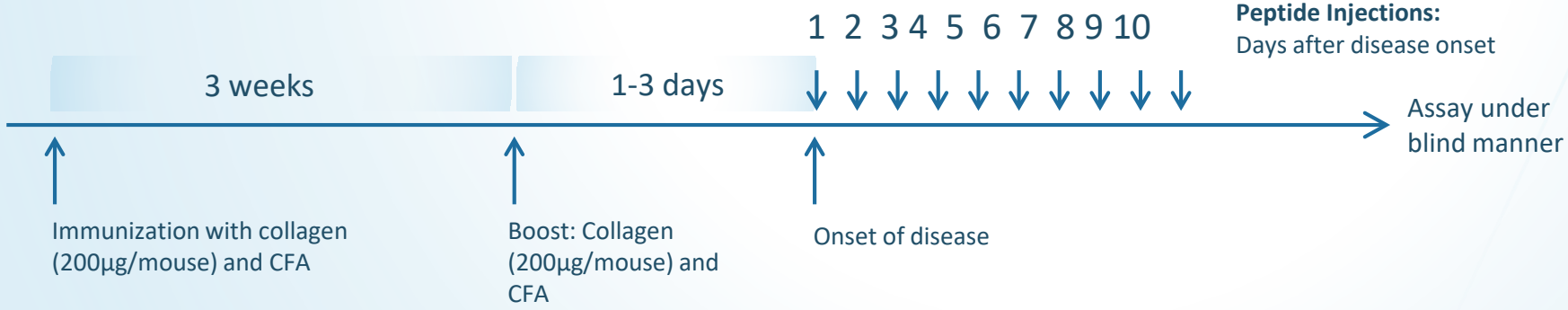
Amilo-5MER Significantly Affects Clinical Symptoms in RA (collagen induced arthritis animal model)

Collagen-induced arthritis (CIA) is the animal model of Rheumatoid Arthritis. CIA Sick C57BL/6 mice were treated daily (8 injections) for 9 days by Amilo-5MER (3.5mg/Kg 70µg/ml). Results demonstrate shrinking of the footpad swelling (measured by Micro-caliper Electronic Archimedes device) indicating that the joint inflammation was suppressed.



Protocol:



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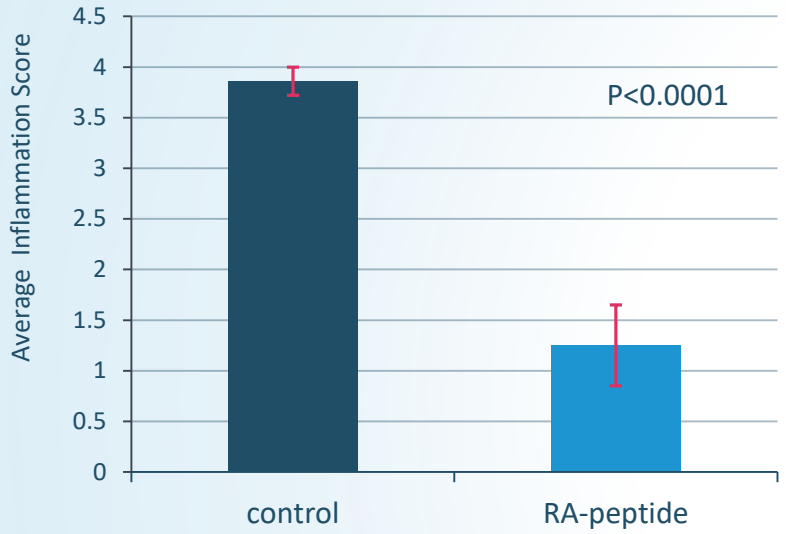
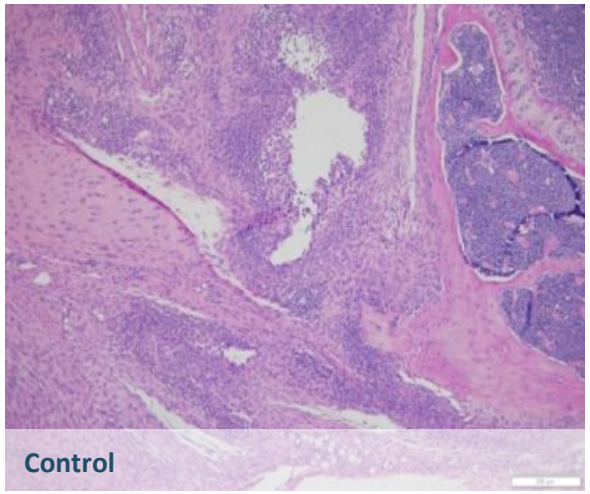
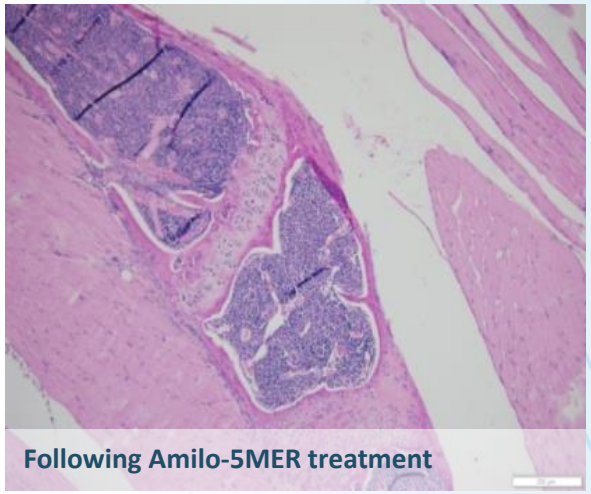
Amilo-5MER Restores the Normal Anatomy of the Inflamed Joint





A representative stained histopathological joint section from a mouse with CIA with no treatment showing severe inflammation in the joint with sever damage to bone and cartilage. Joint inflammation score was 4 on a scale range 0 to 4.



A representative stained histopathological joint section from a mouse with CIA following 9 days treatment with Amilo-5MER). Pathology (blinded) assessment indicate a joint of a normal mouse with no damage to the bone and cartilage. Joint inflammation score was < 1.5 on a scale range 0 to 4.

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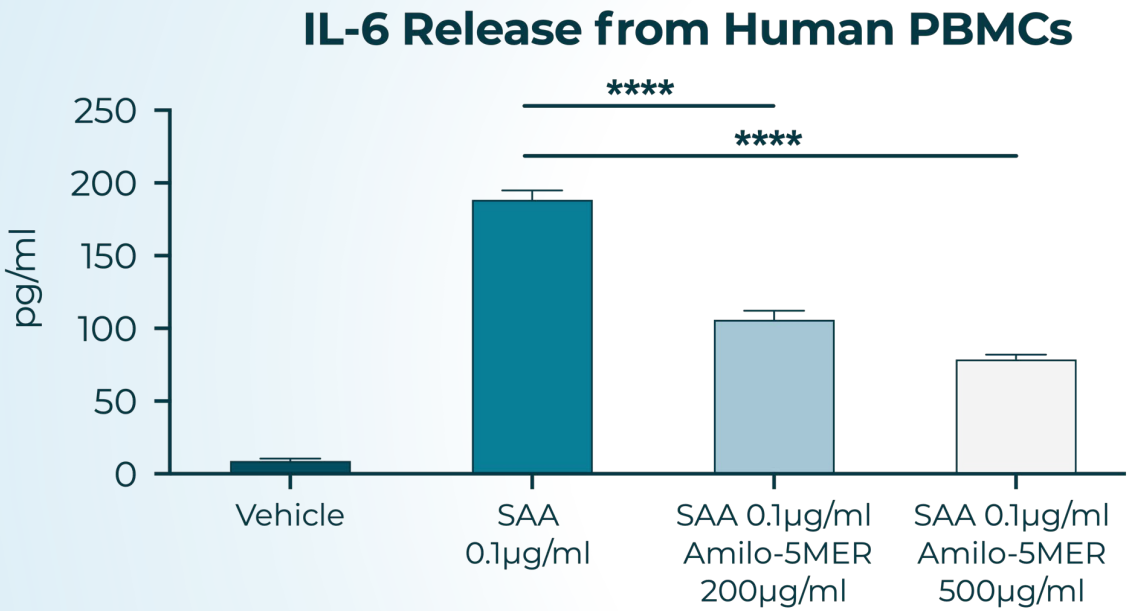
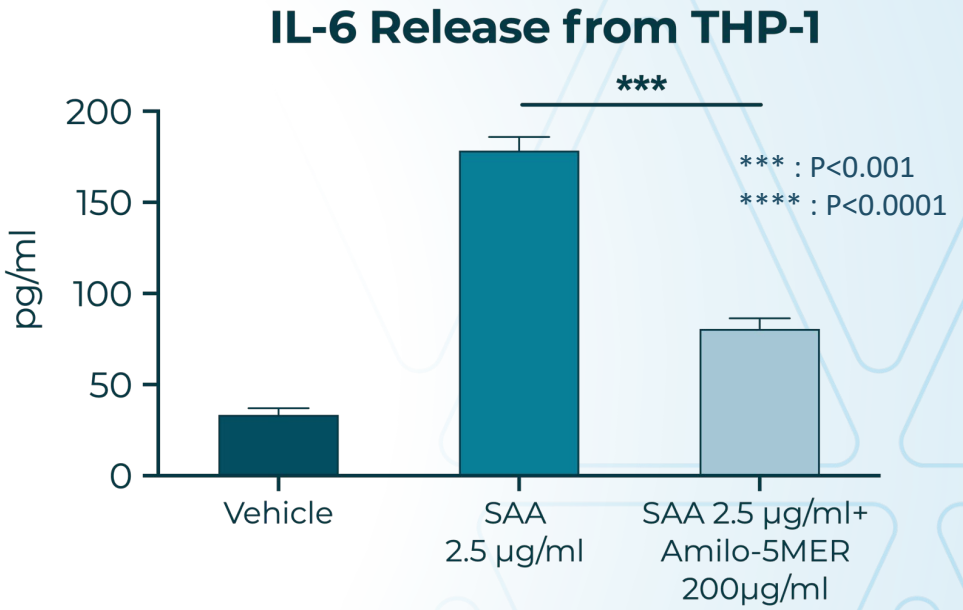
Amilo-5MER Reduces Pro-Inflammatory Cytokines ex-vivo in Human PBMCs





Amilo-5MER inhibits SAA ability to stimulate secretion of pro-inflammatory cytokines from white blood cells (designated peripheral blood mononuclear cells, PBMCs)

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Preclinical Safety Studies in Support of First-in-Human Study Completed

Maximum Tolerated Dose (MTD) studies in mice and dogs

- 7 day MTD in mice at doses up to 1000 mg/kg, in dogs up to 200 mg/kg: No adverse effects were noted
- 28-days in mice at doses up to 175 mg/kg, an in dogs at doses up to 24 mg/kg: No adverse effects were noted

Cardiovascular Safety

- No inhibition of the potassium hERG channel were noted in an in-vitro system
- No adverse effects on the cardiovascular system (ECG, blood pressure and heart rate) in dogs

Respiratory Safety

- No adverse effects on respiratory rate, tidal volume, and minute volume were noted in mice

CNS Safety

- No adverse effects on behavior, body posture, body temperature, motor functions and response to stimuli were noted in the Functional Operational Battery of tests in mice

Genotoxicity

- No potential for genotoxicity was seen in the reverse mutation assay in bacteria and no chromosomal damage was seen in the chromosomal aberration assay in human peripheral blood mononuclear cells

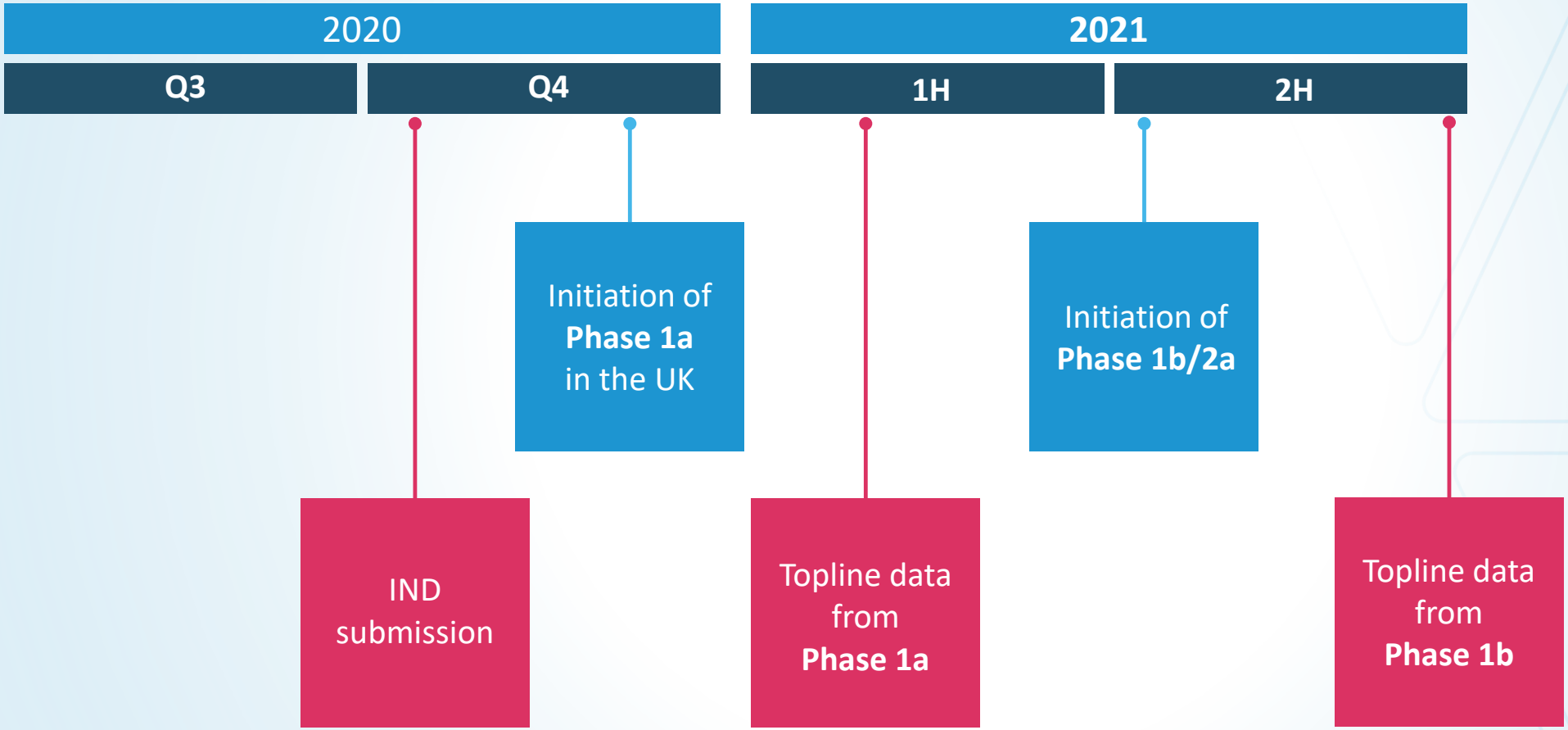
Secondary Pharmacology - Off Target Binding

- Amilo-5MER at 10 µM showed no significant interaction with a large list of known pharmacological molecular targets

Amilo-5MER: Phase 1b/2a IBD Study Design

- **Planned Study Design:** Randomized, double blind, placebo-controlled
- **Population:** 88 subjects aged 18-64 with Inflammatory Bowel Disease (IBD)
- **Dosing:** QD (once daily) doses; 4 cohorts; placebo controlled
- **Treatment duration:** 12 weeks
- **Primary end point:** Powered to show statistical difference in mucosal healing. Colonoscopy & SAA as bio marker
- **Planned trial initiation:** Q2 2021

Significant Near Term Anticipated Milestones



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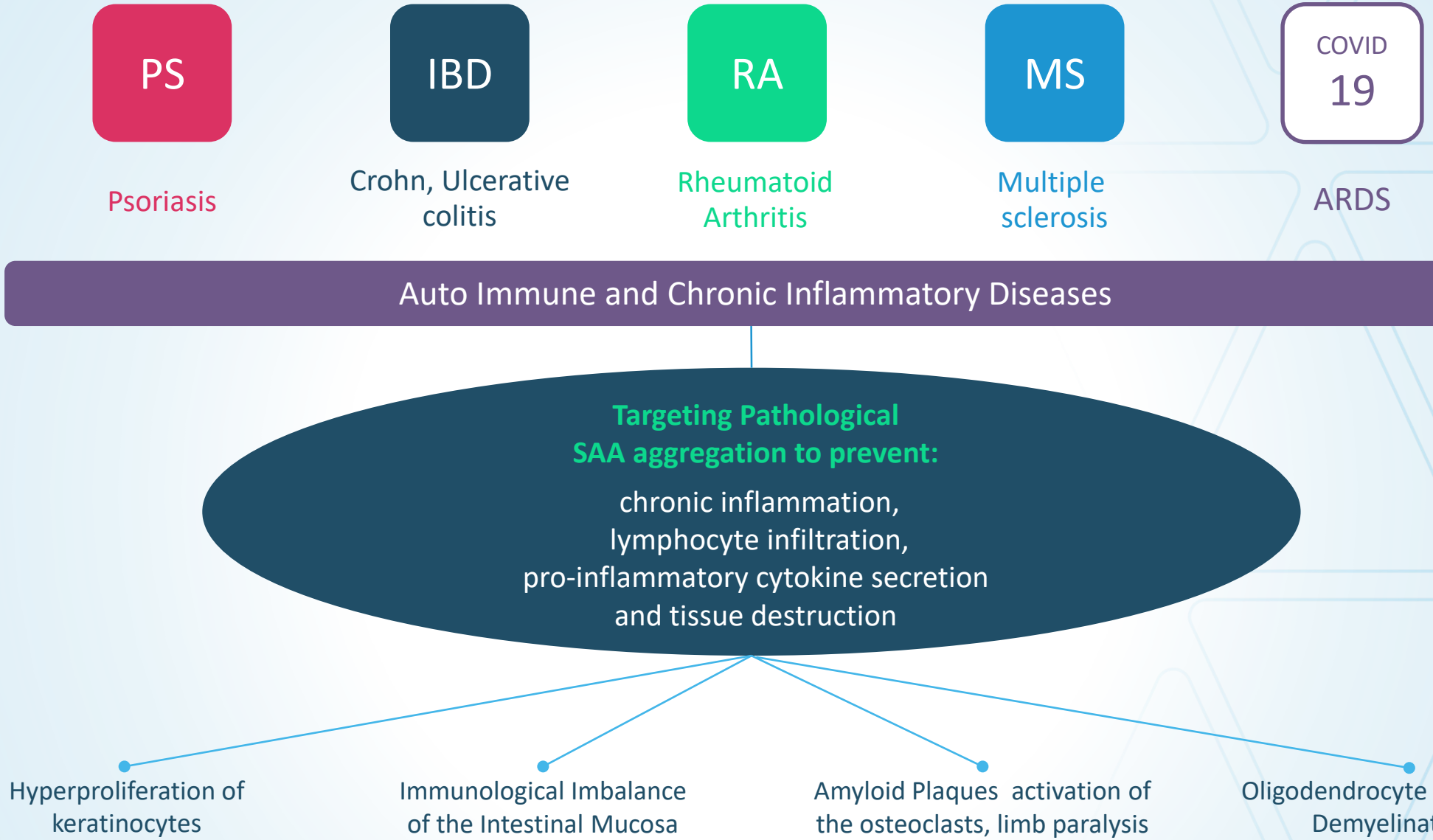
Summary

- Chronic and inflammatory diseases are characterized by significant elevation of SAA which is a bio marker and inducer of this process
- SAA induces inflammation only in its aggregated form
- SAA aggregation and polymerization is a specific target to reduce inflammation
- Prevention of SAA aggregation and polymerization interferes with the pro inflammatory chronic inflammation and reduces tissue damage
- Amilo-5MER is a pentapeptide sequenced specifically to interfere with SAA aggregation to prevent inflammation and tissue damage
- Amilo-5MER has an excellent safety profile with potential for use for long term / chronic conditions
- Phase 1a topline data expected Q1 2021. Phase 1b/2a Study in IBD patients – Inc. biomarkers (SAA in serum) expected 2H21



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