IMMUNE Pharmaceuticals

Corporate Presentation
December 2018

OTCQB: IMNP

www.immunepharma.com

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Overview

Developing Novel Therapeutics for Immunologic and Inflammatory Diseases

Bertilimumab

- Anti-eotaxin-1 mAb blocks a key inflammation driver
- Positive phase 2 results in bullous pemphigoid (BP)
- Ulcerative colitis (UC) data in H1/2019
- Excellent safety profile in over 120 subjects
- Fast Track and US/EU Orphan Status in BP
- Plan to launch pivotal BP trial in 2020
- Seeking partnership

NanoCyclo

- Topical formulation of cyclosporine for atopic dermatitis and psoriasis
- Proprietary nano-encapsulation technology enhances skin penetration
- In late-stage preclinical development
- Awaiting additional *in vitro* proof-of-concept data

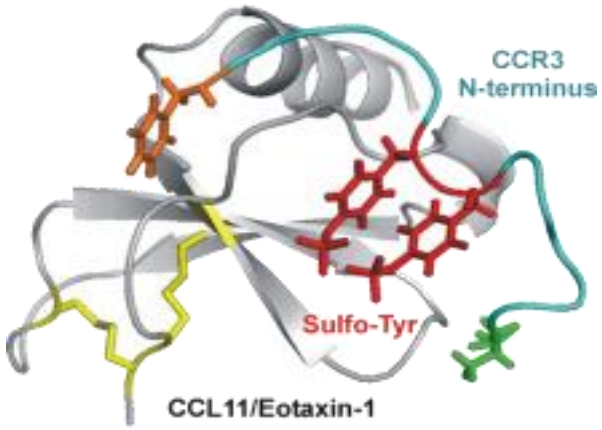
Legacy programs including Amiket (peripheral neuropathy) and Ceplene (oncology), to be divested or discontinued

Robust Pipeline Addresses Significant Unmet Needs

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Bertilimumab	Bullous Pemphigoid		Phase 2/3-Ready		
	Ulcerative Colitis		Phase 2b-Ready (Pending Data)		
	Allergic Rhinitis		No future development planned		
	Allergic Conjunctivitis		No future development planned		
	Atopic Dermatitis		Phase 2-Ready		
	Asthma		Phase 2-Ready		
NanoCyclo	Atopic Dermatitis	Ongoing			
	Psoriasis	Ongoing			

Eotaxin-1 Implicated in Many Inflammatory Diseases

Eotaxin-1 attracts eosinophils to sites of inflammation

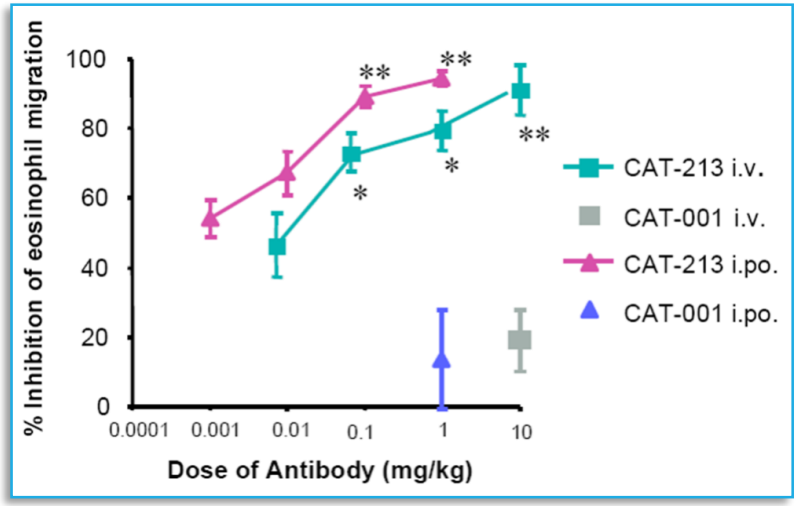


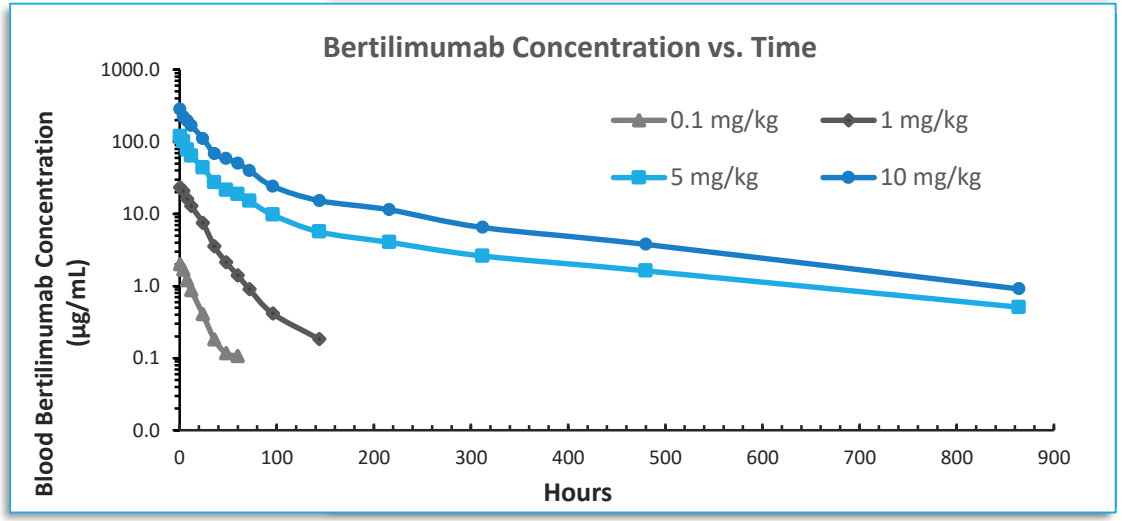
Eosinophil-related cytokines are a clinically and commercially validated target (IL-5 in asthma, IL-4 and IL-13 in atopic dermatitis)

Gastroenterology	Ulcerative Colitis Crohn's Disease Primary Sclerosing Cholangitis (PSC) Eosinophilic Esophagitis
Respiratory	Asthma Nasal Polyps
Dermatology	Bullous Pemphigoid Atopic Dermatitis Cutaneous Drug Eruptions
Oncology	Glioblastoma, Prostate and Ovarian Cancer Cutaneous T-Cell Lymphoma (CTCL)
Other	Eosinophilic Otitis Media Idiopathic Retroperitoneal Fibrosis Age-Related Cognitive Decline, Repetitive Head Injury

Bertilimumab Blocks Eotaxin-1

- Human antibody with picomolar affinity and high specificity for human eotaxin-1
- Prevents eotaxin-1-induced chemotaxis and shape change of eosinophils
- Pharmacokinetic profile consistent with biweekly dosing
- Clean safety profile in more than 120 treated subjects
  - >70 received IV
  - 46 received ocular
  - 8 received intranasal
  - Well-tolerated by all routes of administration
  - Only one drug-related SAE, an infusion reaction that was self-limited





Bullous Pemphigoid

Autoimmune Blistering Disease

30,000 patients in the US and EU[1]

60+

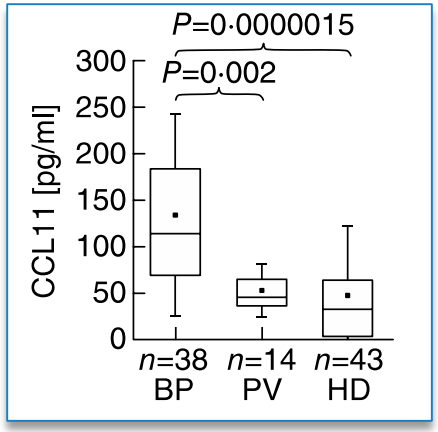
Most common in people >60[1]

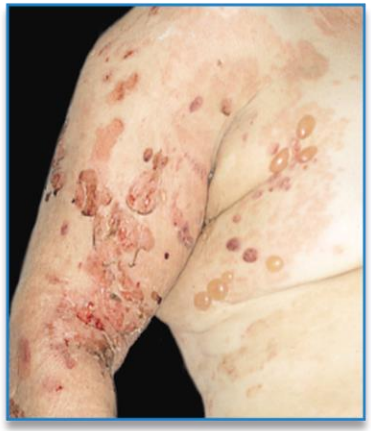
Increased mortality and significant impact on quality of life

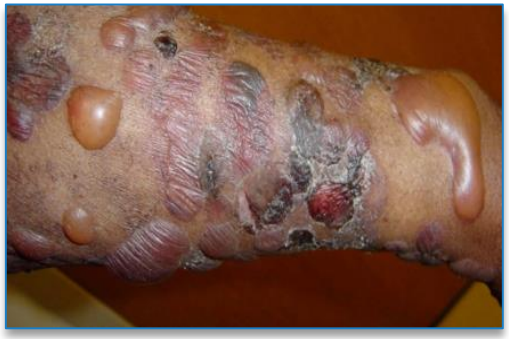
1. http://www.orpha.net/csonor/cgibin/Disease
2. https://www.mayoclinic.org/diseases-conditions/bullous-pemphigoid/symptoms-causes/syc-20350414

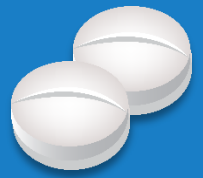
Bullous Pemphigoid Represents Significant Unmet Need

- Driven by autoantibodies to BP180 (type XVII collagen) and BP230 (dystonin)
- IgE and eosinophils play a unique role
- Eotaxin-1 elevated in serum and blisters in BP but not other blistering diseases
- Eotaxin-1 levels correlate with disease severity







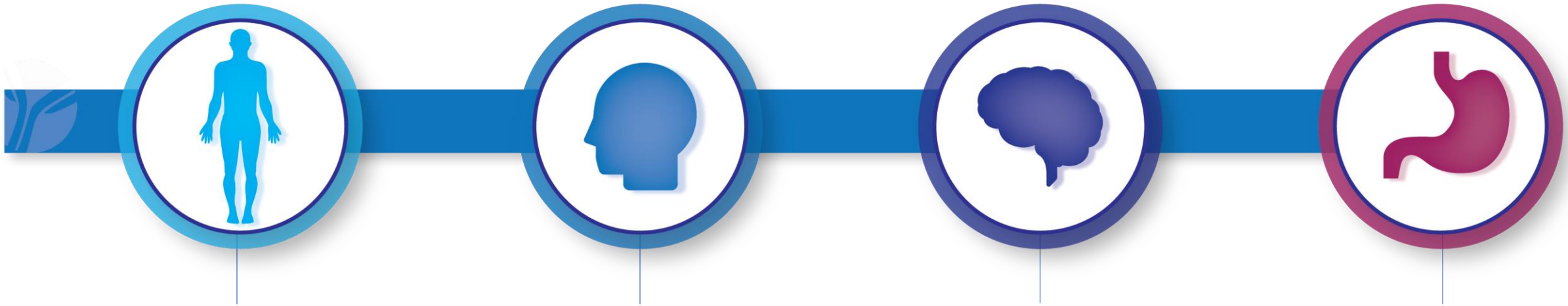


Patients with moderate-to-extensive disease typically treated with high doses of prednisone tapered over 9-12 months

- Effective but major safety and tolerability issues
- 30-45% relapse during tapering
- Second-line immunosuppressants like azathioprine, methotrexate and Rituxan have additional safety issues

Significant unmet medical need for steroid-sparing adjunctive or alternative therapy

Prednisone Has Significant Side Effects



- Immunosuppression and increased risk of infection
- Diabetes
- Osteoporosis
- Weight gain / Buffalo hump
- Weakness
- Thin, fragile skin

- Bulging eyes
- Headache
- Dizziness
- Acne
- Moon face
- Extreme tiredness

- HPA axis suppression
- Extreme changes in mood
- Changes in personality
- Insomnia

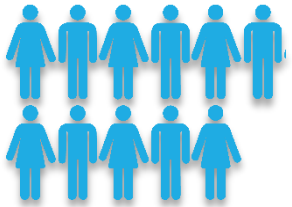
- Peptic ulcers
- Nausea
- Vomiting

Positive Phase 2a Study in Bullous Pemphigoid

Results presented at 2018 AAD and 2018 Pre-IID Pemphigus and Pemphigoid Symposium

Single-arm, open-label PoC trial in moderate-to-extensive BP

9 treated



7 newly diagnosed, 2 taper-resistant

3 IV doses

Every 2 weeks 84 day follow-up

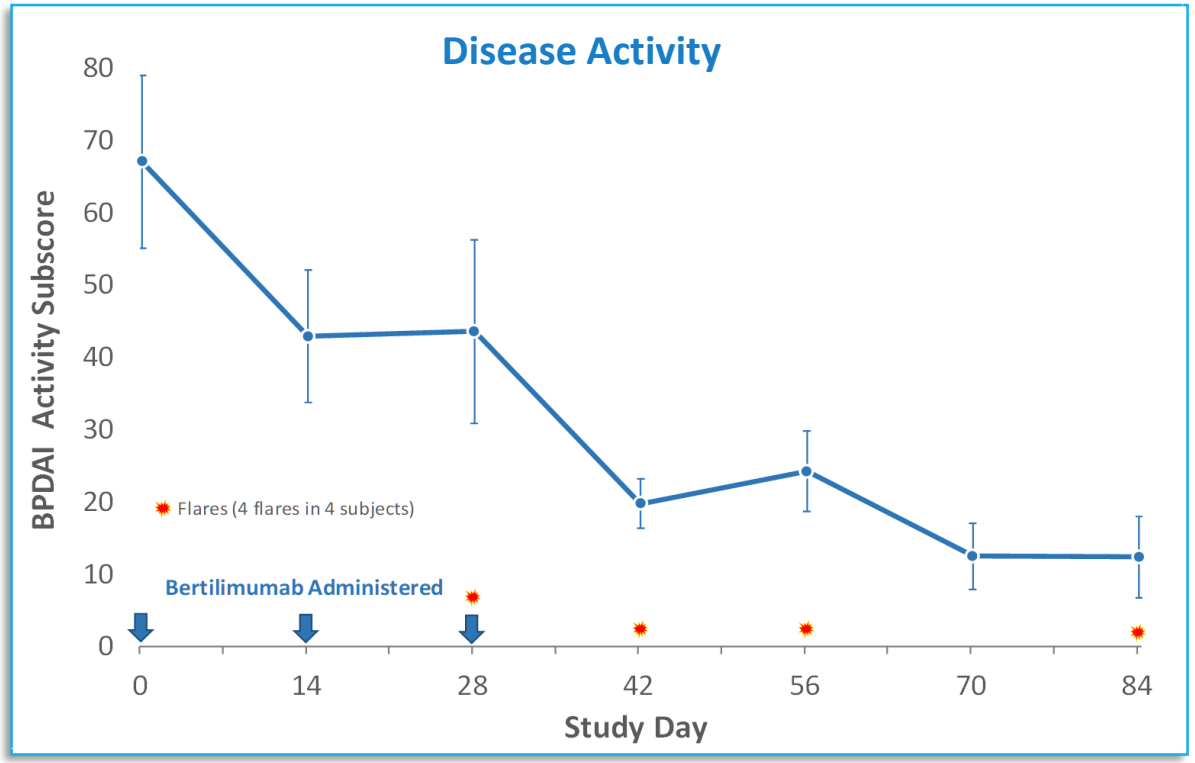
Primary Endpoint:
- Safety

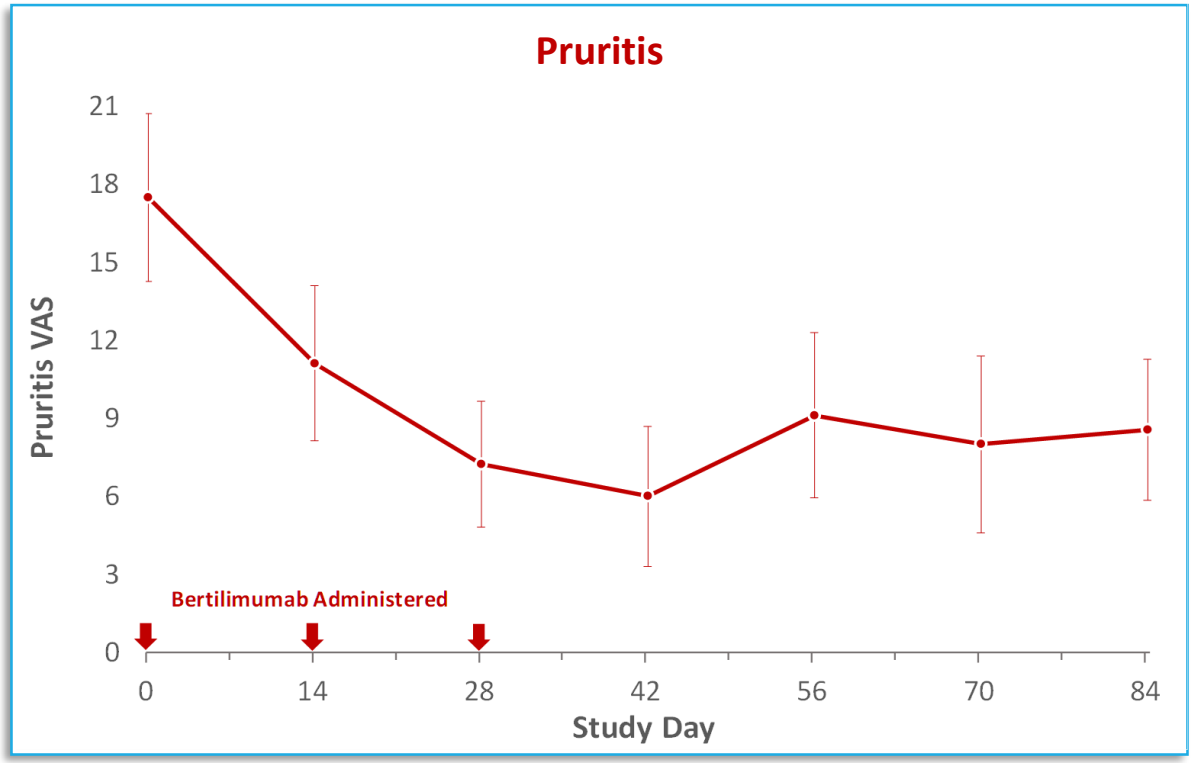
Other Assessments:
- Pharmacokinetics and pharmacodynamics

Efficacy Endpoints:
- BP Disease Area Index (BPDAI)
- Pruritic Visual Analogue Scale (VAS)
- % Responders
- Quality of Life (QOL)

Rapid and Sustained Improvement in BP Signs and Symptoms

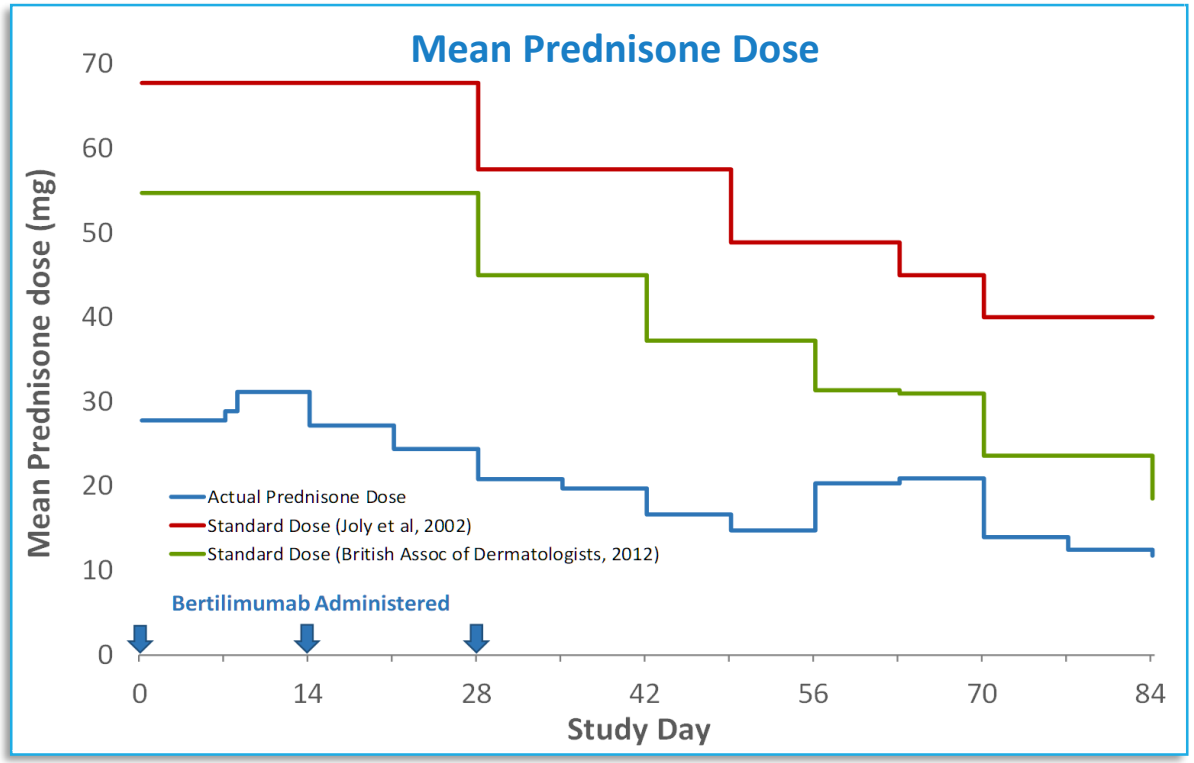
81% Reduction in BPDAI total activity index (p=0.015)
Clinically meaningful benefit in Pruritus VAS

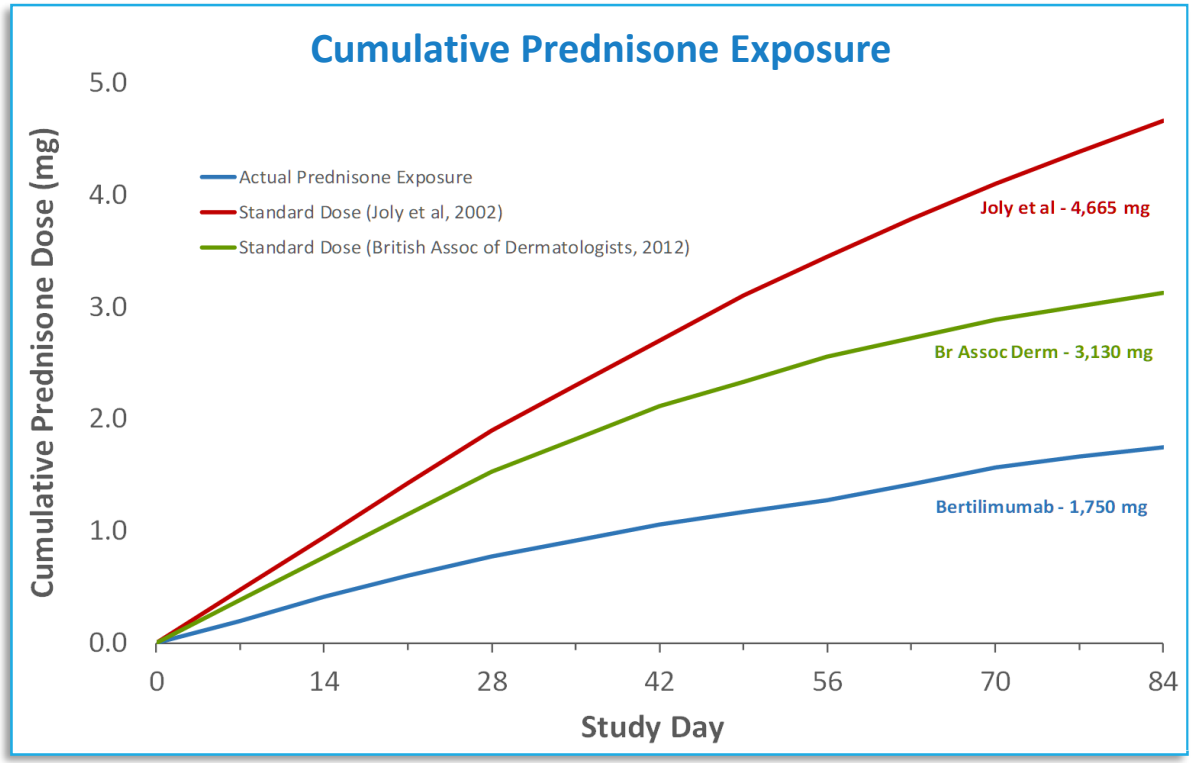




Bertilimumab Provided a Large Steroid-Sparing Effect

Mean starting dose was just 0.33 mg/kg, inadequate for disease control
Subjects received 1,700-2,900 mg less prednisone than standard of care





Positive Phase 2 Supports Plans to Commence Pivotal Study

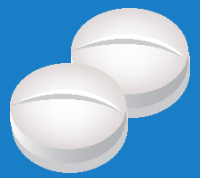
Rapid improvement in disease activity despite receiving low doses of prednisone with rapid taper

- 81% Reduction in BPDAI Activity Score (p=0.015)
  - 86% demonstrated >50% improvement
  - 57% demonstrated >90% improvement
- Mean initial prednisone dose of 28 mg tapered to 12 mg by day 84 (p=0.005)
  - Standard regimens would have begun at 55-70 mg and tapered to 20-40 mg by day 84
  - Subjects received 1,700-2,900 mg less prednisone compared to 2 standard regimens
  - 58% had a prednisone dose of 10 mg/day or less by day 84
- Safe and well tolerated
  - Only 11 AEs in 6 subjects (all mild; 8 unrelated or not likely related to bertilimumab)
  - The only serious AE was clearly not drug-related (angiography in a subject with peripheral vascular disease)

Ulcerative Colitis

Chronic, Inflammatory Bowel Disease

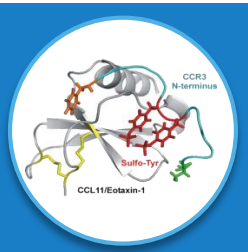
~ 700,000
patients in the US[1]



Moderate-to-severe disease managed with TNF-blockers or other immunosuppressants

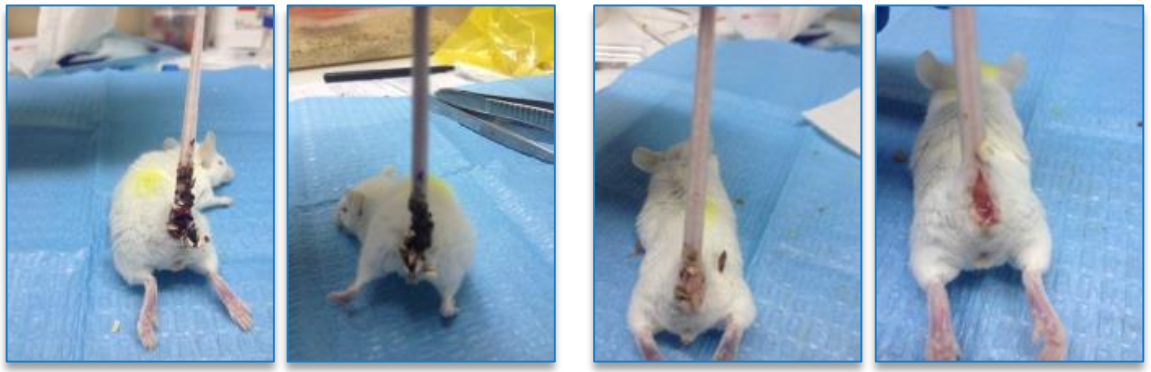
- Many patients do not have adequate disease control or experience toxicities

Eotaxin-1 strongly implicated as a target in IBD

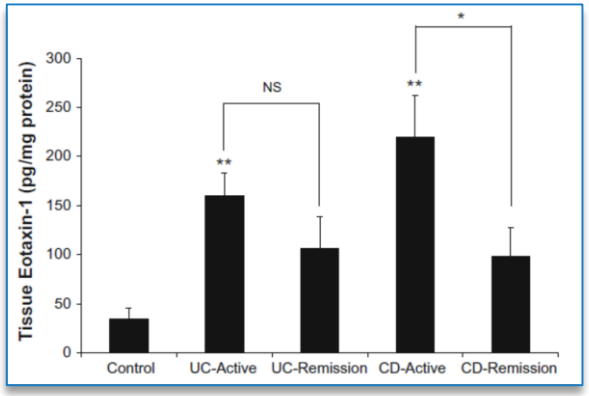


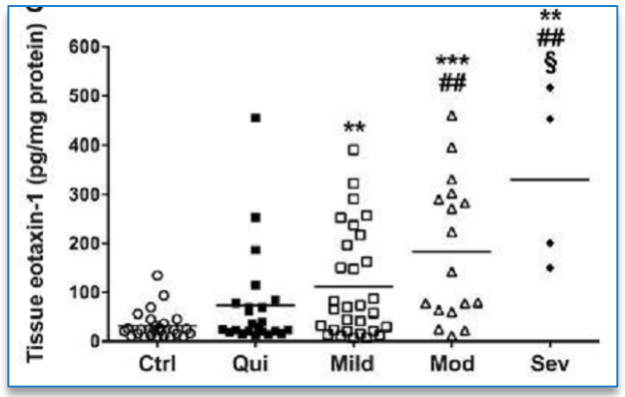
- Tissue eotaxin-1 levels correlated with Mayo Clinic DAI, mucosal injury and histologic severity
- Greater eotaxin-1 levels in areas of active vs. inactive disease

Eotaxin-1 blockade effective in animal models of inflammatory bowel disease



Control mAb Anti-eotaxin-1





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1: https://www.crohnsandcolitis.com/ulcerative-colitis

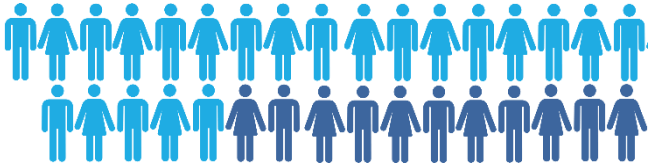
Bertilimumab Proof of Concept Trial in Ulcerative Colitis

Preliminary data expected late Q1 or Q2 2019

Randomized, double-blind, placebo-controlled trial

Screened 58, Enrolled 33

2:1 randomization



Patients selected based on Mayo UC Score and tissue eotaxin-1 levels

3 IV doses

Every 2 weeks
90 day follow-up

Primary Endpoint:

- Clinical response (UC Mayo Clinic Index) at Day 56

Enrollment completed Q3 2019=8

Additional Efficacy Endpoints:

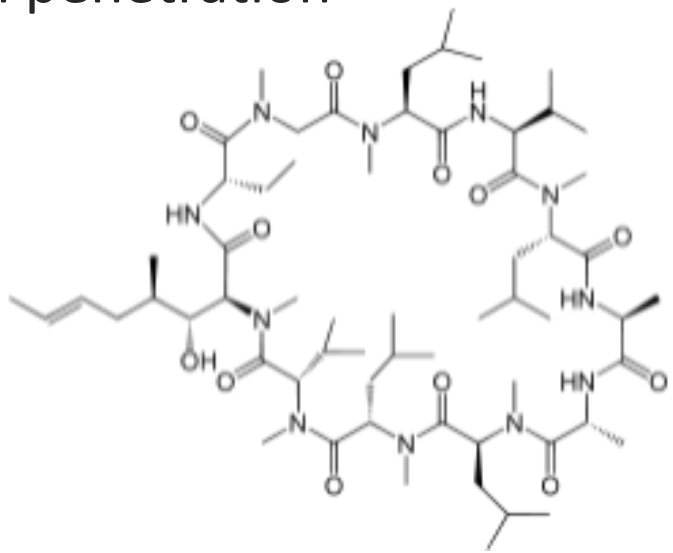
- Mucosal injury
- Fecal calprotectin (validated inflammatory marker)
- Tissue eotaxin-1 and eosinophil levels
- Clinical remission

Bertilimumab Development Plans

- Actively seeking bertilimumab partnership
- Key next steps and milestones:
  - Bridging PK study comparing old and new process bertilimumab to launch late 2019 or early 2020
    - Required by FDA
  - Pivotal bullous pemphigoid phase 2/3 trial to follow immediately – expected launch mid-2020
    - Orphan indication with no approved therapies; standard of care (prednisone) has serious toxicities
  - Ulcerative colitis top-line results expected late Q1 or Q2 2019
    - Phase 2b would follow if pilot results are supportive
  - Asthma will be the next indication into the clinic; additional indications could follow
- Manufacturing
  - Developed a new CHO cell line and new process that is more efficient and scalable
  - WuXi Biologics to complete process development and scale to 2,000L
  - Clinic-ready in late 2019/Q1 2020
- Intellectual Property/Market Exclusivity
  - Current IP portfolio includes patents expiring in 2021-2022, eligible for Patent Term Restoration (up to 5 years)
  - Eligible for 12 years of biologics exclusivity in the US and 10 years in the EU
  - Granted Orphan Drug Designation for bullous pemphigoid in the US and EU

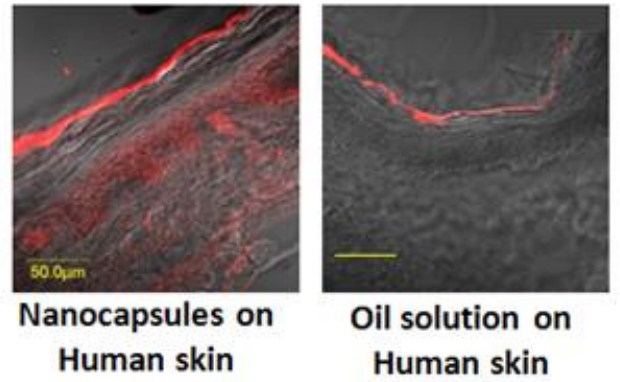
NanoCyclo – Nano-Encapsulated Topical Cyclosporine

- Alternatives to topical steroids for inflammatory skin diseases remain in demand
- Topical Calcineurin Inhibitors (TCIs) address this gap
  - Protopic® and Elidel® WW sales peaked at over $500M (now generic)
  - Black-box warning for ill-defined cancer risk impaired US marketing
- Cyclosporine never developed as a topical because of poor skin penetration
  - High molecular weight (1,203 kD) and highly lipophilic
  - Many methods were unsuccessful in improving skin permeation
    - Electroporation
    - Microemulsion
    - Amphiphilic gels
    - Iontophoresis
    - Liposomes
    - Micellar nanocarriers

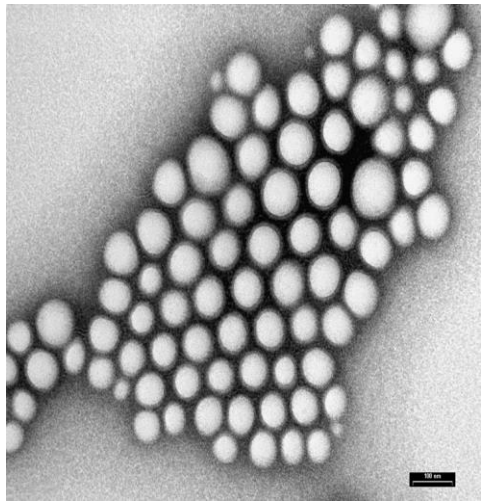


NanoCyclo – Nano-Encapsulated Topical Cyclosporine

- PLGA-based nanocapsules enhance dermal delivery
- Our proprietary nanoencapsulation technology enhances skin delivery of cyclosporine
- Cyclosporine dissolved in lipid core that is encapsulated by a biodegradable polymer

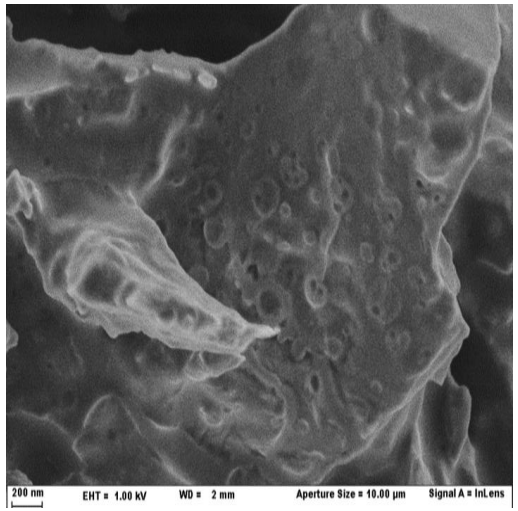


Badihi A et al. *J Control Release* 2014; 189: 65-71



TEM micrograph of 10% CsA-loaded nanocapsules.

- Lyophilized nanocapsules incorporated into a cream or other suitable topical formulation
- Skin permeation studies show enhanced penetration into epidermis and dermis
- Animal models show efficacy



Cryo-SEM micrograph of 2% lyophilized nanocapsules in an anhydrous silicone base.

NanoCyclo Development Plan

- Currently optimizing formulation to bring forward into clinical studies
- Completing “target engagement” study Q1 2019
- Program on hold pending additional financing
- Development plan:
  - Complete target engagement study
  - Validate GMP manufacturing facility built by our partner BioNanoSim in Jerusalem
  - Clinic-enabling toxicity study
  - Human proof of concept study could launch in 2019
    - Psoriasis plaque test (microplaque assay) or atopic dermatitis
- Considering additional projects
  - Combinations with other topically active agents
  - Nano-AmiKet

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Thank You!

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