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## Overview

### Developing Novel Therapeutics for Immunologic and Inflammatory Diseases

<table>
<thead>
<tr>
<th><strong>Bertilimumab</strong></th>
<th><strong>NanoCyclo</strong></th>
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<tbody>
<tr>
<td>• Anti-eotaxin-1 mAb blocks a key inflammation driver</td>
<td>• Topical formulation of cyclosporine for atopic dermatitis and psoriasis</td>
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<tr>
<td>• Positive phase 2 results in bullous pemphigoid (BP)</td>
<td>• Proprietary nano-encapsulation technology enhances skin penetration</td>
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<td>• Ulcerative colitis (UC) data in H1/2019</td>
<td>• In late-stage preclinical development</td>
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<tr>
<td>• Excellent safety profile in over 120 subjects</td>
<td>• Awaiting additional <em>in vitro</em> proof-of-concept data</td>
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<tr>
<td>• Fast Track and US/EU Orphan Status in BP</td>
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<tr>
<td>• Plan to launch pivotal BP trial in 2020</td>
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<tr>
<td>• Seeking partnership</td>
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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**
  - Preclinical: Phase 2/3-Ready
- **Ulcerative Colitis**
  - Phase 1: Phase 2b-Ready (Pending Data)
- **Allergic Rhinitis**
  - Phase 2: No future development planned
- **Allergic Conjunctivitis**
  - Phase 2: No future development planned
- **Atopic Dermatitis**
  - Phase 2: Phase 2-Ready
- **Asthma**
  - Phase 2: Phase 2-Ready

### NanoCyclo
- **Atopic Dermatitis**
  - Ongoing
- **Psoriasis**
  - Ongoing
### Eotaxin-1 Implicated in Many Inflammatory Diseases

**Eotaxin-1** attracts eosinophils to sites of inflammation.

<table>
<thead>
<tr>
<th>Gastroenterology</th>
<th>Respiratory</th>
<th>Dermatology</th>
<th>Oncology</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative Colitis</td>
<td>Asthma</td>
<td>Bulous Pemphigoid</td>
<td>Glioblastoma, Prostate and Ovarian Cancer</td>
<td>Eosinophilic Otitis Media</td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>Nasal Polyps</td>
<td>Atopic Dermatitis</td>
<td>Cutaneous T-Cell Lymphoma (CTCL)</td>
<td>Idiopathic Retroperitoneal Fibrosis</td>
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<tr>
<td>Primary Sclerosing Cholangitis (PSC)</td>
<td></td>
<td>Cutaneous Drug Eruptions</td>
<td></td>
<td>Age-Related Cognitive Decline, Repetitive Head Injury</td>
</tr>
<tr>
<td>Eosinophilic Esophagitis</td>
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</tbody>
</table>

Eosinophil-related cytokines are a clinically and commercially validated target (IL-5 in asthma, IL-4 and IL-13 in atopic dermatitis).
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\(^1\)
- Most common in people >60\(^1\)
- Increased mortality and significant impact on quality of life

1. http://www.orpha.net/csonor/cgibin/Disease
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

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

Disease Activity

Pruritus

BPDAI Activity Subscore

Study Day

Flares (4 flares in 4 subjects)
Bertilimumab Administered

Pruritis VAS

Study Day

Bertilimumab Administered
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

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

~ 700,000 patients in the US

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

Control mAb

Anti-eotaxin-1

1: https://www.crohnsandcolitis.com/ulcerative-colitis
Bertilimumab Proof of Concept Trial in Ulcerative Colitis

Screened 58, Enrolled 33

2:1 randomization

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

Every 2 weeks 90 day follow-up

Randomized, double-blind, placebo-controlled trial

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

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

Enrollment completed Q3 2019=8

Preliminary data expected late Q1 or Q2 2019
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
  - 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

TEM micrograph of 10% CsA-loaded nanocapsules.

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