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Overview

Developing Novel Therapeutics for Immunologic and Inflammatory Diseases

<table>
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<th>Bertilimumab</th>
<th>NanoCyclo</th>
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<tr>
<td>Anti-eotaxin-1 mAb that blocks a key inflammation driver</td>
<td>Topical formulation of cyclosporine</td>
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<td>Positive results demonstrated in phase 2 bullous pemphigoid (BP) study</td>
<td>Proprietary nano-encapsulation technology enhances skin penetration</td>
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<td>Ongoing phase 2 study in ulcerative colitis (UC)</td>
<td>In late-stage preclinical development</td>
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<td>Excellent safety profile in over 120 subjects</td>
<td>Applications in atopic dermatitis and psoriasis</td>
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<tr>
<td>Expect to launch pivotal BP trial in 2019</td>
<td>Human PoC study expected to launch in 2019</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

<table>
<thead>
<tr>
<th>Program</th>
<th>Indication</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
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<tr>
<td>Bertilimumab</td>
<td>Bullous Pemphigoid</td>
<td>Completed</td>
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<tr>
<td></td>
<td>Ulcerative Colitis</td>
<td>Ongoing</td>
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<td>Allergic Rhinitis</td>
<td>Completed</td>
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<td>Allergic Conjunctivitis</td>
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<td></td>
<td>Atopic Dermatitis</td>
<td>Phase 2 Ready</td>
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<td></td>
<td>Other Inflammatory Conditions</td>
<td>Phase 2 Ready</td>
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<tr>
<td>NanoCyclo</td>
<td>Atopic Dermatitis</td>
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<td>Psoriasis</td>
<td>Ongoing</td>
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</table>
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
- Chronic Obstructive Pulmonary Disease (COPD)

**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 Skin 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/consor/cgi-bin/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
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
And a Huge 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 Registration Study in 2019

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)

• Potential to move directly into a registrational phase 2/3 trial
  - Orphan indication with no approved therapies and standard of care has serious toxicities
  - Targeting FDA and EMA meetings in Q3/Q4 2018
  - Expect to launch pivotal study in 2019
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

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

Expect to Complete Enrollment in Q3 2018

42 Subjects
2:1 randomization
Patients selected based on Mayo UC Score and tissue eotaxin-1 levels
Every 2 weeks 90 day follow-up

3 IV doses

Randomized, double-blind, placebo-controlled trial

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

Enrolling at 5 sites in Israel and 4 in Russia

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

Expect to Complete Enrollment in Q3 2018

Enrolling at 5 sites in Israel and 4 in Russia
Additional Bertilimumab Development Plans

• Future studies and new indications
  - Pivotal phase 2/3 in BP
  - Phase 2b in ulcerative colitis pending outcome of current proof-of-concept study
  - Pilot clinical studies in atopic dermatitis and asthma

• 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
  - Expect release of new clinical supply in 2019

• Intellectual Property/Market Exclusivity
  - Current IP portfolio includes patents expiring in 2021-2022, eligible for Patent Term Restoration (up to 5 years)
  - Pursuing substantial new IP around new bertilimumab manufacturing process
  - Eligible for 12 years of biologics exclusivity in the US and 10 years in the EU
  - Granted Orphan Drug Designation in the 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

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

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
- If formulation performance is adequate, will validate GMP manufacturing facility built by our partner BioNanoSim in Jerusalem
- Will then move into clinic-enabling toxicity study
- Human proof of concept study expected to launch in 2019
  - Psoriasis plaque test (microplaque assay) or atopic dermatitis
- Considering additional projects
  - Combinations with other topically active agents
  - Nano-AmiKet
Management Team

Elliot Maza, JD - **President and CEO**
Extensive and successful experience in managing micro-cap biotech and drug manufacturing companies

Tony Fiorino, MD, PhD – **CMO and COO**
Broad experience in leading clinical-stage biotech companies and a former successful healthcare fund manager

John Zhang, MD, PhD - **VP, R&D**
20 years’ experience in preclinical/early clinical drug development in pharmaceutical/biotech industry
Expected Near-Term Milestones

Bertilimumab
- Presented interim BP data as late-breaker at AAD
- Achieved target BP enrollment
- Report additional BP results at IPPF
- Select CMO for new manufacturing process
- Initiate tech transfer
- Type C meeting with FDA
- Report PK and PD data from BP study
- Complete enrollment in UC study
- Pilot run of new process
- Scientific Advice meeting with EMA
- Production and release of new process drug
- Unblind UC study
- Launch pivotal BP study
- Enter clinic with new indication

NanoCyclo
- Select formulation for clinical development
- Additional product optimization studies
- Initiate GMP production
- Launch clinic-enabling toxicity study
- Proof-of-concept clinical trial
- Initiate GMP production
- Launch clinic-enabling toxicity study
- Production and release of new process drug
- Unblind UC study
- Launch clinical-enabling toxicity study
- Proof-of-concept clinical trial
Investment Highlights

• Lead program, bertilimumab, demonstrated positive results in phase 2 BP study
• Expect to enter BP pivotal registrational study in 2019
• Results from UC phase 2 UC study expected early 2019
• Potential for additional high value indications, including atopic dermatitis and asthma
• NanoCyclo expected to enter the clinic 2019
• Management team focused on executing turnaround and driving value into the Company
Thank You!