Seneca Biopharma (NASDAQ: SNCA)

NASDAQ listed company dedicated to developing reduced-risk innovative biopharmaceuticals for the treatment of human immunological diseases
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INTRODUCTION

Opportunity,
Team and Pipeline
Seneca Biopharma: De-risked Drug Development Pipeline

Rapid, differentiated platform: rabbit mAb drug development engine

- **Humanized rabbit** monoclonal antibody platform with rich and deep repertoire
- **Differentiated**: Better mAb’s; novel, patentable epitopes
- **Rapid**: Speed to market
- **Product Engine**: Evergreen source of new mAb clinical candidates

Second Mover Advantage – novel products focused on:

- **Proven, growing markets**: lead SCN005 is fast follower to Dupixent ($5.8 B market)
- **Validated targets** and known MoA with limited competitors in development
- **Well-defined** development and regulatory pathways

Capital efficiency: global development of regional product candidates

- **Deep pipeline** of clinical products through QYuns partnership (equity-based deal)
- **Low costs** of pre-clinical development and manufacturing at QYuns in China
- **Complementary data** from clinical trials conducted by QYuns
Drug Development Programs

New Pipeline

• New pipeline of biologics for immunological disease and engine for future product candidates
• 6 novel drugs; plus at least one additional candidate per year from platform
• Lead drugs address multi-billion dollar markets

Legacy Assets

• NSI-566: cell therapy for treatment of ALS and Stroke
• NSI-189: small molecule drug for treatment of mood disorders
The Opportunity: Risk-Mitigated Clinical Stage Assets with Blockbuster Potential in US and Global Markets

Lead programs

- SNC005: Asthma and Atopic Dermatitis
  - Anti-IL4R
  - “Second Mover” to Dupixent®
- SNC006: Systemic Lupus Erythematosus (SLE)
  - Anti-IFNR
  - “Second Mover” to Anifrolumab

Current Status of Autoimmune Pipeline

- 2 Novel mAbs entering Phase 1 in China
- 4 products in research/preclinical
## Immunological Disease Pipeline for the Global Market (Planned)

<table>
<thead>
<tr>
<th>Program</th>
<th>Target</th>
<th>Indication</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
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<td>IL-4R</td>
<td>Asthma</td>
<td></td>
<td>Phase I (CN)</td>
<td>Phase I &amp; II (US)</td>
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<td>Atopic Dermatitis</td>
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<td>Phase II (US)</td>
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<td>Phase II (CN)</td>
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<td>IL-17A</td>
<td>Asthma</td>
<td>Phase I (CN)</td>
<td>Phase I (US)</td>
<td>Phase II (US)</td>
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<td>SNCA006</td>
<td>IFNR</td>
<td>Systemic lupus erythematosus</td>
<td>Preclinical (CN)</td>
<td>Phase I (CN)</td>
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<td>Phase I (US)</td>
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<tr>
<td>SNCA007</td>
<td>IL-33</td>
<td>Asthma and COPD</td>
<td>Preclinical (CN)</td>
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<tr>
<td>SNCA008</td>
<td>TSLP</td>
<td>Asthma</td>
<td>Preclinical (CN)</td>
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</tbody>
</table>
QYuns: A Regional Partner Developing World-class Drugs

- Deep pipeline of biologics being developed for China and regional market
- Successful US-trained team with deep experience in mAb drug development
- Robust pre-clinical and manufacturing capabilities to US Standards
- Pipeline Partnership: Seneca developing novel pipeline for Global market
- Exclusive license: Seneca will not owe any milestones or royalties on the pipeline.
QYuns’ Novel Rabbit mAb Platform and Product Engine

**Broader range of antigens**
- 50-fold more B-cells for screening due to larger spleen compared to mouse
- Additional mechanisms (somatic gene conversion of rearranged VDJ genes)
- Rabbit CDRs possess greater diversity than mouse CDRs

**Ideal for fast-follower “second mover advantage” strategy**
- Rabbit mAb often have higher affinity – leading to better efficacy
- Multiple novel patentable binding epitopes
- Leading to potentially superior product profile

**Proven ability to produce best in class products**
- Brolucizumab (Novartis) approved 2019 based on superiority for Wet AMD
Seneca Biopharma Management & Key Advisors

Kenneth Carter, Ph.D.
Executive Chairman
• 20+ years as CEO/Chairman of public and private companies
• Multiple successful biotechnology companies
• Broad pharma, R&D and Business networks

Mathew Kalnik, Ph.D.
Senior Operations Consultant
• 20+ years executive roles in R&D and BD
• Led development of several drugs
• President, CEO and COO credentials

Dane Saglio
Senior Financial Consultant
• 20+ years CFO public and private biotech companies
• Deep operational experience
• Extensive capital markets experience

David Recker, MD
CMO
• 30+ years of clinical development expertise
• Deep small molecule and cell therapy expertise
• Experience in multiple therapeutic areas

Thomas Hazel, Ph.D.
VP of R&D
• 17 years at Neuralstem; 10+ in senior executive roles
• 25 years of experience in human neural stem cell R&D
• Broad expertise in manufacturing and scale-up
LEAD PROGRAM

SNC005
SNC005: Anti-IL4R “Second Mover” To Dupixent: Asthma & Atopic Dermatitis

**Target:** Anti-IL4R mAb with affinity and preclinical efficacy comparable to or better than Dupixent (dupilumab)

**Blockbuster market:** $5.8 billion Dupixent peak sales forecast: $2.5 billion in Asthma (43%)

**Robust sales trajectory:** $931 million across the first six months of 2019 and is on its way to annualizing around $2 billion. (2018 sales $922 million)

**Low competition:** Only 2 other anti-IL4R biologics in clinical development (Phase 1)\(^2\)

**Clear development path:** Rapid and predictive POC clinical trial design in Asthma (N<150)

**Plan to Leverage POC Data, GLP Studies and Early Clinical Data to Move into Clinical Studies in the US by 2020**

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1. EvaluatePharma, October 2018
2. GlobalData, April 2019
SNC005 Targets IL-4Rα Subunit, Inhibiting IL-4 & IL-13 Type 2 Inflammatory Response

SNC005 (anti-IL4Rα)

Dupixent

Casele, TB, J Allergy Clin Immunol 2017;139:1411-21

Th2 cytokines
IL-4, IL-5, IL-13, IL-22

- Impaired KC differentiation
- Increased expression of CCL17 and CCL26
- Eosinophil recruitment
- Increased fibroblast production of CCL11
- IgE production by B-cells
- TH2 differentiation and survival
- Airway remodeling
- Collagen deposition
- Goblet cell hyperplasia
- Mucus production by epithelial cells
- Enhancement of airway smooth muscle cells contractility

Atopic dermatitis, Asthma, Nasal polyposis, Chronic Obstructive Pulmonary Disease
SNC005 Inhibits IL-4/IL-13 Induced Signal Transduction – Similar To Dupixent \textit{in vivo}

\begin{align*}
\text{Affinity to Human IL-4R\alpha (Biacore):} \\
SNC005 &= 378 \text{ pM (binds different epitope)} \\
\text{Dupixent} &= 136 \text{ pM}
\end{align*}
# SNC005 Is Better Than Or Comparable To Dupixent In Extensive Battery Of *in vitro* Binding & Functional Assays

<table>
<thead>
<tr>
<th>Assay</th>
<th>SNC005</th>
<th>Dupixent</th>
<th>Ratio</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bioactivity (in vitro)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Blocking IL-4 binding to IL-4Ro (ELISA)</td>
<td>IL-4</td>
<td>30.2</td>
<td>27.5</td>
<td>0.91</td>
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<tr>
<td>Inhibiting IL-4/IL-13 induced HEK Blue</td>
<td>IL-4</td>
<td>2.4</td>
<td>3.8</td>
<td>1.6</td>
</tr>
<tr>
<td>IL-4/IL-13 signal transduction</td>
<td>IL-13</td>
<td>11.9</td>
<td>20.6</td>
<td>1.7</td>
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<tr>
<td>Inhibiting IL-4/IL-13 induced A549 release</td>
<td>IL-4</td>
<td>32.6</td>
<td>44.9</td>
<td>1.4</td>
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<tr>
<td>CCL-17</td>
<td>IL-13</td>
<td>28.9</td>
<td>37.3</td>
<td>1.3</td>
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<tr>
<td>Inhibiting IL-4/IL-13 induced HFL-1 release</td>
<td>IL-4</td>
<td>24.8</td>
<td>29.0</td>
<td>1.2</td>
</tr>
<tr>
<td>CCL-11</td>
<td>IL-13</td>
<td>106.0</td>
<td>165.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Inhibiting IL-4/IL-13 induced TF-1 proliferation</td>
<td>IL-4</td>
<td>13.9</td>
<td>21.9</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>IL-13</td>
<td>15.5</td>
<td>20.5</td>
<td>1.3</td>
</tr>
<tr>
<td>Inhibiting IL-4/IL-13 induced PBMC release</td>
<td>IL-4</td>
<td>24.8</td>
<td>29.0</td>
<td>1.2</td>
</tr>
<tr>
<td>CCL-17</td>
<td>IL-13</td>
<td>68.6</td>
<td>98.4</td>
<td>1.4</td>
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<tr>
<td>Inhibiting IL-4/IL-13 induced PBMC (B cell)</td>
<td>IL-4</td>
<td>Better than Dupixent</td>
<td></td>
<td></td>
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<tr>
<td>expressing CD23</td>
<td>IL-13</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Inhibiting IL-4/IL-13 induced PBMC (B cell)</td>
<td>IL-4</td>
<td>Similar to Dupixent</td>
<td></td>
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</tr>
<tr>
<td>release IgE</td>
<td>IL-13</td>
<td></td>
<td></td>
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<tr>
<td><strong>Bioactivity (ex vivo)</strong></td>
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<tr>
<td>Inhibiting IL-4/IL-13 induced whole blood</td>
<td>IL-4</td>
<td>Trend to better than Dupixent</td>
<td></td>
<td>Whole blood</td>
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<tr>
<td>release CCL-17</td>
<td>IL-13</td>
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</tbody>
</table>


SNC005: Demonstrates Comparable Efficacy to Dupixent in Human Transgenic B-hIL4/IL4R Asthma Model (Mouse)

Eosinophil count

Serum IgE

Alum/ovalbumin sensitization

0 7 14 20

Daily OVA challenge

21 22 23 24 25 26 (day)

N=4/group
i.p. administration
- Vehicle control
- SNCA005N 30 mg/kg
- DUP 30 mg/kg
SNC005: Few Early-Stage Anti-IL4R Competitors Beyond Dupixent

Phase 2 Atopic Dermatitis
• Dupixent + REGN-3500: IL4R & IL33 (Regeneron/Sanofi)
  ▪ Recent study results indicated that combo was no more effective than Dupixent alone

Phase 1 Asthma
• AZD-1402/PRS-060: IL4R (AstraZeneca/Pieres) Anti-calin, inhaled
• CBP-201: IL4R (Suzhou Connect Biopharmaceuticals, Ltd)
SNC005: Key Atopic Dermatitis and Asthma Competitors Beyond IL4R

**Late Stage Asthma Pipeline**
- Fevipirprant (CRTH2 inhibitor/Novartis – oral) Phase 3 program (6 trials) across different asthma endotypes (incl. moderate to severe)
- Tezepelumab (anti-TSLP/Astrazeneca) Phase 3 program targets broad moderate to severe asthma population

**Late Stage Atopic Dermatitis Pipeline**
Two leading JAK/STAT inhibitors in development both appear to be inferior to dupilumab
- Baricitinib Phase 3 data shows much lower response rate than dupilumab
- Abrocitinib Phase 2b data shows good response rate but poor tolerability (high rates of headache, nausea)
$3.5B+ Global Sales For Asthma Biologics

<table>
<thead>
<tr>
<th>Class</th>
<th>Drug</th>
<th>H1 2019 WW Sales</th>
<th>YoY Change</th>
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<tbody>
<tr>
<td>IgE</td>
<td>Xolair</td>
<td>$1.5B</td>
<td>+1% US; +11% ROW**</td>
</tr>
<tr>
<td>IL-5</td>
<td>Nucala</td>
<td>$450M</td>
<td>+38%</td>
</tr>
<tr>
<td></td>
<td>Fasenra</td>
<td>$296M</td>
<td>+244%</td>
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<tr>
<td></td>
<td>Cinqair</td>
<td>N/R likely low</td>
<td></td>
</tr>
<tr>
<td>IL-4R</td>
<td>Dupixent</td>
<td>$931M* (Includes both atopic derm and asthma)</td>
<td>+166%</td>
</tr>
</tbody>
</table>

- Share shifting rapidly between drugs
- Fasenra launched 2017
- Xolair came off patent in 2018
- Dupixent approved in Asthma in 2019
- Dupixent peak sales forecast in Asthma $2.5 Billion

*Sources:
- Xolair sales: Roche and Novartis 2018 FY earnings reports and H2 2019 earnings reports. Xolair sales have been converted from CHF and Nucala from British pound at current rates as of October 2019.
Peak Market Sales Estimate for SNC005 (Targeting IL4Ra)

- **SNC005** Positioned as *“Fast - Follower”* to Dupixent

- Order of magnitude peak sales opportunity for SNC005 estimated at between $1 to $2B USD for Asthma alone
Future Intellectual Property & Exclusivity Strategy Post QYuns License

Robust In-Licensed IP on Novel Rabbit mAbs

- Multiple Chinese patent applications on humanized lead selection for all products
- Several upcoming PCT filings on one-year anniversary
- Issued Claims in China & Published Patent Application SNC002 “Anti-human interleukin 17A monoclonal antibody and application thereof” (CN108640991)
  - Filed 12/10/2018, Issued (China): 8/23/2019, PCT filed

Biologic Data/Regulatory Exclusivity

- US: 12 years
- EP: 10 years (+ 1 for substantial new indication)
- Japan: 8 years (Re-Examination period)
- Patent Extension (added to patent term) up to 5 years in US/EU/JP
SUMMARY
Beyond Lead Programs: Leveraging Future Potential of High Efficiency QYuns Platform

8 mAbs developed in 5 years: 4 in Phase 1 in China

<table>
<thead>
<tr>
<th>Program QX</th>
<th>Target</th>
<th>Pre-Clinical</th>
<th>Clinical Trials</th>
<th>BLA</th>
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<tr>
<td>QX001S</td>
<td>IL-12/23</td>
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<td>Phase 1</td>
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<td>QX003S</td>
<td>IL-6R</td>
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<td>QX002N</td>
<td>IL-17A</td>
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<td>Phase 3</td>
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<td>QX008N</td>
<td>TSLP</td>
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Evergreen source of new mAb Phase 1 candidates (1/yr)
Summary: Seneca Biopharma; De-risked Drug Development

Multi Billion Dollar Global Peak Sales Opportunity
• Second Mover Advantage: SNC005 “Fast-Follower” to Dupixent
• Follow-on Global opportunities: SNC002 (Asthma, anti-IL17A) & SNC006 (SLE, anti-IFNR)

Rapid differentiated drug-development platform
• Better mAbs binding novel patentable epitopes
• Rapid engine for generating new Phase 1 candidates (1/yr.)

Globalization of in-licensed clinical assets
• Establish robust clinical-stage pipeline in the US
• Multiple shots on goal in proven blockbuster markets
• Leverage existing investments by partner/licensor

Capital Efficient and Rapid Achievement of Key Clinical Milestones
• By 2023, 4 Phase 2 trials across 3 candidates with subsequent financing
Thank you

THANK YOU

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