Expertise in Drug Discovery for Respiratory Viral Diseases

Nasdaq: BOTA

June 2014
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Biota is a data driven, clinically focused organization, developing therapeutics to treat respiratory viral infectious diseases

- Two royalty revenue generating influenza products
- Two late-stage respiratory antivirals that have demonstrated clinical proof-of-concept
- Product portfolio that has the potential to address significant market opportunities globally
- Well capitalized to execute clinical development strategy
  - Low net burn rate
  - $80.1 M cash-on-hand as of 3/31/2014
Zanamivir - First approved neuraminidase inhibitor (NI) for the prevention and treatment of uncomplicated influenza
  ➢ Marketed globally as Relenza® by GSK

Laninamivir octanoate (LANI) - 2nd generation long-acting NI for the prevention and treatment of uncomplicated influenza A & B
  ➢ Marketed in Japan as Inavir® by Daiichi Sankyo
  ➢ Data from global Phase 2b IGLOO trial anticipated in Q3 2014

Vapendavir (BTA-798) - Oral antiviral to treat human rhinovirus (HRV) infections in patients with moderate to severe asthma
  ➢ Phase 2b trial initiation anticipated in Q3 2014

BTA-C585 - Fusion inhibitor for the treatment of RSV in pediatrics and adults with cardiac and pulmonary disease
  ➢ Potential for IND filing in 1H 2015
## Current Antiviral Pipeline

<table>
<thead>
<tr>
<th>Treatment &amp; Prophylaxis</th>
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<tbody>
<tr>
<td><strong>Preclinical</strong></td>
</tr>
<tr>
<td>Zanamivir (Relenza®)</td>
</tr>
<tr>
<td>Influenza A&amp;B</td>
</tr>
<tr>
<td>Laninamivir Octanoate (Inavir®)</td>
</tr>
<tr>
<td>– Japan</td>
</tr>
<tr>
<td>- Influenza A&amp;B</td>
</tr>
<tr>
<td>Laninamivir Octanoate (LANI)</td>
</tr>
<tr>
<td>- U.S./ROW</td>
</tr>
<tr>
<td>- Influenza A&amp;B</td>
</tr>
<tr>
<td>Vapendavir (BTA-798)</td>
</tr>
<tr>
<td>- Human rhinovirus (HRV)</td>
</tr>
<tr>
<td>RSV fusion inhibitor (BTA-C585)</td>
</tr>
<tr>
<td>- Respiratory syncytial virus</td>
</tr>
</tbody>
</table>

1. Receive 7-10% royalty on global net sales
2. Receive 4% royalty on net sales in Japan
Laninamivir Octanoate

Long-Acting Neuraminidase Inhibitor (LANI)
Laninamivir Octanoate (LANI)

- Next generation member of a clinically-proven class of influenza antivirals (neuraminidase inhibitors)
  - “One and done” single inhaled therapeutic dose
- Simple to use dry powder inhaler (TwinCaps® DPI)
- Potent, direct-acting antiviral
  - Potent inhibitor of influenza neuraminidases (N1-N9) and associated viruses including highly pathogenic avian influenza
- Favorable resistance profile
  - Active against clinically relevant oseltamivir and peramivir resistant viruses (H1N1; H275Y)
- Substantial amount of preclinical, clinical, and commercial data supporting the efficacy and safety of the product
Daiichi-Sankyo markets LANI (Inavir®) for the treatment and prevention of influenza A & B in Japan

- Treatment: 40 mg adults; 20 mg children (approved in 2010)
- Prophylaxis: 2 x 20 mg (approved in 2013)

Favorable competitive profile has resulted in Inavir® becoming the market leading neuraminidase inhibitor in Japan in less than 3 years

- >45% market share achieved in seasonal market in 2013
- >10 million courses since product launch in 2010
Seasonal Neuraminidase Inhibitor Market

Average Year = $781M
Median Year = $714M

Source: IMS
Outside of Japan, Biota is developing LANI for the treatment of influenza A and B under an IND

Phase 2 Randomized, Double Blind, Placebo Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled Laninamivir Octanoate TwinCaps® Dry Powder Inhaler in Adults with Symptomatic Influenza A or B Infection (IGLOO)

- Enrollment was completed in April 2014
- Top-line data anticipated in Q3 2014

Additional clinical trials in support of LANI NDA

- Phase 1 QT/QTc study - study completed; results anticipated in Q3 2104
- Phase 1 trial in adults with asthma - study completed; results anticipated in Q3 2014
- Phase 1/2 Frosty trial in children aged 5-17 infected with influenza; enrollment suspended pending IGLOO data and the beginning of the Northern Hemisphere influenza season
Phase 2 IGLOO Trial

- 642 patients randomized; ≈ 256 patients in the ITT-i (infected) database

- (≈ 214 patients) x (40% PCR+) ≈ 86 patients

- 40 mg

- (≈ 214 patients) x (40% PCR+) ≈ 86 patients

- 80 mg

- Placebo  (≈ 214 patients) x (40% PCR+) ≈ 86 patients

- Primary endpoint is median time to alleviation of influenza symptoms and fever for ≥ 24 hours

- Time to alleviation of symptoms >20 hours vs. than placebo

- We believe there should be sufficient efficacy and pharmacokinetic data to select a dose for Phase 3
BARDA Update

- On May 8, 2014, the Department of Health and Human Services Office of Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) terminated its contract for the development of LANI for the convenience of the U.S. Government.

- Reasons verbally communicated to Biota for terminating the LANI contract for convenience were:
  - Not a performance-related decision
  - Time, costs and challenges associated with enrolling the IGLOO Phase 2 and future trials
  - Increasing concerns about the resistance profile of the neuraminidase inhibitors class and LANI against emerging H7N9 mutations
  - LANI was not amenable to an IV formulation to provide a solution to treat critically ill, hospitalized patients with complicated flu

- Negotiation of termination settlement in process

- Approximately $80M spent on the development program through end of April 2014 (CMC and clinical)
Next Steps for LANI

- Top-line data from three clinical trials expected in Q3 2014
  - Phase 2 IGLOO
  - Phase 1 QT/QTc
  - Phase 1 Asthma

- Size and timing of the LANI pivotal Phase 3 program will be dictated by the Phase 2 IGLOO data and feedback at the EoP2 meeting from the FDA

- Future development paths include:
  - Licensing the rights outside of Japan
  - Co-development agreement
  - Independently conducting a Phase 3 program
Vapendavir (BTA-798)

VP-1 Capsid Binding Inhibitor of Human Rhinovirus (HRV)
Multiple unmet needs present numerous opportunities for clinical development

- Moderate to severe asthmatics, COPD, pediatrics (asthma) and hematopoietic stem cell transplant recipients

Rhinovirus infection is a leading cause of the loss of asthma control and asthma exacerbations

- Guidelines recommend that treatment decisions should be based on level of asthma control
- Level of asthma control predicts future potential for adverse pulmonary risk

Proof of principle established in Phase 2a HRV challenge study as well as in Phase 2b natural infection study in mild to moderate asthma patients

Vapendavir has demonstrated a favorable safety and tolerability profile in ≈ 300 subjects
Treatment of HRV Infections Represent a Robust U.S. Market Opportunity

<table>
<thead>
<tr>
<th>Risk Group*</th>
<th>Total Prevalence*</th>
<th>1.3 Colds Per Year#</th>
<th>HRV (+) (≈40%)^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent Asthma</td>
<td>10,420,000</td>
<td>13,962,800</td>
<td>5,585,120</td>
</tr>
<tr>
<td>Mild Persistent Asthma</td>
<td>3,877,000</td>
<td>5,195,180</td>
<td>2,078,072</td>
</tr>
<tr>
<td>Moderate Persistent Asthma</td>
<td>5,331,000</td>
<td>7,143,540</td>
<td>2,857,416</td>
</tr>
<tr>
<td>Severe Persistent Asthma</td>
<td>4,604,000</td>
<td>6,169,360</td>
<td>2,467,744</td>
</tr>
<tr>
<td>Mild COPD</td>
<td>15,319,000</td>
<td>20,527,460</td>
<td>8,210,984</td>
</tr>
<tr>
<td>Moderate COPD</td>
<td>10,457,000</td>
<td>14,012,380</td>
<td>5,604,952</td>
</tr>
<tr>
<td>Severe/Very Severe COPD</td>
<td>2,333,000</td>
<td>3,126,220</td>
<td>1,250,488</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>52,341,000</strong></td>
<td><strong>70,136,940</strong></td>
<td><strong>28,054,776</strong></td>
</tr>
</tbody>
</table>

*DataMonitor, 2012 – Asthma Epidemiology
*DataMonitor, 2011 – Chronic Obstructive Pulmonary Disease: Epidemiology Forecast
#Hurst, JR – *Eur Respir J* 26:846-852, 2014
Vapendavir Phase 2 Trial

- Randomized, placebo-controlled Phase 2 trial of naturally acquired HRV infections in chronic mild-moderate asthma patients (N=299)
  - Vapendavir treatment - 400 mg BID X 6 days
  - Primary efficacy endpoint utilized the WURSS-21 (Wisconsin Upper Respiratory Symptom Survey-21)
    - A validated cold symptom survey used to assess the severity of cold symptoms

- ITT-I population (HRV PCR +) for efficacy analysis (Placebo N=51, Vapendavir N=42)
  - Demonstrated a statistically significant reduction in the WURSS-21 severity score (ITT-I; p<0.02) over days 2-4 (primary efficacy endpoint)
  - Vapendavir treatment resulted in a least square mean difference (reduction) in Asthma Control Questionnaire (ACQ-5) score at day 14 compared to the placebo (ITT-I; p=0.08)
  - Daily β2 agonist use (# of puffs) over days 1-14 was reduced in the vapendavir treated cohort compared to placebo (ITT-I; p=0.09)

- Safety profile generated to-date among 263 unique subjects is favorable
  - No serious adverse events (SAE) in vapendavir arm, 1 in placebo
  - The most common adverse events (<5%) occurring to vapendavir-treated patients were headache, URI, sinusitis, bronchitis, nausea, diarrhea, and pyrexia
Next Steps with Vapendavir

- Bioavailability study of vapendavir initiated in May
- Drug-drug interaction study to be initiated in June
- Subject to these trial results, plan to initiate a Phase 2b trial in Q4 2014
  - Study population: Moderate and severe asthma subjects, with a history of asthma worsening or exacerbation within the last 14 months due to presumed viral respiratory infections that required asthma rescue medication treatment
  - Study Objective - To evaluate the effect of vapendavir on asthma control following HRV infection, as measured by the Asthma Control Questionnaire (ACQ-6)
  - Primary endpoint - Least Square (LS) mean change from baseline to study day 14 in ACQ-6 total score
Respiratory Syncytial Virus (RSV)

Fusion (F Protein) Inhibitors
Target Product Profile

- Small molecule RSV fusion inhibitor
  - Acts at early stage of viral replication
  - Active against both RSV A & B

- Oral and intravenous dose forms
  - PK supports potential for QD dosing

- Primary indication
  - Treatment of clinical manifestations of RSV infections in pediatric patients based on clinical and/or definitive diagnosis
  - Secondary indications for patients with underlying pulmonary and cardiac disease
## Treatment of RSV Infections Represent a Robust U.S. Market Opportunity

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Total Prevalence</th>
<th>RSV Infected</th>
<th>Hospitalized due to RSV Infection</th>
<th>RSV Infected but not Hospitalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elderly (&gt;65 years of age and older)</td>
<td>37,196,000</td>
<td>1,766,810</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults with underlying pulmonary or cardiac disease</td>
<td>22,929,000</td>
<td>1,490,385</td>
<td>223,400</td>
<td>3,033,795</td>
</tr>
<tr>
<td>Children (&lt;4 years of age)</td>
<td>20,639,000</td>
<td>4,540,580</td>
<td>127,136</td>
<td>4,413,444</td>
</tr>
<tr>
<td>Premature Infants</td>
<td>527,000</td>
<td>210,800</td>
<td>52,700</td>
<td>158,100</td>
</tr>
<tr>
<td>Bone Marrow Transplants</td>
<td>4,000</td>
<td>400</td>
<td>400</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>81,295,000</strong></td>
<td><strong>8,008,975</strong></td>
<td><strong>403,636</strong></td>
<td><strong>7,605,339</strong></td>
</tr>
</tbody>
</table>

DataMonitor, 2006 - Stakeholder Opinions: Respiratory Syncytial Virus (RSV) Infection
BTA-C585 Potent Antiviral Activity in a Human Lung Model

MatTek EpiAirway™: Human-derived tracheal/bronchial epithelial cells (TBE) that have been cultured to form a multilayered, highly differentiated model which closely resembles the epithelial tissue of the respiratory tract.

<table>
<thead>
<tr>
<th>Compound</th>
<th>MatTek tissue EC$_{50}$ (nM)</th>
<th>MatTek tissue CC$_{50}$ (µM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV604 (Novartis)</td>
<td>167.2</td>
<td>ND</td>
</tr>
<tr>
<td>BTA-585</td>
<td>8.4</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>
# Excellent Cell Cytotoxicity Profile

<table>
<thead>
<tr>
<th>Cell Line</th>
<th>Origin</th>
<th>BTA-C585 CC$_{50}$ (µM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>H9C2</td>
<td>Rat heart myoblast</td>
<td>&gt;100</td>
</tr>
<tr>
<td>NRK</td>
<td>Rat kidney</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Clone 9</td>
<td>Rat liver</td>
<td>&gt;100</td>
</tr>
<tr>
<td>MDCK</td>
<td>Canine kidney</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Vero</td>
<td>Monkey Kidney</td>
<td>&gt;100</td>
</tr>
<tr>
<td>HeLa Ohio</td>
<td>Human epithelial</td>
<td>&gt;100</td>
</tr>
<tr>
<td>HEK293</td>
<td>Human kidney</td>
<td>&gt;100</td>
</tr>
<tr>
<td>HepG2 galactose</td>
<td>Human liver</td>
<td>&gt;100</td>
</tr>
<tr>
<td>HepG2 glucose</td>
<td>Human liver</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Cardiomyocytes</td>
<td>Human heart</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>
BTA-C585 Program Timelines

- Oral dose range finding toxicological studies
  - 7-day studies (completed)
    - No adverse histological or laboratory value observations
  - Additional non-GLP in vivo toxicology studies (in progress)
    - 28-day toxicology studies
    - 21-day MTD studies
    - Top-line results anticipated Q3 2014
- Subject to results of these studies, goal is to progress BTA-C585 into IND-enabling GLP studies in mid-2014
- Successful IND-enabling studies could support filing of IND in approximately 12 months
<table>
<thead>
<tr>
<th>Financials (3/31/2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasdaq Symbol</td>
</tr>
<tr>
<td>Commons Shares Outstanding (primary)</td>
</tr>
<tr>
<td>Cash and short-term investments</td>
</tr>
</tbody>
</table>
Summary

- Leveraging our antiviral respiratory expertise and franchise
  - Two royalty-generating products
  - Two clinical late-stage antiviral compounds that have demonstrated Phase 2 human proof of concept

- Well capitalized to execute our business plan through potential value inflection milestones over the next 12-24 months
  - Phase 2 IGLOO trial top-line data Q3 2014 → P3 planning
  - Phase 2 Vapendavir HRV program → Two Phase 1 trials beginning in Q2/Q3 2014; Phase 2 planned for Q4
  - RSV program → IND enabling studies planned for Q3/Q4 and IND 1H 2015

- Future corporate and clinical development strategies for LANI will be driven by the Phase 2 IGLOO data
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