



**Astelin Day
Life Cycle Plan
November 1, 2002**



Agenda

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|----|---|----------------|-------------------------------|
| 1) | Review of Detailed Proposals and Discussion | 45 Min. | R. Spivey/
D. Fink |
| 2) | Breakout Session Instruction | | D. Fink |
| 3) | Breakout <ul style="list-style-type: none">– What else do we want?– Supply source/packaging?– Trademarks/specifications?– Studies directed specifically toward target messages? | 60 Min. | All |
| 4) | Reconvene and Report Back | 30 Min. | D. Fink/
R. Spivey |
| 5) | Prioritize and Next Steps | 30 Min. | D. Fink/
R. Spivey |
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Projects

Packaging Configuration Projects

- **Pediatric packaging**
 - **V-Bottom bottle/cap configuration – trade (30.0 mL)**
 - **V-Bottom bottle/pump configuration – trade (30.0 mL)**
 - **V-Bottom bottle – sample (5 mL)**
 - **Calmar – Albert pump**
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Pediatric Packaging

- **Single 17 mL flat-bottom bottle**
- **Current VP3 Valois pump**
- **Straight-forward; high probability of success**
- **Timing influenced by whether “value added” materials are included**
- **Cost is minimal**

V-Bottom Bottle/Cap Configuration – Trade (30 mL)

- **Back-up strategy for “pump on” plan for new V-bottom bottle**
 - **High likelihood of success**
 - **Requires development of data, submission, and approval by FDA**
 - **Available in 18 - 24 months**
 - **Cost is relatively small**
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V-Bottom Bottle/Pump Configuration – Trade (30 mL)

- **Current, planned configuration for new V-bottom bottle**
 - **Requires additional engineering efforts to perfect pump placement**
 - **In addition, particulates may be an issue**
 - **Available in 6 – 9 months**
 - **Cost is estimated at \$350 – 400k**
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V-Bottom Bottle – Sample (5 mL)

- **Already approved by FDA**
- **Issues similar to 30 mL V-bottom bottle**
- **Available in 6 – 9 months**

Colman – Albert Pump

- **Qualification of back-up pump supplier**
- **Moderate likelihood of success**
- **Available in 18 – 24 months**
- **Cost is approximately \$2.5 million**

Formulations Projects

- **Astelin/steroid combination**
- **Taste masking – meet current specifications**
- **New optimized formulation**

Astelin/Steroid Combination

- **High degree of technical difficulty**
- **Need to reconcile combination of solution/suspension**
- **Dosing differences**
- **4 – 5 years to develop; \$75 million**

Taste Masking – Meet Current Specifications

PTX1005-00012

- **Multiple attempts made but all altered specifications**
- **No feasibility to make modifications without extensive product characterization and some clinical trials**

New Optimized Formulation

- **To improve taste and optimize dosing**
- **Need to assemble taste panels to determine success**
- **3 – 4 years in development**
- **Would likely cost \$4.5 million**

Clinical Programs

- **One spray per nostril bid (supplemental NDA)**
 - **Perennial allergic rhinitis (supplemental NDA)**
 - **Protocol 415 (follow-on to Protocol 414 Claritin failure trial)**
 - **SAR and asthma**
 - **Somnolence/cognitive function studies**
 - **Nasal polyps (pilot study)**
 - **Pediatric labeling (children 2 to 4 years of age)**
 - **Non-allergic asthma (NIH study)**
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One Spray BID

- **New dosage regimen (current formulation)**
- **At least 2 trials**
- **Cost is approximately \$2.5 - \$3 million**
- **New labeling by 2005**

Perennial Allergic Rhinitis

- **New indication**
- **High feasibility; moderate to high likelihood of success**
- **Available mid-2005**
- **Cost is approximately \$3 million**

Follow-up to 414

- **Follow-up to Claritin failure trial**
- **Could duplicate study 414 or study different antihistamine (Allergen or Zyrtec)**
- **Study completed mid-2003**
- **Cost is approximately \$2 million**

SAR and Asthma

- **Effect of Astelin on SAR symptoms in patients with both asthma and SAR. Evaluate if any impact on asthma symptoms.**
 - **Low-to-moderate likelihood of success**
 - **Cost is approximately \$1 million**
 - **Publication available in 2004**
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Somnolence/Cognitive Function Studies

PTX1005-00019

- **Provide data for PI in Clinical Pharmacology section on sleep latency and/or cognitive function**
- **Two studies, total of \$600K**
- **Submission in 2004, label change by end of 2004**

Nasal Polyps (Pilot Study)

PTX1005-00020

- **Evaluate effect of Astelin on nasal polyps**
 - **Depends on anti-inflammatory effect**
 - **Cost is approximately \$850K**
 - **Outcome is publication**
 - **Low likelihood of success**
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Pediatric Labeling (2 – 4 years)

- **Formally requested by FDA**
 - **Lengthy enrollment process (over 2 allergy seasons)**
 - **Cost is approximately \$700K**
 - **Could result in 6 months of exclusivity**
 - **Submit to FDA by 2005**
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Non-allergic Asthma (NIH funded)

PTX1005-00022

- **Investigator is Dr. Jonathan Bernstein**
- **Low-to-moderate likelihood of success**
- **Drug supplier only (already committed)**

Preclinical Program

PTX1005-00023

- **Otitis media (animal model)**

Otitis Media

- **Effects of antihistamine on middle ear effusion**
- **Study to be conducted in rats**
- **Publication**
- **Drug supplier committed**