

**Periodontal Disease Advisory Board Discussion Guide**  
**OraPharma, Inc.**  
**June 11, 2011**  
**7:30 AM – 3:15 PM**  
**The Hilton @ Short Hills**  
**Short Hills, New Jersey**

**Friday, June 10th**

3:00PM

**Check-In**

7:00- 9:00 PM

*The Dining Room  
Lobby Level*

**Welcome Dinner**

*OraPharma, Centron, and Advisors (optional)*

**Saturday, June 11<sup>th</sup>**

7:15 – 8:30 AM

*Chatham Foyer*

**Meeting Registration Desk**

*Centron*

*Note: When advisors check in, they will be given a welcome packet, which contains a confidentiality form and schedule of events. They will be asked to fill out the confidentiality form prior to the meeting start.*

7:30 - 8:30 AM

*Chatham Room  
Conference Level*

**Buffet Breakfast**

8:30 - 8:45 AM

*Millburn Room*

**Meeting Begins: Program Objectives/Introductions**

*Michael Lynch, DMD, PhD, OraPharma, Inc.*

- Understand what lasers are being used and what claims are being made about laser therapy
- Discuss what is needed to incorporate Arestin into the laser treatment algorithm?

8:45 – 9:15 AM

**Current and Future Laser Use in Periodontal Therapy**

*Charles Cobb, DDS, PhD*

- Mechanism of action (MOA) of laser therapy
- How and why lasers are currently being used for periodontal treatment
- The future of laser therapy in 5 years? 10 years
- Distribution of biofilms in the periodontal pocket
- Comparison of laser curettage and SRP in bacterial load reduction
- The impact of healthcare reform and state regulations on laser utilization

9:15 - 9:30AM

**Discussion**

- Why and how are lasers being used in periodontal therapy?
- Are there data to show superiority of laser curettage vs. SRP?

- How effectively do lasers penetrate biofilm?
- What do you think the reimbursement climate will be for lasers now and in future?
- How do different state regulations affect who can and can't administer treatment with laser therapy?
- Is it appropriate for RDHs to use lasers for periodontal therapy and are there broader safety risks?

9:30 – 10:00 AM

**Laser Use in Periodontal Therapy: What Do the Data Say?**

*Sebastiano Andreana, MS, DDS*

- Review of published data

10:00– 10:15 AM

**Discussion**

- Are there existing data or literature trends that state that LASRP is superior to mechanical SRP?
- Are lasers alone a comprehensive treatment?
- What do the data say?
- What claim(s) is being made about laser therapy that is not supported by data?
- Are there gaps in the existing evidence? What's missing, insufficient, lacking?

10:15 - 10:40AM

**Coffee Break (*Check-out of Sleeping Rooms*)**

10:40 – 11:10 AM

**Arestin in Combination with Laser Treatment:  
Case Report Presentation**

*Arthur Levy, DMD*

- Review of long-term case studies

11:10 – 12:00 PM

**Discussion**

- What percentages/types of patients are good candidates for laser therapy?
- Are the results that you have seen with combination therapy consistent patient-to-patient?
- If not, is there a specific patient type that benefits more from combination therapy.
- What results do you see with laser alone? Arestin alone? How do these results differ? Do you find the results surprising? Why? Why not?

- Are there issues with patient acceptances? If so, how do you address these issues?
- What is the duration of the effect of lasers? Arestin? lasers + Arestin?
- When do you make the decision to use combination therapy?
- Would publication of these case studies be useful? What is the optimal way of presenting these case reports in the literature? Any recommendations of the best place to publish these case reports?
- What additional publications would be of value?

12:00 – 12:15 PM

**What Research is Needed?**

*Michael Lynch, DMD, PhD – Clinical Director, OraPharma*

- Research discussion - general objectives, timeline, endpoints, and duration of studies

12:15 – 12:30PM

**Discussion**

- What laboratory or animal studies would you find relevant and interesting?
- What objectives should studies of lasers and Arestin address?
- How should sites be determined for placement of Arestin?
- What is the optimal protocol and where would Arestin fit in?
  - Endpoints?
  - Study duration?

12:30 – 1:30 PM

**Buffet Lunch**

*Chatham Room*

1:30 – 3:00 PM

**Q&A Session**

*Millburn Room*

**Moderator**

- How would you summarize the current understanding regarding use of lasers to treat chronic periodontitis, specifically in the context of laser-assisted scaling and root planing (LASRP)?
- What is the current status of comparison of data evaluating lasers in the treatment of chronic periodontitis? Is it meaningful? Useful?
- How would you assess the roles of biofilms as a challenge to effective treatment of periodontal diseases as they pertain to RCB and practical clinical applications including LASRP and local antibiotic delivery?
- Do you feel bacterial models are useful, ie, do planktonic, biofilm, or other microbiologic studies of RCB and other bacteria lend themselves well to evaluating relative advantages of LASRP and local antibiotics?

- How can lasers and local antibiotics best be used independently and together to attack biofilms, and what clinical information supports this (in vitro/lab testing, clinical trials)?
- How would you describe the clinical relevance of RCB, and how would you characterize their greatest impact on the treatment of chronic periodontitis?
- Describe and rank (from least important to most important) what you feel are key clinical and microbiologic variables to assess in measuring the efficacy of non-surgical periodontal therapy.
- What importance do you place on CAL as a clinical common denominator for efficacy of lasers or local antibiotics in periodontal therapy, and how important is it in relation to probing depth in relation to treatment outcomes for chronic periodontitis?
- At what phases of periodontal treatment (and at what disease severity levels) should dental lasers or antibiotics be used, and what variables affect when/how lasers are used in initial therapy with SRP, at subsequent visits, or at maintenance visits?
- What type of dental laser do you use most commonly to treat periodontitis in general, and how (and why) would you rank the clinical utility of each available laser type/wavelength as part of a comprehensive LASRP treatment program?
- What role do you envision for photodynamic therapy (PDT) as part of a comprehensive periodontal disease management program that includes SRP or LASRP, specifically in regard to reduction in RCB load, bleeding on probing, CAL and other clinical variables you consider important?
- Who counsels patients about combination therapy/LASRP/local antibiotic, and in what context? What issues might arise in regard to patient acceptance of treatment based on who is counseling?
- What do the current clinical peer-reviewed literature--and your own clinical experience/data--suggest regarding the relative impact of SRP, LASRP, local antibiotic, or combinations of these approaches on the effective management of chronic periodontitis (rank modalities/factors from lowest to highest in importance)?

3:00 – 3:15 PM

### **Wrap Up/Closing Thoughts on Day**

Final guidance, feedback and recommendations