Biodegradable Sustained Release Drug Delivery Systems Fabricated using a Dissolvable Hydrogel Template Technology for the Treatment of Ocular Indications

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Financial Disclosures

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Presentation Overview

- Importance of sustained release (SR) therapeutics
- Drawbacks of current microparticle technology
- Advantages of Ohr SR microfabrication technology
- Microparticle manufacturing process using proprietary technology
- Release profiles from select Ohr SR therapeutic programs
Drawback of Current Microparticle Technology

**Broad Particle Size Distribution**

![Current Microemulsion Image](image)

**Chart:**
- **Y-axis:** Volume (%)
- **X-axis:** Particle Diameter (µm)

Legend: Current Microemulsion
Advantages of Ohr SR Microfabrication

Narrow Particle Size Distribution
## Ohr Technology vs. Other Ocular SR Systems

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bevacizumab Ranibizumab Aflibercept</th>
<th>External Systems</th>
<th>Implant Systems</th>
<th>Micro-emulsion</th>
<th>Ohr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injectable through small gauge needle</td>
<td>+ +</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+ +</td>
</tr>
<tr>
<td>Sustained release (4-6 months)</td>
<td>- -</td>
<td>+</td>
<td>+ +</td>
<td>+</td>
<td>+ +</td>
</tr>
<tr>
<td>Biodegradable: Does not require removal</td>
<td>+ +</td>
<td>-</td>
<td>-</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Initial release is controlled and tunable</td>
<td>- -</td>
<td>-</td>
<td>-</td>
<td>+ -</td>
<td>+ +</td>
</tr>
<tr>
<td>Simple formulation and process designed for fragile biologics</td>
<td>+ +</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+ +</td>
</tr>
<tr>
<td>High drug loading capability</td>
<td>- -</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+ +</td>
</tr>
<tr>
<td>Load different drugs into same particle</td>
<td>- -</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+ +</td>
</tr>
</tbody>
</table>
Microfabricated Microparticles Using a Dissolvable Hydrogel Template

Microparticles are Released by Dissolving Hydrogel Template in Water
Routes of Administration
Ohr Sustained Release Therapeutics

- SR therapeutics would markedly enhance patient compliance, reduce treatment burden, and improve visual outcomes

- Ohr SR programs address unmet medical needs in:
  - Glaucoma
  - Steroid-Induced Glaucoma
  - Ocular Allergy
  - Retinal Diseases
**Ophthalmic Indication: Glaucoma**

*Tunable release capabilities for a hydrophilic drug molecule*

Different formulations to meet desired target profiles
Ophthalmic Indication: Glaucoma

Layering process reduces burst release for a hydrophilic drug molecule.
Ophthalmic Indication: Glaucoma
Layering process reduces burst release
Ophthalmic Indication: Inflammation

Tunable release profile obtained using biodegradable polymers

Polymer B

Polymer A+B

Polymer A

Cumulative Release (%)

Months

0 2 4 6 8 10
Ophthalmic Indication: Steroid-Induced Glaucoma
Sustained release obtained for a hydrophobic drug molecule

OHR1031
57% Drug Load
Ophthalmic Indication: Retinal Diseases
Sustained release obtained for a biologic ~150 kDa
Summary

- Ohr microparticle sustained release technology offers significant advantages
  - Narrow particle size distribution
  - High drug content capability
  - Burst release controlled
  - Tunable release from weeks to months
  - Simple process compatible with hydrophilic or hydrophobic drugs and biodegradable polymers
  - Amenable to small molecules and biologics
Thank You!

Ohr Pharmaceutical, Inc. Team

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