Seladelpar 12-Week Topline Data
NASH Phase 2b Study

June 11, 2019
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Seladelpar Phase 2b Study in NASH
Paired-liver Biopsy 52-Week Study Design

- Enrollment initiated April 2018; Completed in Feb 2019
- Study design meets FDA/EMA guidance criteria to enable a Ph 3 program

![Study Design Diagram]

- Primary Outcome: $\Delta$ in MRI-PDFF
- Key Secondary Outcome: $\Delta$ in 52-week Histology
Seladelpar Phase 2b Study in NASH
Study Population and Outcome Measures

**Population**
- Histologically confirmed NASH at baseline
- Liver fat content (LFC) ≥10% by MRI-PDFF
- F1 to F3 fibrosis, NAS > 4 with 1 point in each component
- Includes diabetics and non-diabetics

**12-Week Outcome Measures**
- 12-week relative change in LFC
- Liver biochemistry: ALT, AST, GGT, AP
- Lipid markers: LDL-C, triglycerides
- Other inflammatory markers: high sensitivity C-reactive protein

**Other Key Outcome Measures**
- Safety and tolerability
- 52-week histological improvement in NAS and fibrosis
- LFC and cT1 by LMS
- Liver stiffness by MRE and Fibroscan
- Biochemical fibrosis markers and Histoindex® quantitative digital pathology
### Seladelpar Phase 2b Study in NASH

**Baseline Demographics and Patient Characteristics (mITT)**

<table>
<thead>
<tr>
<th>Parameter (Mean + SD)</th>
<th>Placebo (n = 26)</th>
<th>10 mg (n = 50)</th>
<th>20 mg (n = 47)</th>
<th>50 mg (n = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>54 (10.5)</td>
<td>53 (12.6)</td>
<td>57 (12.0)</td>
<td>53 (11.3)</td>
</tr>
<tr>
<td>Male/Female (%)</td>
<td>30.8/69.2</td>
<td>30.0/70.0</td>
<td>31.9/68.1</td>
<td>33.3/66.7</td>
</tr>
<tr>
<td>Body Weight (kg)</td>
<td>104.4 (19.9)</td>
<td>95.3 (21.6)</td>
<td>100.7 (22.9)</td>
<td>99.9 (19.9)</td>
</tr>
<tr>
<td>MRI-PDFF (%)</td>
<td>22.3 (9.5)</td>
<td>22.0 (7.8)</td>
<td>20.8 (6.1)</td>
<td>20.5 (6.8)</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>61.0 (34.7)</td>
<td>60.4 (29.6)</td>
<td>57.4 (26.3)</td>
<td>67.6 (40.2)</td>
</tr>
<tr>
<td>AST (U/L)</td>
<td>43.5 (24.5)</td>
<td>45.2 (24.9)</td>
<td>46.0 (21.1)</td>
<td>46.3(27.9)</td>
</tr>
<tr>
<td>GGT (U/L)</td>
<td>99.3 (177.5)</td>
<td>84.7 (124.4)</td>
<td>97.4 (80.6)</td>
<td>66.5 (45.2)</td>
</tr>
<tr>
<td>AP (U/L)</td>
<td>82.1 (34.1)</td>
<td>83.9 (25.1)</td>
<td>81.1 (28.0)</td>
<td>76.5 (21.6)</td>
</tr>
<tr>
<td>NAS</td>
<td>5.3 (1.1)</td>
<td>5.2 (1.0)</td>
<td>5.1 (1.0)</td>
<td>5.1 (1.0)</td>
</tr>
<tr>
<td>Fibrosis Stage</td>
<td>2.1 (0.65)</td>
<td>2.1 (0.70)</td>
<td>2.3 (0.72)</td>
<td>2.1 (0.65)</td>
</tr>
<tr>
<td>LDL-C (mg/dL)</td>
<td>114.2 (45.5)</td>
<td>103.8 (33.0)</td>
<td>111.0 (47.6)</td>
<td>106.7 (40.0)</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>151.2 (51.3)</td>
<td>166.4 (79.5)</td>
<td>173.4 (72.8)</td>
<td>154.2 (93.8)</td>
</tr>
</tbody>
</table>

*mITT = modified intent-to-treat population*
Seladelpar Phase 2b Study in NASH
Changes in Relative Liver Fat Content by MRI-PDFF

Comparative Relative Change from Baseline

Proportion of Subjects with > 30% Relative Change from Baseline

p-values relative to placebo
Seladelpar Phase 2b Study in NASH
Changes in Absolute Liver Fat Content by MRI-PDFF

Comparative Absolute Change from Baseline

Proportion of Subjects with > 5%
Absolute Change from Baseline

p-values relative to placebo
Seladelpar Phase 2b Study in NASH
Changes in Absolute and Relative ALT

### Change in Relative ALT Over Time

*Weeks*

- **Placebo (n=27)**
- **10 mg (n=53)**
- **20 mg (n=51)**
- **50 mg (n=50)**

### Change in Absolute ALT Over Time

*Weeks*

- **Placebo (n=27)**
- **10 mg (n=53)**
- **20 mg (n=51)**
- **50 mg (n=50)**
Seladelpar Phase 2b Study in NASH
Relative Changes in Key Markers of Hepatic Injury

<table>
<thead>
<tr>
<th>%, LS Mean (SE)</th>
<th>Placebo (n = 27)</th>
<th>10 mg (n = 53)</th>
<th>20 mg (n = 51)</th>
<th>50 mg (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT</td>
<td>-8.9 (5.1)</td>
<td>-22.9 (3.8)</td>
<td>-32.0 (4.0)</td>
<td>-37.5 (4.0)</td>
</tr>
<tr>
<td></td>
<td>p=0.08</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>AST</td>
<td>-12.9 (5.8)</td>
<td>-11.6 (4.4)</td>
<td>-15.2 (4.5)</td>
<td>-17.3 (4.5)</td>
</tr>
<tr>
<td></td>
<td>p=0.03</td>
<td>p=0.009</td>
<td>p=0.001</td>
<td>p=0.002</td>
</tr>
<tr>
<td>GGT</td>
<td>-4.5 (4.3)</td>
<td>-28.2 (3.2)</td>
<td>-37.6 (3.3)</td>
<td>-43.1 (3.4)</td>
</tr>
<tr>
<td></td>
<td>p=0.3</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>AP</td>
<td>4.4 (2.9)</td>
<td>-19.1 (2.1)</td>
<td>-25.1 (2.2)</td>
<td>-33.4 (2.2)</td>
</tr>
<tr>
<td></td>
<td>p=0.12</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

ALT, AST, GGT and AP data from safety population; p-values relative to baseline
Treatment with seladelpar resulted in reductions in both LDL-C and triglycerides

HDL-C levels remained stable in all treatment arms

Treatment with seladelpar resulted in reductions in hs-CRP

No clinically meaningful changes in fasting glucose or HbA1C

No significant changes in body weight or BMI
Seladelpar was safe and generally well tolerated in patients with NASH at doses up to 50 mg.

The majority of treatment emergent adverse events were mild to moderate and deemed unrelated to study drug.

The most common (>5%) treatment emergent adverse events included nausea, constipation, dizziness, headache, gastroesophageal reflux disease and upper abdominal pain.

Two SAEs both deemed unrelated to study drug.

No Grade 3 or greater ALT/AST elevations.
Summary and Q&A

1.8 Å RMSD X-ray Crystal Structure
Seladelpar - PPARα Ligand Binding Domain