PROMISE 1
Top-Line Data Results

June 27, 2017
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Randall Schatzman
President and Chief Executive Officer
Strong Pivotal PROMISE 1 Top-Line Results

- **PROMISE 1 met primary endpoint**: highly statistically significant reductions in monthly migraine days for the 300 mg and 100 mg doses for weeks 1 through 12
  - 30 mg dose was not tested per statistical analysis plan
- **Significant clinical benefit on Day 1**
  - >50% reduction in the proportion of patients experiencing a migraine on day 1 post-dose
- **Significant 75% responses at all key time points**
  - 1/3 of patients achieved a >75% reduction in migraine days through 4 and 12 weeks, increasing to 40% of patients at 24 weeks
- **Average 1 in 5 patients had 100% response**: no migraines in any given month, months 1 through 6
- **The safety profile was similar to placebo**: consistent with previously reported eptinezumab studies

These highly positive results, consistent with previous studies, support the unique clinical profile of eptinezumab as a potential first-of-its-kind infusion therapy to prevent migraines.
Migraine affects 36 million Americans; 13 million experience more than four migraines per month and are candidates for prevention therapy.

**Migraine is a devastating chronic disease:**

- As migraine frequency increases the susceptibility to future migraine increases.
- The biggest risk for Chronic Migraine is Frequent Episodic Migraine.
- Migraine begins in early life and continues for decades.

**High unmet need for new, effective, and well-tolerated prevention options:**

- Current treatments fail to meet the needs of most patients.
- Treatment, if effective, can take weeks to months to achieve meaningful clinical benefit.
- Most patients discontinue within 6 months to 1 year due to lack of efficacy and/or side effects.
Eptinezumab: Unique And Competitively Differentiated Paradigm For Migraine Prevention

• Eptinezumab, the only anti-CGRP in clinical development administered quarterly via infusion that allows for 100% of the dose available to inhibit CGRP

• Eptinezumab development program was designed to redefine physician and patient expectations for migraine prevention.

• Two successful Phase 2 studies meeting primary and secondary endpoints
  • Frequent episodic migraine, chronic migraine

• Ongoing global Phase 3 program
  • PROMISE 1: Frequent episodic migraine
  • PROMISE 2: Chronic migraine – Data expected 1H 2018
  • Open label: One year safety study – Completion expected 1H 2018

• Planned BLA submission in 2H 2018
Roger Cady
Vice President of Neurology, MD, FAHS
PROMISE 1 Phase 3 Trial
Evaluating Patients with Frequent Episodic Migraine
Pivotal PROMISE 1 FEM study (n=888)*

**Study Schema**

1. **Screening**
2. **Baseline Run-In**
3. **Randomization**
   - 30 mg ALD403 iv Q3M x 4, N=223
   - 100 mg ALD403 iv Q3M x 4, N=221
   - 300 mg ALD403 iv Q3M x 4, N=222
   - Placebo IV iv Q3M x 4, N=222

4. **Infusion Schedule**
   - Day 0 Infusion
   - Week 12 Infusion
   - Week 24 Infusion
   - Week 36 Infusion

5. **Study Endpoints**
   - 12 week (primary), 24 week, and 56 week

* Full analysis set
## Frequent Episodic Migraine - Phase 3 Top-line Efficacy Endpoints Designed To Capture Unique Attributes Of Eptinezumab

| Primary Endpoint | • Mean change from baseline in monthly migraine days  
|                 |   • Weeks 1 through 12 |
| Key Secondary Endpoints | • Day 1 post-dose  
|                 |   • Proportion (%) of patients experiencing a migraine  
|                 |   • Weeks 1 through 4  
|                 |   • ≥75% responder rates  
|                 |   • Weeks 1 through 12  
|                 |   • ≥50% responder rates  
|                 |   • ≥75% responder rates |
| Additional Secondary Endpoints | • Day 1 through Week 4  
|                 |   • Day 1 Post Dose Percent of Patients with Migraine Reduction Sustained Through Week 4  
|                 | • Weeks 13 through 24  
|                 |   • ≥75% responder rates  
|                 | • Months 1-6  
|                 |   • 100% response: no migraine in any given month |
## Patient Demographics – Well Balanced Across Treatment Groups

<table>
<thead>
<tr>
<th></th>
<th>Eptinezumab 300mg N=222</th>
<th>Eptinezumab 100mg N=221</th>
<th>Eptinezumab 30mg N=223</th>
<th>Placebo N=222</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Age - years</strong></td>
<td>40.2</td>
<td>40.0</td>
<td>39.1</td>
<td>39.9</td>
</tr>
<tr>
<td><strong>Mean Weight - kg</strong></td>
<td>80.2</td>
<td>82.4</td>
<td>82.0</td>
<td>82.4</td>
</tr>
<tr>
<td><strong>Female Gender - %</strong></td>
<td>88.8</td>
<td>80.3</td>
<td>84.5</td>
<td>83.8</td>
</tr>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean Migraine Days per Month</strong></td>
<td>8.6</td>
<td>8.7</td>
<td>8.7</td>
<td>8.4</td>
</tr>
<tr>
<td><strong>Mean Years from Diagnosis</strong></td>
<td>18.2</td>
<td>17.4</td>
<td>17.0</td>
<td>16.9</td>
</tr>
</tbody>
</table>
Primary Endpoint Met – Demonstrates Highly Statistically Significant Reductions in Monthly Migraine Days: Weeks 1 through 12

Mean change in Monthly Migraine Days from Baseline

- 300mg IV: N=222, Mean change = -4.3, p=0.0001
- 100mg IV: N=221, Mean change = -3.9, p=0.0179
- Placebo IV: N=222, Mean change = -3.2

*Primary endpoint met: Demonstrates highly statistically significant reductions in monthly migraine days from baseline.*
>50% Reduction In The Proportion Of Patients Experiencing Migraine On Day Following Infusion

Percent Reduction in the Proportion of Patients Experiencing a Migraine on Day 1

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline (%)</th>
<th>Day 1 (%)</th>
<th>Reduction (%)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>300mg IV</td>
<td>N=68(^1)</td>
<td>N=32</td>
<td>53.6%</td>
<td></td>
</tr>
<tr>
<td>100mg IV</td>
<td>N=69(^1)</td>
<td>N=33</td>
<td>51.3%</td>
<td>p=0.0087*</td>
</tr>
<tr>
<td>Placebo IV</td>
<td>N=66(^1)</td>
<td>N=53</td>
<td>20.7%</td>
<td>p=0.0167*</td>
</tr>
</tbody>
</table>

1. Mean number of patients having migraine on any 1 day during the 28 day baseline period
*Unadjusted
Day 1 through Week 4: Percent of Patients with Migraine Reduction
Day 1 Post Dose Sustained Through Day 28

- Placebo (N=222)
- 100mg (N=221)
- 300mg (N=222)

* Unadjusted p=0.0167
** Unadjusted p=0.0087
Day 1 through Week 4: Percent of Patients with Migraine Reduction
Day 1 Post Dose Sustained Through Day 28

* Unadjusted p=0.0167
** Unadjusted p=0.0087
Day 1 through Week 4: Percent of Patients with Migraine Reduction
Day 1 Post Dose Sustained Through Day 28

- **20.7%**
- **53.6%**
- **15.1***
- **14.3****

Day 1
Week 1
Week 2
Week 3
Week 4

100mg N=221
300mg N=222
Placebo N=222

* Unadjusted p=0.0167
** Unadjusted p=0.0087
Weeks 1 Through 12: More Than 1/2 Of Patients Achieved A ≥50% Statistically Significant Reduction In Migraine Days

% of patients Achieving ≥50% Reduction

- 300mg IV: 56.3% (N=222)
- 100mg IV: 49.8% (N=221)
- Placebo IV: 37.4% (N=222)

*p<0.001
*p<0.0085 (unadjusted)

*Unadjusted
Weeks 1 Through 4: ~1/3 Of Patients Achieved A ≥75% Statistically Significant Reduction In Migraine Days

- 31.5% for 300mg IV (N=222)
- 30.8% for 100mg IV (N=221)
- 20.3% for Placebo IV (N=222)

Statistical significance:
- p=0.0066
- p=0.0112
Weeks 1 Through 12: ~1/3 Of Patients Achieved A ≥75% Statistically Significant Reduction In Migraine Days

p=0.0007

Percent of patients Achieving ≥75% Reduction

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>300mg IV</td>
<td>222</td>
<td>29.7%</td>
</tr>
<tr>
<td>100mg IV</td>
<td>221</td>
<td>22.2%</td>
</tr>
<tr>
<td>Placebo IV</td>
<td>222</td>
<td>16.2%</td>
</tr>
</tbody>
</table>

NS=Not Significant
Weeks 13 Through 24: 40% Of Patients Achieved A ≥75% Significant Reduction In Migraine Days Following A Second Dose
Weeks 1 through 24: >30% of patients achieved a ≥75% reduction in migraine days which is improved through Week 24.
Months 1 through 6: Average 1 In 5 Patients Had 100% Response With No Migraines In Any Given Month

Percent of Patients Who Had 100% Response with No Migraine by Month
## Safety Profile

- Similar to placebo
- Consistent with earlier eptinezumab studies

<table>
<thead>
<tr>
<th></th>
<th>ALD403 300 mg (N=224)</th>
<th>ALD403 100 mg (N=223)</th>
<th>ALD403 30 mg (N=219)</th>
<th>Placebo (N=222)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with Any TEAE, n (%)</td>
<td>119 (53.1)</td>
<td>132 (59.2)</td>
<td>114 (52.1)</td>
<td>124 (55.9)</td>
</tr>
<tr>
<td>Subjects with Any Serious TEAE*, n (%)</td>
<td>2 (&lt;1)</td>
<td>4 (1.8)</td>
<td>4 (1.8)</td>
<td>6 (2.7)</td>
</tr>
<tr>
<td>Subjects with Any TEAE Leading to Study Drug Withdrawal, n (%)</td>
<td>4 (1.8)</td>
<td>4 (1.8)</td>
<td>9 (4.1)</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Most Frequent TEAEs**:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>14 (6.3)</td>
<td>16 (7.2)</td>
<td>15 (6.8)</td>
<td>11 (5.0)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>10 (4.5)</td>
<td>5 (2.2)</td>
<td>7 (3.2)</td>
<td>14 (6.3)</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>23 (10.3)</td>
<td>20 (9.0)</td>
<td>23 (10.5)</td>
<td>15 (6.8)</td>
</tr>
</tbody>
</table>

TEAE = Treatment Emergent Adverse Event;  
* All Serious TEAEs judged unrelated to study drug;  
** ≥ 5% in any treatment group
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