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Outline of Today’s Presentation
Belapectin (GR-MD-02) and NASH CIRRHOSIS

• Highlights of NASH-CX Phase 2 study
• The road to Adaptively-Designed (Phase 2b/Phase 3) NASH-RX trial start
  • Regulatory input and recent FDA interactions
  • Revised study design
    • Benefits and risks
  • Sites & study status
  • Next steps
• Summary
Targeting NASH Cirrhosis – Cirrhosis Stage

Progression to Cirrhosis (5%)

Fatty Liver → NASH: Cell Death → Inflammation → Fibrosis

Progression to Varices

Cirrhosis Stage
Clinical
Hemodynamic (HVPG, mmHg)
Biological

Stage 1
Compensated
No varices or complications

Stage 2
Compensated
Varices present

Stage 3 and 4
 Decompensated
Complications

Scar and X-linking

Thick (acellular) scar and Nodules

Insoluble scar

Estimated US Prevalence

80-100M
24-30M
3-5M
1.5-2.5M
1.5-2.5M

NASH-CX Trial Showed Positive Efficacy in Stage 1 NASH Cirrhosis

1 Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:14451449
Critical Importance of Esophageal Varices in NASH Cirrhosis

An important goal of treatment of patients with Stage 1, compensated cirrhosis without esophageal varices is to prevent progression to varices and complications

“No varices means no potential for bleeding varices”

Esophagus: No Varices  Esophageal Varices  Bleeding Esophageal Varices
THE NASH-CX TRIAL

Highlights of results
Belapectin (GR-MD-02) Development Program: Summary

• Gal-3 null mice are resistant to development of NASH \(^1\) and liver fibrosis \(^1, 2\)

• GR-MD-02 is a glycopolymer (polysaccharide), considered a Nonbiological Complex Drug (NBCD) that binds to galectin-3 protein, has strong global patent protection, and is administered intravenously

• GR-MD-02 has robust efficacy in pre-clinical models of NASH and toxic cirrhosis, with action at a nexus of multiple pathophysiological processes \(^3, 4\)

• Well tolerated and safe in preclinical toxicology and clinical trials (2 P1, P2a and P2b)

• *NASH-CX phase 2b clinical trial showed clinically meaningful positive results of GR-MD-02 in patients with NASH cirrhosis without esophageal varices (Stage 1 Cirrhosis)*

• NASH-CX trial identified endpoints and patient population that can form the basis of phase 3 trials in NASH cirrhosis without esophageal varices

\(^1\) Journal of Hepatology 2011;54:975-983  
\(^2\) PNAS 2006;103:5060-5065  
\(^3\) Traber PG and Zomer E.PLOS ONE 2013;8:e83481  
### Major Inclusion Criteria
- NASH cirrhosis (biopsy)
- HVPG ≥ 6 mmHg
- No cirrhosis complications
- No or small varices

#### Every other week infusion X 26
- Placebo (54)
- GR-MD-02 2 mg/kg (54)
- GR-MD-02 8 mg/kg (54)

#### Primary endpoint
<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 26</th>
<th>Week 54</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVPG²</td>
<td>X</td>
<td></td>
<td>X</td>
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</tbody>
</table>

#### Secondary endpoints
<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 26</th>
<th>Week 54</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver Biopsy³</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>FibroScan</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MBT⁴</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Complications⁵</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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1. All subjects were enrolled across 36 sites in the US
2. HVPG = Hepatic Venous Pressure Gradient
3. Histologic staging & quantitative morphometry for collagen
4. MBT = ¹³C Methacetin Breath Test
5. Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)
Patient Populations – NASH-CX

Definitions:
- ITT = Intention to Treat
- ITT/LOCF = ITT/Last Observation Carried Forward
- mITT = ITT with end of study HVPG
- PP = Per Protocol
- MPH = Mild Portal Hypertension
- CSPH = Clinically Significant Portal Hypertension

Note: All analyses done with ITT/LOCF; results were similar with other analysis sets

Patients Screened: N = 290

Screening Failures N = 128

Patients Randomized: N = 162

1 Discontinued before 1st dose
10 Discontinued during dosing without end of study HVPG

Study Analysis Sets
- ITT: 161
- ITT/LOCF: 161
- mITT: 151
- PP: 145

Baseline Esophageal Varices
N = 80 (ITT/LOCF)

CSPH
N = 67

MPH
N = 13

No Baseline Esophageal Varices
N = 81 (ITT/LOCF)

CSPH
N = 41

MPH
N = 40

Demographic characteristics (age, gender, BMI, nationality, diabetes) and baseline HVPG measurements were balanced across the three treatment groups in study analysis sets
NASH-CX: HVPG Primary Endpoint
Total Patient Population

1. Trend toward benefit with drug, but not statistically significant
2. Drug effect was significantly dependent on dose*varices in total group (p<0.02)
3. GR8 dose group, based on pK, was above upper limit of the therapeutic window

<table>
<thead>
<tr>
<th>Mean Change</th>
<th>0.3</th>
<th>-0.37</th>
<th>-0.42</th>
</tr>
</thead>
<tbody>
<tr>
<td>From Baseline to Week 54(^1)</td>
<td>p=0.45</td>
<td>p=0.49</td>
<td>(Absolute Change)</td>
</tr>
<tr>
<td></td>
<td>p=0.10</td>
<td>p=0.10</td>
<td>(Percent Change)</td>
</tr>
</tbody>
</table>

Overall mean baseline
HVPG=12.22 mmHg
(No significant difference between groups at baseline-ANOVA)

Mean ± SEM

\(^1\)ITT with LOCF, ANCOVA with LSD
### NASH-CX Patients Without Varices at Baseline (50% of total population)

Statistically significant effect of 2 mg/kg dose on absolute change in HVPG

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Change From Baseline to Week 54</th>
<th>p Value</th>
<th>Absolute Change</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>0.8</td>
<td>p &lt; 0.01</td>
<td>p = 0.01</td>
<td>p = 0.17</td>
</tr>
<tr>
<td>GR-MD-02 2 mg/kg</td>
<td>-1.08</td>
<td>p = 0.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GR-MD-02 8 mg/kg</td>
<td>0.15</td>
<td>p = 0.17</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Overall mean baseline HVPG=10.6 mmHg**
(No significant difference between groups at baseline-ANOVA)

1ITT with LOCF, ANCOVA with LSD
* Results at 8 mg/Kg dose, based on pK, may reflect doses outside the therapeutic window as observed in preclinical studies
Among patients without varices at baseline, there were more new varices in the placebo group than in the GR2 group.
Both the GR2 and GR8 treatment groups had a statistically significant effect on the percent change in HVPG in patients without varices and MPH.
NASH-CX: HVPG in Patients Without Varices at Baseline and Clinically Significant Portal Hypertension (HVPG >10 mmHg)

Like the MPH group shown earlier, in patients with CSPH, the GR2 group showed a statistically significant reduction in HVPG when compared to placebo.
NASH-CX: Major Conclusions

- GR-MD-02 had a statistically significant and clinically meaningful effect in reducing HVPG in patients with NASH cirrhosis who did not have baseline esophageal varices (50% of total patient population)
- Important drug effect in the total study population on liver biopsy, with a statistically significant improvement in hepatocyte ballooning (cell death)
- Statistically significant reduction in the development of varices in drug-treated patients compared to placebo
- While there was a drug effect in both dosage groups on liver biopsy and in the mild portal hypertension group, there was a consistently greater and statistically significant effect of the 2 mg/kg dose
- GR-MD-02 appears to be safe and well tolerated in this one year, phase 2b clinical trial
- We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with NASH cirrhosis without varices
- It is estimated that 50% of those suffering with NASH cirrhosis have not yet developed esophageal varices
- Full length paper accepted by Journal of Gastroenterology
The NASH-RX trial

Adaptively-Designed Phase 2b/3 Trial of Belapectin in NASH Cirrhosis
The Road to Phase 3 is often a Long Path

There is light at the end of the tunnel
Road to Phase 3: Sequence of Events and Highlights

- **Feb 2019 - FDA Meeting**
  - Purpose: Discuss potential surrogate endpoint of progression to varices for Phase 3 trial
  - Indicated supportive of “the potential use of progression to varices as a surrogate endpoint and progression to large varices (or to small varices with a weal) as a component of a composite clinical benefit endpoint …”
  - FDA requested follow up review of Phase 3 protocol via Type C, Written Request Only (WRO) submission

- **July 2019 – Filed WRO Submission**
  - Phase 3 and Phase 4 protocols
  - Addressed other FDA questions and suggestions

- **October 2019 – FDA responded**
  - FDA felt justifications for not doing Hepatic Impairment (HI) study and dose selections seemed reasonable
  - FDA suggested we affirm NASH-CX efficacy and dose selection
  - In conjunction with KOLs and Covance, developed a response plan – Adaptively-designed Phase 3 trial with interim analysis and accelerated review with proposed surrogate endpoint

- **November 2019 - GALT filed 10-Q and Press Release describing key FDA responses**
  - Conservatively described what we felt were the key FDA messages
    - Solidify dose selection and reaffirm efficacy seen in NASH-CX trial
    - Recommending a traditional approval pathway (not surrogate)
  - Highlighted a revised study approach and few month delay in study start

- **November 14, 2019 - GALT and co-PIs had informal teleconference with FDA seeking clarifications and proposed a new study design to address FDA comments**
  - FDA indicated they felt the new design was more reasonable (subject to review of protocol)
  - FDA indicated they were still supportive of the surrogate end-point concepts proposed
What’s the plan?
NASH-RX: Adaptively-Designed Phase 3 Study in NASH Cirrhotics

Key eligibility criteria
1. NASH cirrhosis
2. Without varices
3. CTP score <7
4. Clinical signals suggesting portal hypertension, with at least 2 of:
   • thrombocytopenia
   • spleen size ≥ 15 mm
   • evidence of collaterals by imaging

Interim Analysis (DMC): to inform Phase 3
1◦ endpoint: incidence of varices (by EGD)

Pre-planned adaptations
Select optimal dose based on Ph2b data
Randomize additional patients
Incorporation of results of the HI study

Accelerated approval application
1◦ endpoint: development of new varices

2◦ endpoints
• Proportion of patients with large varices or red wales
• Varices requiring treatment
• Decompensation events
• All cause mortality
• MELD ≥ 15 in patients with baseline MELD <12
• Liver transplant
• Biomarkers

Hepatic Impairment Study
Completed prior to Interim Analysis

Phase 4 begins before marketing application
Final approval
Clinical Benefit

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• Inclusion/Eligibility Criteria
  • NASH cirrhosis
  • No varices
  • CTP score < 7 (Class A)
  • Clinical signals suggesting portal hypertension with at least 2 of:
    • Thrombocytopenia
    • Spleen size ≥ 15 mm
    • Evidence of collaterals by imaging

• Double-blind
  • Duration 12-18 months (to be refined)
  • Size: 75-100 patients/study arm
  • GR-MD-02 (belapectin) at dose of 2 mg/Kg and 4 mg/Kg LBM
    • Expected to be well within therapeutic window based on NASH-CX pK results
Key Feature of NASH-RX Design at End of Segment 1
Interim Analysis (DMC) to inform Phase 3

- Interim Analysis informs:
  - Primary EP: Incidence of varices
  - Confirms dose selection from NASH-CX results and dose adjustment
    - Informs a single dose into Phase 3
  - Event rate allows ‘right-sizing’ of Phase 3
    - e.g., randomization of additional patients
  - Hepatic Impairment study may allow inclusion of ≥ CTP B patients
  - Potential adjustment in randomization ratio
  - Termination of Study – e.g., due to ‘futility’
- Segment 1 patients expected to roll into next study phase
  - Creates a cohort with an additional year of treatment at time of the accelerated approval application presuming positive results
NASH-RX: End of Segment 2
Accelerated approval application

• Accelerated approval
  • Primary Endpoint
    • Development of new varices
  • Secondary Endpoints
    • Proportion of patients with large varices or red wales
    • Varices requiring treatment
    • Decompensation events
    • All-cause mortality
    • MELD > 15 in patients with baseline MELD<12
    • Liver transplant
    • Biomarkers
  • Informs Phase 4 features – sizing, duration
• Study features potentially improving likelihood of showing Drug effects
  • Clarity and reaffirmation of NASH-CX efficacy & safety
  • Appropriate selection of dose – e.g., single dose (2 or 4 mg/kg) for P3 or both
  • Hepatic Impairment study results may allow inclusion of CTP-B / CTP-C patients which have a much higher rate of varices progression and bleeding & other decompensating events
  • Reduced frequency of EGDs and elimination of biopsy and HVPG subgroup may make it easier to enroll trial; offset by robust sizing in P2 component (e.g. 75-100+ pts/group) and a difficulty in frequently monitoring patients for varices progression
  • Potential to select a single dose for P3 component simplifying trial and to adjust randomization ratio for P3
  • Patients from P2 will roll into P3 component adding patients with another year (tot. ~2.5 to 3 yrs.) exposure to drug and increasing the likelihood of showing drug effect as patient cirrhosis progresses
  • Adaptation to size and power calculations based on more robust Phase 2b component will allow better estimates of Phase 3 cohort sizing and statistical power estimations
  • Interim Analysis – provides preplanned adaptations and interim efficacy and safety results

• Study Features increasing risk
  • Interim Analysis – affects statistics ("statistical hit") requiring larger size P3 component
  • Interim Analysis – could result in trial being stopped for lack of at least a clear trend in efficacy
  • Preplanned Adaptations at time of Interim Analysis – we may have insufficient knowledge to pre-plan for adaptations that a more robust P2 dataset would have given insight into
Sites qualified by Covance
- ~130 sites in 12 countries
- Revisiting sites passed over due to biopsy, EGD testing frequency and HVPG requirements of earlier study design
- Sites being kept informed of status of study start

Work completed for
- NASH-specific site network and numerous vendor contracts
- EGD and associated adjudication processes
- Patient questionnaires – QoL and Alcohol Use Assessment
- Databases: Study & Central Lab will require tweaking

Foreign regulatory filings proceeding according to timeline

Protocol being tweaked for new design elements
- Biostatistics assessing sizing and duration

Response to other minor FDA suggestions being addressed
NASH-RX: Additional Considerations & Next Steps

- There is a delay due to modifying the protocol and resubmitting to FDA
- Change in first patient first visit to late Q1, 2020
  - Sites have been informed to maintain their interests
- Costs being reassessed
  - Elimination of HVPG subgroup and reduced frequency of EGDs will reduce costs compared to original estimate
  - Offset by potentially increased patient numbers and perhaps sites which will be determined when the final protocol is established
- Revised protocol expected to be filed with FDA mid to late first quarter 2020
THANK YOU