KEY TAKEAWAY MESSAGE

• COVID-19 exposure did not impact the overall safety and efficacy results of TERN-101 in a 12-week, Phase 2a study in patients with presumed NASH.

1 INTRODUCTION

• TERN-101 is a potent, non-steroidal FXR agonist with enhanced liver distribution, being developed for the treatment of NASH.

• The Phase 2a LIFT study assessed multiple doses of TERN-101 vs placebo for 12 weeks in non-cirrhotic patients with NASH (Figure 1).

• The LIFT study showed TERN-101 was overall safe and well-tolerated with significant reductions in corrected T1 (ct1) and decreases in atarne anilinotransferase (ALT) and magnetic resonance imaging proton density fat fraction (MRI-PFF).

• The LIFT study was conducted entirely during the COVID-19 pandemic, thereby allowing analyses of TERN-101 administered in the setting of COVID transmission.

• We evaluated overall safety and key efficacy parameters in NASH patients with COVID-19 exposure during the LIFT study.

Figure 1: TERN-101 Phase 2a LIFT Study Design

2 OBJECTIVE

• To explore any potential impact of COVID-19 exposure on safety or efficacy of TERN-101 in Phase 2a LIFT study.

3 METHODS

• LIFT was a randomized, double-blind, placebo-controlled Phase 2a study (NCT04332077) which was conducted entirely in the U.S. between June 2020 and May 2021 and evaluated 5 mg, 10 mg, and 15 mg TERN-101 administered for 12 weeks in 100 adults with NASH (Figure 1).

• All study participants were randomized between July 2020 and January 2021, prior to the availability of COVID-19 vaccinations in the U.S.

• COVID-19 testing was performed at Screening and at Weeks 0 (Day I), 6, and 12 during the study. Antibody testing was required, with no antibody and/or PCR testing in the event of the COVID-19 symptoms (Figure 2).

• COVID-19 vaccination was permitted and was recorded as a concurrent medication (COVID-19 vaccines became available in the U.S. after LIFT enrollment was completed and while study medication dosing was ongoing).

• COVID-19 exposure was defined as:
  – COVID-19 infection reported as an adverse event (AE), or
  – Detectable COVID-19 antibodies during the study (Week 0 to Day 1 or later).

Figure 2: Screening and On-Study COVID-19 Testing

4 RESULTS

OVERVIEW OF COVID-19 TESTING RESULTS AND TOTAL CASES OF COVID-19 EXPOSURE

• COVID-19 Polymerase Chain Reaction (PCR) testing
  – 7 out of 446 potential participants screened for the study had a positive acute respiratory syndrome coronavirus 2 (SARS-CoV-2) PCR test at screening and were excluded from the study.
  – No positive SARS-CoV-2 PCR test results were reported through on-study testing.

• COVID-19 Antibody (Ab) testing
  – 20 patients with positive COVID-19 antibody results (Edi or Abbot or local lab) from Week 0 through Week 12
  – 4 of the patients developed detectable antibodies after COVID-19 vaccinations.

• A total of 24 COVID-19 exposure cases were identified during the study: 20 patients with COVID-19 antibody at Week 0 or later and 4 additional patients with COVID-19 AEs.

• The demographics and baseline characteristics of patients with or without identified COVID-19 exposures are shown in Table 1.

Table 1: Patient Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Patient Demographics and Baseline Characteristics</th>
<th>No Identified COVID-19 Exposure</th>
<th>Identified COVID-19 Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean; SD) [years]</td>
<td>44.8 (7.1)</td>
<td>44.7 (6.9)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>18 (45.5)</td>
<td>13 (33.3)</td>
</tr>
<tr>
<td>Male</td>
<td>10 (25.0)</td>
<td>18 (45.5)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>18 (45.5)</td>
<td>13 (33.3)</td>
</tr>
<tr>
<td>White</td>
<td>11 (27.5)</td>
<td>12 (30.8)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td>18 (45.5)</td>
<td>13 (33.3)</td>
</tr>
<tr>
<td>Hispanic or Latinian</td>
<td>11 (27.5)</td>
<td>12 (30.8)</td>
</tr>
<tr>
<td>BMI, mean (SD) [kg/m²]</td>
<td>27.8 (6.8)</td>
<td>27.9 (5.8)</td>
</tr>
<tr>
<td>ALT, median [SD] [IU/L]</td>
<td>37.9 (30.0)</td>
<td>42.0 (24.0)</td>
</tr>
<tr>
<td>MRI-PFF, median [SD] [nm²/g]</td>
<td>12.2 (7.5)</td>
<td>12.1 (7.4)</td>
</tr>
<tr>
<td>cT1, median [SD] [ms]</td>
<td>29.0 (14.0)</td>
<td>31.1 (17.1)</td>
</tr>
</tbody>
</table>

ADVERSE EVENTS

• Of 166 enrolled and treated patients, 96% completed the LIFT study with no discontinuations due to AEs and no deaths.

• AEs occurred in 38.5% of the placebo and 56.8% of the TERN-101 groups (Table 2).

• COVID-19 infection was reported for 3 patients during the study (Table 2).

• 6 who received TERN-101 and had mild to moderate AEs (Grade 1 or 2).

• 1 placebo patient who had a severe/serious AE that eventually resolved.

• Similar rates of AEs were reported between patients without COVID-19 exposure and with COVID-19 exposure.

Figure 2: Overall Summary of Adverse Events

<table>
<thead>
<tr>
<th>Adverse Events by category, n (%)</th>
<th>No Identified COVID-19 Exposure</th>
<th>Identified COVID-19 Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>All AEs</td>
<td>14 (35.9)</td>
<td>25 (50.0)</td>
</tr>
<tr>
<td>Gastrointestinal AEs</td>
<td>11 (27.5)</td>
<td>19 (38.0)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5 (12.5)</td>
<td>9 (18.0)</td>
</tr>
<tr>
<td>Skin AEs</td>
<td>3 (7.5)</td>
<td>10 (20.0)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (5.0)</td>
<td>6 (12.0)</td>
</tr>
<tr>
<td>Any AE</td>
<td>14 (35.9)</td>
<td>25 (50.0)</td>
</tr>
<tr>
<td>Any AE of Grade 3 or higher</td>
<td>1 (2.5)</td>
<td>3 (6.0)</td>
</tr>
</tbody>
</table>

RESPONSES TO THERAPY

• Relative changes in MRI-PFF (Figure 3A) and changes in cT1 (Figure 3B) at Week 12 in patients with COVID-19 exposure were generally similar to those in patients without COVID-19 exposure.

Figure 3A: MRI-PFF Relative Changes at Week 12

Figure 3B: cT1 Changes at Week 12

CONCLUSIONS

• Patient recruitment and retention in the LIFT study was feasible during the COVID-19 pandemic with successful implementation of COVID-19 testing.

• The TERN-101 safety profile and responses in the key efficacy imaging endpoints including MRI-PFF and cT1 were overall similar between the patients with identified COVID-19 exposure and those without.

• Utilization of COVID-19 testing supported successful study conduct despite the COVID-19 pandemic with an obvious impact on the study results (NCT04332077).

5 CONTACTS AND DISCLOSURES

• Luiz Lee, PharmD
• Teresa Pharmaceuticals
• faa@ternspharma.com

• TERN-101 is an investigational drug being developed by Teresa Pharmaceuticals, which is evaluating the study for the funding as well as the post-trial preparation services.

6 ACKNOWLEDGEMENTS

• The authors are grateful to the LIFT study participants, investigators, and research staff for participation and conduct of the study. Writing assistance was provided by Lu X K Ho, PharmD (Forward WE Go, a division of Wiley Enterprise, Inc.)

7 REFERENCE