Real-world utilization of the new fixed-dose combination elbasvir/grazoprevir in adult patients with chronic hepatitis C in Canada: Z-PROFILE study

Edward Tam1, Chris Fraser2, Julie Tremblay3, Brian Conway4, Benoît Ramji5, Sergio Borgia7, Kris Stewart8, Youb Chalabi9

1Laurel Centre, BC, Canada; 2The Coal Aid Community Health Centre, BC, Canada; 3Centre Sœrè Amélie, QC, Canada; 4Vancouver Infectious Diseases Centre, BC, Canada; 5Clinique Médicale du Quartier Latin, QC, Canada; 6Research Institute (GIRI), Gastroenterology Division, BC, Canada; 7William Osler Health System, ON, Canada; 8Saskatchewan Infectious Disease Care Network, SK, Canada; 9Merck Canada Inc., QC, Canada.

• Multicentre retrospective chart review study.

STUDY DESIGN
- Multicentre retrospective chart review study.
- Sites per province for interim analysis: 25.

INCLUSION CRITERIA
- Male or female ≥18 years of age at time of EBR/GZR treatment initiation.
- Confirmed diagnosis of chronic hepatitis C.
- Patient was initiated on EBR/GZR treatment for their HCV infection.

EXCLUSION CRITERIA
- Not applicable.

STUDY FLOW CHART

<table>
<thead>
<tr>
<th>N = 102</th>
<th>PP for EOT</th>
<th>PP for SVR</th>
<th>PP for SVR 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 79</td>
<td>PP for EOT</td>
<td>PP for SVR</td>
<td>PP for SVR 24</td>
</tr>
<tr>
<td>N = 66</td>
<td>PP for EOT</td>
<td>PP for SVR</td>
<td>PP for SVR 24</td>
</tr>
<tr>
<td>N = 53</td>
<td>PP for EOT</td>
<td>PP for SVR</td>
<td>PP for SVR 24</td>
</tr>
<tr>
<td>N = 33</td>
<td>PP for EOT</td>
<td>PP for SVR</td>
<td>PP for SVR 24</td>
</tr>
<tr>
<td>N = 13</td>
<td>PP for EOT</td>
<td>PP for SVR</td>
<td>PP for SVR 24</td>
</tr>
</tbody>
</table>

N = 102
- 13 patients received 16 weeks EBR/GZR+RBV:
  - GT1a, GT1b, GT 2; 2 patients had mixed GT1a and GT1b.
  - The majority were treatment-experienced (n=11) and failed
    - DAA (n=2)
    - *1st gen PI-boceprevir (n=3)
    - PegIFN+RBV OTF (n=1)
    - PegIFN+RBV relapse (n=1)
    - Sofosbuvir (n=2)
  - 2 were treatment-naïve patients with GT1a and RAS (N53 or NS5A).
- All 15 patients infected by GT3 were prescribed EBR/GZR in combination with sofosbuvir.

N = 79
- SVR12 for Evaluable Population = 76/79 (96.2%). (data not shown)
- Overall, at the end of treatment (EOT), all (100.0%) patients with available data had undetectable levels of HCV RNA.

Figure 3a: Effectiveness – Per Protocol

SVR12 was achieved by more than 97% of patients for all HCV genotypes.

TREATMENT INFORMATION AT EBR/GZR INITIATION
- Baseline resistance-associated substitutions (RAS) testing was performed in 13 (12.7%) patients.
  - The genotypes of the 13 patients tested for RAS testing were: GT1a (n=11), GT1b (n=1), GT1 (n=1).
  - 1 patient had NS5A RAS: H58wt/Y. This patient was treatment-naïve, infected by GT1a and prescribed 16 weeks + RBV.

Figure 3b: SVR12 by HCV Genotype – Per Protocol

SVR12 rates were comparable among HCV genotypes and among different treatment combinations.

Figure 3c: SVR12 by Prior Treatment Group – Per Protocol

SVR12 rates were comparable among HCV genotypes and among treatment-naïve and treatment-experienced patients.

Figure 3d: SVR12 rates were achieved in GT1a infected patients, even in the absence of NS5A RAS screening for most patients.

Conclusion
- This study reports data on the real-world utilization and effectiveness of EBR/GZR in 102 patients across Canada.
- Important findings from this study population include:
  - In the Canadian cohort, the majority of individuals treated had early stage fibrosis and were infected by GT1a.
  - 28% had documented illicit drug use within the last 12 months.
  - 25% had chronic hepatitis C Disease Stage 3-6.
  - SVR12 was achieved in 75/76 (98.7%) of patients with virologic data available at that timestamp.
  - All patients with GT3 were treated with EBR/GZR+SOFO/RBV and obtained an SVR12.
  - SVR12 rates were comparable among HCV genotypes and among treatment-naïve and treatment-experienced patients.
  - SVR12 rates were achievable in GT1a infected patients, even in the absence of NS5A RAS screening for most patients.

More sites and more patients will be included in the near future.

Acknowledgements
- To all the investigators, study coordinators and the patients enrolled.

Dr. Tam: Speaker honoraria: AbbVie, BMS, Gilead, Merck Canada Inc.(Kirkland, QC, Canada), PendoPharm; Research support: AbbVie, BMS, Glaxol, Merck Canada Inc.(Kirkland, QC, Canada), PendoPharm; Research support: AbbVie, BMS, Glaxol, Merck Canada Inc.(Kirkland, QC, Canada), PendoPharm.

EASL April 19-23, 2017 – Amsterdam, Netherlands
THU-266