NO DOSE ADJUSTMENT IS NEEDED FOR PATIENTS UNDERGOING HD (RECEIVING ORAL MOXIFLOXACIN (MXF))

RESULTS

SAFETY AND TOLERABILITY

Moxifloxacin was well tolerated in this study.

SAFETY ANALYSIS

Analysis of moxifloxacin, M1 and M2 following enzymatic hydrolysis and respective metabolites following dialysis.

PK ANALYSIS

Analysis of moxifloxacin, M1 and M2 following enzymatic hydrolysis and respective metabolites following dialysis.

Figure 3: Plasma-concentration vs. time profiles of metabolite M1 following administration of a single oral 400 mg dose to healthy volunteers (SD I) and following multiple dose administration (400 mg OD over 7 days) Period 2, 1D 0H to 7D 0H, N=8, geometric mean/geometric standard deviation, horizontal line represents the limit of quantification.

Table 1: High comparison of pharmacokinetic parameters of moxifloxacin following oral 400 mg doses to healthy volunteers and patients with severe renal impairment

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Healthy volunteers</th>
<th>Severe renal impairment (CLCr&lt;30ml/min/1.73m2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC</td>
<td>mg/L h</td>
<td>37.61</td>
<td>23.41</td>
</tr>
<tr>
<td>Cl (M1)</td>
<td>mg/L h</td>
<td>2.47 1.31</td>
<td>2.60 1.24</td>
</tr>
<tr>
<td>Cl (M2)</td>
<td>mg/L h</td>
<td>1.56 1.37</td>
<td>1.80 1.78</td>
</tr>
<tr>
<td>Cmax</td>
<td>mg/L</td>
<td>17.0 11.7</td>
<td>11.0 7.8</td>
</tr>
<tr>
<td>tmax</td>
<td>h</td>
<td>1.2</td>
<td>0.8</td>
</tr>
<tr>
<td>CL/f</td>
<td>mL/min</td>
<td>158 1.33</td>
<td>154 1.37</td>
</tr>
<tr>
<td>t1/2</td>
<td>h</td>
<td>11.6 1.57</td>
<td>14.5 1.21</td>
</tr>
<tr>
<td>n = 8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSIONS

Moxifloxacin was well tolerated when administered as a single dose or multiple doses in patients undergoing HD.

REFERENCES