Predicted Plasma Exposures

<table>
<thead>
<tr>
<th>Dose</th>
<th>Day</th>
<th>Cycle</th>
<th>Cmax (ng/mL)</th>
<th>AUC 0-24 (hr*ng/mL)</th>
<th>AUC 0-48 (hr*ng/mL)</th>
<th>AUC 0-72 (hr*ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td>1</td>
<td>1</td>
<td>112.3</td>
<td>1230.7</td>
<td>2291.1</td>
<td>3372.5</td>
</tr>
<tr>
<td>100 mg</td>
<td>3</td>
<td>1</td>
<td>112.3</td>
<td>1230.7</td>
<td>2291.1</td>
<td>3372.5</td>
</tr>
<tr>
<td>100 mg</td>
<td>7</td>
<td>1</td>
<td>112.3</td>
<td>1230.7</td>
<td>2291.1</td>
<td>3372.5</td>
</tr>
</tbody>
</table>

Population PK Modeling

A) Dose-dependent Total Exposure

B) Pharmacokinetic Summary

Day 1: Cmax 485 (ng/mL), AUC 762 (hr*ng/mL) Day 7: Cmax 1622 (ng/mL), AUC 18236 (hr*ng/mL)

Conclusions: RX-3117 appears to be well tolerated.

Study Design

This is a Phase 1 multicenter, dose-finding, open-label, single agent study of RX-3117 administered orally to subjects with advanced or metastatic solid tumors. One subject was treated per dose group until the appearance of a related grade 2 or greater adverse event, after which 3 subjects were treated using a modified Fibonacci dosing schedule.

For the population PK compartmental modeling, the concentration data was analyzed using Phoenix NLME and WinNonlin. Plasma concentrations were modeled with a 3 compartment oral administration models (panels A and B), and predict the more frequent dosing schedules in (panel C) 5/week and 7/week at 500 mg/day and (panel D) 5/week and 7/week at 700 mg/day.

Conclusions

- Based upon the pharmacokinetic profile of 3 times per week dosing a more frequent (5 or 7 times per week) dosing schedule is recommended.
- Preliminary pharmacokinetic data helped validate the pharmacokinetic simulations to predict pharmacokinetic profiles at more frequent dosing.

Investigator Disclosures

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