**Background**

Ana598 was a potent non-nucleoside inhibitor of the HCV genotype-1 (GT-1) NS5B polymerase.

**Objectives**

- To assess the proportion of patients achieving cEVR (defined as undetectable HCV RNA at Week 12).
- To assess the proportion of patients achieving RVR (defined as undetectable HCV RNA at Week 4).
- To assess the baseline viral load reduction from 400 mg BID ANA598 plus SOC compared to placebo.
- To determine safety and tolerability of ANA598 administered with SOC compared to placebo.
- To assess the proportion of patients achieving undetectable HCV RNA with ANA598 plus SOC compared to placebo.

**Methods**

**Study Design**

- A randomized, double-blind, placebo-controlled study in treatment-naïve GT-1 HCV patients (Figure 2).

**Study Patients**

- In the 200 mg BID cohort, 44 patients received at least one dose of study drug (29 received ANA598 and 15 placebo).
- In the 400 mg BID cohort, 37 patients received at least one dose of study drug (26 received ANA598 and 11 placebo).
- Approximately 40% of patients in the 200 mg BID and 36% of patients in the 400 mg BID group completed 12 weeks of treatment.
- Patients who achieved undetectable virus at weeks 4 and 12 were randomized to SOC alone for 8 weeks; patients who did not achieve undetectable virus at week 12 were randomised to SOC alone for 8 weeks.

**Primary**

- To assess the proportion of patients achieving cEVR (defined as undetectable HCV RNA at Week 12).

**Safety and Antiviral Activity of ANA598 in Combination with Pegylated Interferon a2A Plus Ribavirin in Treatment-Naïve Genotype-1 Chronic HCV Patients**

- Approximately 90 patients were planned, 30 at each dose level of ANA598 and 30 on placebo, enrolled in the 2-stage design. Each cohort comprised 30 patients on ANA598 and 15 on placebo.

**RESULTS**

- The mean baseline viral load was 2.3 log10 (range 0.2 to 3.4 log10) at 300 mg BID, 2.3 log10 (range 0.3 to 3.4 log10) at 400 mg BID, and 2.2 log10 (range 0.6 to 3.4 log10) at 800 mg BID on Day 1 (EDT).

**Study Assessments**

- Safety assessments included physical examination, vital signs, hematology, blood chemistry, and assessment of adverse events.

**Baseline Demographics**

- Table 1. Demographics and Baseline Characteristics

**Study Patients**

- In the 300 mg BID cohort, 44 patients received at least one dose of study drug (29 received ANA598 and 15 placebo).
- 2 patients discontinued during the 1st week for personal reasons (unrelated to study drug).
- 2 patients had protocol violations (ANA598 levels below target).
- 2 patients were lost to follow-up (Week 4).
- 1 patient on ANA598 discontinued study drug at Week 4 due to Grade 3 rash, resumed ANA598 at Week 8, and returned to study drug at Week 12.
- 1 patient on placebo withdrew due to Grade 3 rash at Week 4, discontinued placebo, and returned to study drug at Week 8.

**Antiviral Activity**

- ANA598 in combination with SOC accelerated the rate of achieving undetectable levels of virus in genotype-1 patients compared to patients receiving Placebo plus SOC.
- ANA598 200 mg BID plus SOC resulted in a 73% cEVR. All patients undergoing treatment with ANA598 200 mg BID plus SOC achieved a 73% cEVR.

**Conclusion**

- ANA598 has been well tolerated and efficacious in this study.

**Disclaimers**


**Disclosure**

- The combination of ANA598 with SOC accelerated the rate of achieving undetectable levels of virus in genotype-1 patients compared to patients receiving Placebo plus SOC.
- ANA598 200 mg BID plus SOC resulted in a 73% cEVR. All patients undergoing treatment with ANA598 200 mg BID plus SOC achieved a 73% cEVR.