MedicalXpress

Shorter treatment course potentially on the horizon for hep C patients

April 15 2016

Data from a Phase 2 clinical trial show that an investigational injectable treatment known as RG-101 in combination with a four week course of oral direct-acting antiviral (DAA) treatment was well tolerated and resulted in high virologic response rates post-treatment among Hepatitis C (HCV) infected patients with genotypes 1 and 4, who had not been treated previously.

The findings, presented today at The International Liver Congress 2016 in Barcelona, Spain are an interim analysis, with ongoing research to assess virologic response over a 48 week follow-up period to further assess the safety and efficacy of a four week treatment course.

The investigational treatment, RG-101 works on microRNA-122, which the virus uses to replicate. Drugs that interfere with miR-122 could inhibit HCV replication, acting earlier in the viral lifecycle than currently approved HCV protease, polymerase or NS5A inhibitors.1 The current standard of care treatment in HCV consists of eight-12 weeks of DAA oral agents.2

"These early results indicate the potential for RG-101 with oral DAA combination therapy to provide an effective Hepatitis C regimen for patients with a short treatment course of just four weeks," said Dr Mihaly Makara from the Buda Hepatology Centre, Budapest, Hungary, and lead study author. "We very much hope the long-term, 48-week follow-up data follows the same trend."

This international study enrolled 79 patients with chronic HCV, genotype 1 or 4 who had not previously received treatment. Each patient received a 2mg/kg injection of RG-101 on Day one, with a four week course of oral DAAs (either ledipasvir/sofosbuvir, simeprevir, or daclatasvir), following by a second 2mg/kg injection of RG-101 on Day 29. The mean baseline viral load among patients was 5.805 IU/mL.

Interim analysis showed that 97.4% (37/38) and 100% (14/14) of patients at eight and 12 weeks respectiviely had a high virologic response . This was determined by assessing HCV levels 'below the lower limit of quantification' (