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New study demonstrates efficacy of all-oral treatment regimens in adolescents with hepatitis C virus

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Adolescents with Hepatitis C (HCV) could benefit from a combination of direct-acting antivirals, according to new data presented today at The International Liver Congress 2016 in Barcelona, Spain. The study demonstrated that adolescent patients with HCV genotype 1 aged 12 to 18 years who were treated for 12 weeks with a fixed dose combination of ledipasvir and sofosbuvir attained high sustained virologic response (SVR) rates.

Hepatitis C causes about 86,000 deaths per year in World Health Organization (WHO) European (EU) Region.1 Between 130 and 150 million people globally have chronic Hepatitis C infection,2 including approximately 15 million people in the EU.3 Children represent approximately 10% of those infected with the Hepatitis C virus (HCV), however some of these children have chronic disease and are at risk for complications. While direct-acting antivirals have been used to treat and cure almost all patients with HCV,4,5,6,7 they have been exclusively studied in adults, leaving adolescents to take pegylated interferon with ribavirin for 24 to 48 weeks.

"While there have been many studies investigating different treatment regimens for Hepatitis C in adults, data in adolescents have been lacking," says study presenting author Dr Sanjay Bansal, Consultant Paediatric Hepatologist at King's College Hospital, London and author of the study. "These data in HCV-infected adolescents confirm that this

drug combination is effective in a younger population and has a more favourable side-effect profile than the treatments currently licensed for teenagers."

The study included 100 patients aged between 12 and 18 years, infected with HCV genotype 1. In the open-label study, 100 patients received treatment with ledipasvir and sofosbuvir (90mg/400mg) once daily over a 12 week period. The primary efficacy endpoint was sustained viral response at 12 weeks post-treatment (SVR12).

Results from this study showed that of the 100 patients enrolled, 97% achieved SVR12 (n=97); the 3 patients who did not achieve SVR12 were lost to follow-up. No serious adverse events were reported, and the most common adverse events (reported by ?10% of subjects) were headache (27%), diarrhoea (14%), fatigue (13%), nausea (12%), cough (10%) and vomiting (10%).

"These are very promising data for a patient group that has until now been excluded from the studies of newer agents in HCV infection," said Professor Franck Tacke, Member of the EASL Governing Board. "We hope that this treatment regimen will provide these young patients with relief from this challenging condition."

More information: Reference:

1 World Health Organization. Hepatitis data and statistics. Available from: www.euro.who.int/en/health-top … /data-and-statistics. Last accessed: March 2016.

2 World Health Organization. Hepatitis C Fact Sheet N°164. Available from: www.who.int/mediacentre/factsheets/fs164/en/. Last accessed: March 2016.

3 World Health Organization. Global Alert and Response - Hepatitis C. Available from: www.who.int/csr/disease/hepati … o2003/en/index3.html. Last accessed: March 2016.

4 1 Afdhal N, et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. N Engl J Med. 2014 May 15;370(20):1889-98.