Interim results from phase IIa trial evaluating triple combination including simeprevir demonstrates high level of efficacy in HCV patients

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that interim results from a phase IIa study being conducted by Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen), were published as part of the abstracts released for the upcoming European Association for the Study of the Liver (EASL) Special Conference, September 23-24, 2016, in Paris, France.

Interim results from cohorts 1-4, summarized in the table below, showed that the triple combination regimen, including simeprevir, was highly effective and well tolerated in non-cirrhotic patients with GT1 HCV. Additional results, including sustained viral response 12 weeks after completion of therapy (SVR12) for all cohorts, will be presented in the eposter presentation on Friday, September 23, 2016.

Cohort #	Simeprevir dose (mg)	Odalasvir dose (mg)	AL-335 dose (mg)	Treatment Duration (weeks)	Number (%) with undetectable* HCV RNA at EOT or SVR12 or 24
1	100 QD	50 QD	400 QD	8	20/20 (100%), SVR24
2	--	50 QOD	800 QD	8	18/20 (90%), SVR12
3	75 QD	50 QOD	800 QD	8	20/20 (100%), SVR4
4	75 QD	50 QOD	800 QD	6	20/20 (100%), EOT

**Or below the limit of quantification (N=2; Cohort 4 only)*
EOT: end of treatment; QD: every day; QOD: every other day; RNA: ribonucleic acid; SVR: sustained virologic response.

Of the 20 patients treated in cohort 1, who received the triple combination of odalasvir (50mg QD), AL-335 (400mg QD) and simeprevir (100mg QD) for eight weeks (triplet, 8 weeks), 100 percent remained HCV RNA undetectable 24 weeks after completing therapy (SVR24). Additional patients were subsequently enrolled into two further cohorts (3 & 4), where they received adjusted doses of the same triple combination for either eight or six weeks. In cohort 3 all patients were HCV RNA negative (N=18) or below the limit of quantitation (N=2) and remained HCV RNA undetectable 4 weeks after completing therapy (SVR4) and in cohort 4 all patients were HCV RNA negative at end of treatment. Of the 20 patients treated in cohort 2, who received the dual combination of odalasvir (50mg QOD) and AL-335 (800mg QD) for eight weeks (8 weeks), 90 percent remained HCV RNA undetectable twelve weeks after completing therapy (SVR12).

These all-oral combination regimens containing odalasvir and AL-335, with or without simeprevir, were generally safe and well tolerated. The majority of adverse events (AEs) were mild, most commonly headache, fatigue, and upper respiratory tract infection. No clinically significant laboratory abnormalities were observed. In cohort 1, there was a single serious adverse event (Mobitz Type 1 2nd degree atrioventricular block), which was attributed to treatment. This ECG abnormality was not associated with clinical or echocardiographic abnormalities, was transient and resolved following treatment discontinuation, and the patient went on to achieve SVR24.

Further Development of the Triple Combination
Based upon the interim data from the phase IIa study, a phase II program is in place for the development of the triple combination of simeprevir, odalasvir and AL-335. This program will include two multi-center, randomized, open-label studies that will enroll treatment-naive and treatment-experienced non-cirrhotic patients chronically infected with hepatitis C virus genotypes 1, 2, 4, 5, and 6. These two studies will be complemented by an expansion of the ongoing phase IIa study, to allow the triple combination to be studied in additional patients with or without compensated cirrhosis, and with HCV genotype 2 and 3 infection.

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 12.30 CET on 9th of September 2016.

About Medivir

Medivir is a research based pharmaceutical company with a research focus on oncology and infectious diseases. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Our commercial organization provides a portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.