The European Commission has granted Orphan Medicinal Product Designation in the EU for MIV-818

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that the European Commission, in accordance with the opinion from the European Medicines Agency (EMA), has granted orphan medicinal product designation in the EU for MIV-818 for the treatment of patients with hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

Orphan Medicinal Product designation provides certain regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union. This designation can give access to several incentives, including protocol assistance, the EU centralized authorization procedure and reduced regulatory fees and a potential for a 10-year market exclusivity in the EU.

For further information, please contact:
Dr Uli Hacksell, CEO, Medivir AB, phone: +46 (0)8 5468 3100.

About hepatocellular carcinoma
HCC represents the fifth most common cancer worldwide but is a rare disease in Europe and the US. Although therapies exist, treatment benefits for intermediate and advanced HCC are low and death rates remain high. HCC is a very diverse disease with multiple cancer cell types and without the tumor-specific mutations. This has contributed to the lack of success of molecularly targeted agents in HCC. The limited overall benefit, taken together with the poor overall prognosis for patients with intermediate and advanced HCC, results in a large unmet medical need.

About MIV-818
MIV-818 is a pro-drug designed to selectively treat liver cancer cells and to minimize side effects. It has the potential to become the first liver-targeted, orally administered drug for patients with HCC.

About Medivir
Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The drug candidates are directed toward indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Collaborations and partnerships are important parts of Medivir’s business model, and the drug development is conducted either by Medivir or in partnership. Medivir’s share (ticker: MVIR) is listed on Nasdaq Stockholm’s Small Cap list. www.medivir.com