

## **FDA grants MIV-818 Orphan Drug Designation for the treatment of hepatocellular carcinoma**

**Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR)** today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to MIV-818 for the treatment of patients with hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

FDA grants orphan status to drugs intended to treat rare diseases affecting fewer than 200,000 people in the U.S. The orphan designation provides certain benefits to drug developers, including tax credits for clinical trial expenditures, waived user fees for marketing applications, and eligibility for seven years of marketing exclusivity.

"It is very satisfying that MIV-818 has received a positive opinion on orphan medicinal drug designation by EMA and has been granted orphan drug designation by the FDA for the treatment of HCC", says Uli Hacksell, CEO at Medivir.

### **For further information, please contact:**

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*Medivir AB is obliged to make this information public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.30 CET on 6 May, 2020.*

### **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](http://www.medivir.com)