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Medivir—focusing on cancer one prodrug at a time

Medivir is developing tumor-directed nucleotide oral prodrugs to treat cancers with highly unmet medical needs. The company's lead drug candidate, MIV-818, is a liver cancer targeted prodrug that Medivir is looking to develop alone in the USA and the EU and through partnerships elsewhere.

Swedish pharmaceutical company Medivir focuses on the development and commercialization of innovative treatments for cancers for which existing therapies are limited or missing. The company's therapeutic strategy consists of designing tumor-directed nucleotide prodrugs. Once taken up by the tumor cells, the nucleotide prodrugs are cleaved, and the nucleotides can efficiently disrupt cell proliferation.

Medivir's approach combines in-house clinical development skills and industry experience that allow the company to leverage knowledge and experience from academic, health-care and global industrial partnerships.

Medivir's lead asset is MIV-818, a liver-directed, oral nucleotide prodrug that has the potential to be an effective and well-tolerated treatment of liver cancer. Hepatocellular carcinoma (HCC) is the most common form of primary liver cancer and the third-leading cause of cancer-related deaths globally. HCC is classified as an orphan disease in the EU and the USA, but exhibits a disproportionately high incidence in Asia. HCC's orphan disease status may provide an opportunity to shorten the drug development lead time of MIV-818 through fast track designations from the European Medicines Agency and the US Food and Drug Administration and reaching cancer patients more rapidly.

"Our innovative prodrug approach could provide benefit to patients worldwide," said Christina Herder, EVP and COO of Medivir. "Through our highly collaborative approach, we aim to accelerate the process of bringing these new medicines to patients in need."

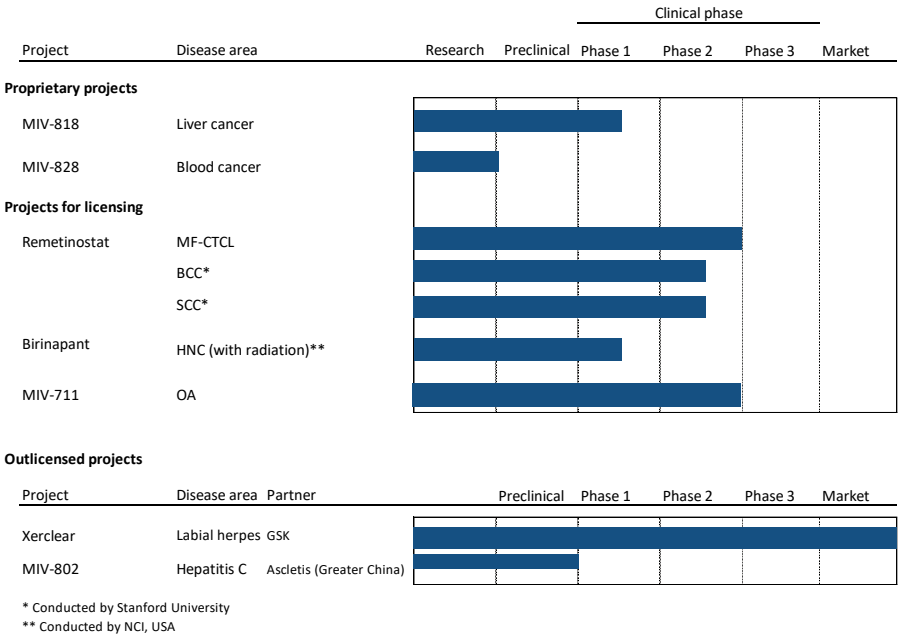

Fig.1 | Medivir's pipeline includes already out-licensed projects, projects requiring licensing partners and the latest generation of prodrug-based anticancer drugs: MIV-818 and MIV-828. HDAC, histone deacetylase; MF, mycosis fungoides; SMAC, second mitochondrial-derived activator of caspases.

Targeting liver cancer

Hepatocellular carcinoma is counted among the deadliest of cancers, with a 5-year survival rate of just 11%. HCC is genetically heterogeneous, making it challenging to identify good molecular targets for therapeutic intervention. Surgery is the only curative option, with all other systemic treatments—chemotherapy, immunotherapy and radiotherapy—having a mostly palliative effect. First-line therapies include sorafenib and lenvatinib, and second-line therapies consist mostly of a range of immuno-oncology drugs approved in the USA.

The nucleoside analog troxacitabine has been shown to have anticancer activity but development was suspended in 2008 owing to an insufficient therapeutic window for this intravenous drug candidate. Medivir has developed MIV-818, a prodrug which is cleaved inside the tumor cells to produce the active metabolite TRX-TP. Subsequently, TRX-TP is incorporated into DNA, causing double-strand DNA breaks and cell death. MIV-818 also exhibits an enhanced antitumor effect in preclinical models of HCC when administered in combination with sorafenib.

In a clinical phase 1 study, clear signals of effect, measured as DNA damage observed in liver biopsies from tumor tissue of patients treated with MIV-818, provided early proof of concept. Normal liver tissue did not appear to have been affected.

The clinical potential of MIV-818 includes its use as monotherapy and as add-on to standard-of-care for treatment of liver cancer.

According to Herder, "our experience with MIV-818 will enable us to progress our candidate drug, MIV-828, into clinical development for hematological tumors next."

Global outlook

Medivir is building a solid pipeline of innovative cancer treatments by leveraging strategic partnerships to accelerate the development of its new drug candidates and reducing the time for them to reach patients in need.

For MIV-818, Medivir is looking for a partner to co-develop and commercialize the compound in Asia. In particular, the company is looking for a partner with proven clinical development experience in key territories, e.g. China or Japan, up-to-date knowledge of local regulatory processes and a good commercial understanding of the Asian liver cancer market. Medivir also has a number of other advanced clinical programs available for partnering (Fig. 1).

As pointed out by Herder, "Medivir uses its internal clinical development competence in combination with geographic partnering to optimize its ability to move innovative compounds to the market in key territories."

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