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CureVac and Boehringer Ingelheim - two strong partners forge cancer immunotherapy alliance

Two German companies have teamed up to become a driving force in the immunotherapy of lung carcinomas. CureVac GmbH from Tübingen and Boehringer Ingelheim are working together on the development of a therapy for non-small cell lung cancer using CureVac's vaccine CV9202. The drug is based on messenger RNA and will be used in combination with other therapies with the goal of fighting the tumour on several fronts.

The filling system of CureVac's GMP facility conforms to the highest cleanroom standards (grade A).

The chemistry seems right: CureVac and Boehringer Ingelheim had been working together for quite some time in research and development, and thus had time to get to know each other before actually announcing their cooperation with the goal of developing lung cancer therapies in September 2014. "Boehringer Ingelheim is one of the top-20 pharmaceutical companies worldwide and thus an attractive partner for us. In addition, Boehringer Ingelheim is open to new technologies and CureVac's therapeutic vaccines fit well into the company's portfolio. The cooperation with Boehringer Ingelheim also means that our approach and the entire RNActive platform is thoroughly validated. And this makes us very happy," said Dr. Florian von der Mülbe, co-founder and Chief Operating Officer of CureVace.

In financial terms, the cooperation between CureVac and Boehringer Ingelheim is likely to have a major impact and has therefore attracted attention around the world. Upon signature of the agreement, CureVac received EUR 35 million and can achieve milestone payments of up to EUR 430 million and royalties on sales.

The production of the therapeutic vaccine remains with CureVac. Von der Mülbe commented: "Although we cooperate on all levels in order to bring the product into the clinic, the therapeutic substance itself will not be changed. We continue to be responsible for the production of the vaccine and we will deliver it, ready-to-use, to Boehringer Ingelheim. Boehringer is in charge of the

clinical trials and everything related to obtaining approval and marketing authorisation. We are supporting our partner in this work and will bring in our own expertise." Boehringer Ingelheim will start clinical trials of CV9202 in three different settings. What makes the trials so special is that they will investigate the effect of CureVac's vaccine in combination with existing treatments in the hope that the combination of different therapies will improve treatment outcome.

The vaccine in a glass vial – the ready-to-use mRNA product is a fine powder.

Enormous potential strength of the CureVac approach: combining it with other treatments

In one of the upcoming clinical investigations, patients with advanced or metastatic mutated non-small cell lung cancer (NSCLC) will be treated with CV9202 in combination with the antibody afatinib, which was developed by Boehringer Ingelheim. Afatinib blocks specific receptors on the tumour cells that are important for cell growth. The trial involves patients whose tumour cells carry a particularly large number of these receptors on their surface due to a mutation. These cells therefore represent a particularly attractive target for afatinib.

The two companies hope that the combined action of afatinib and CV9202 will enable particularly effective tumour treatment. "It is quite possible that the active substances target the same cells. The trial will have to show whether the combined treatment is synergistic and not only additive. In preclinical studies, we have seen synergistic effects when different combinations were used. Any improvement of existing therapies will be a great success for the patients," says von der Mülbe.

Another trial is aimed at patients with unresectable stage III NSCLC who will receive standard chemo-radiation therapy in addition to CV9202. There is also a third option – the combination of CV9202 with a checkpoint inhibitor which the Ludwig Institute for Cancer Research in the USA is working on. Checkpoint inhibitors block receptors that inhibit the immune response by preventing it from activating T cells. The checkpoint inhibitors reverse the blockade, resulting in the activation of T cells against cancer. The partners hope that combining CureVac's CV9202 with these checkpoint inhibitors will significantly improve cancer patient survival.

CV9202 and the preceding cancer vaccine CV9201 were tested in initial clinical trials by CureVac and have already demonstrated their great potential. The vaccine CV9202 (now BI 1361849) is a combination of mRNA molecules coding for six antigens overexpressed in lung cancer, including antigens that are directed against surface proteins that are typically found on non-small cell lung carcinoma cells.

This is how CureVac's vaccines work: In addition to providing the construction plan for antigens which are later produced by the patient's body, the mRNA also provides an activating alarm signal. This combination is essential for an effective vaccine. The immune system recognises the antigens and responds by producing specific B and T cells, which in turn recognise and destroy the tumour

cells.

In the initial clinical trials, CV9202 showed a favourable safety profile and induced immune responses against the antigens. "In the clinical phase I and II trials, we did not see any serious adverse effects. At most, slight temporary reddening occurred at the injection sites and some of the patients developed flu-like symptoms. However, all this is justifiable in consideration of purported benefits and risks of the treatment. Such reactions are also typical immune system responses. The side effects are thus very positively different from those of other cancer medications," said von der Mülbe.

Typical CureVac laboratory with an HPLC system that is used for RNA purification.
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Dr. Florian von der Mürbe - co-founder and Chief Operating Officer of CureVac.
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mRNA therapeutics – long underestimated, now close to therapeutic breakthrough?

It will still take several years before mRNA-based lung cancer therapy becomes standard treatment. However, the present findings are a major step towards a new type of cancer treatment. "We are pioneers in this field and our ideas were initially met with great skepticism. In the early stages of development, few people believed that we would be able to achieve such effects with RNA," recalled von der Mülbe. CureVac has turned mRNA into a drug, without it being a classical drug as the mRNA is only used to pass on information. In the case of therapeutic vaccines, the patient's body receives mRNA-encoded information for proteins that act as antigens and thus trigger an immune response. "We also achieve an adjuvant effect, so that we do not need to add substances to increase the body's immune response to the vaccine," added von der Mülbe.

Meanwhile, CureVac has developed a number of RNA vaccines that have the potential of being used not only for the treatment of cancer, but in future also for many other diseases. Earlier this year, CureVac moved with the prophylactic options of its drugs into the worldwide spotlight: The Bill & Melinda Gates Foundation announced its commitment to invest 46 million euros in CureVac. The foundation will also provide funding for several projects to develop prophylactic vaccines against a number of viral, bacterial and parasitic infectious diseases. These financial injections, as well as the commitment of CureVac's longstanding investor dievini Hopp BioTech holding to invest 21 million euros of additional equity, highlight the enormous potential of the company.

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