EVAXION

Evaxion Granted Approval for Clinical Trial Application and Investigation Medicinal Product Dossier

January 9, 2019

The clinical trial application (CTA) and investigational medicinal product dossier (IMPD) for EVX-01 NeoPepVac was approved by the European Medicines Agency (EMA) on September 26th, 2018.

Evaxion is excited to receive a swift approval, a pivotal moment for the advancement of the company's cancer program. This phase I clinical trial is an investigator initiated, open-label, single-arm pilot study that evaluates the safety, tolerability (primary endpoint) and immunogenicity (secondary endpoint) of a patient-tailored, neo-epitope-based vaccine in cancer patients.

EVX-01 NeoPepVac, an ongoing collaboration between Evaxion Biotech, CCIT, SSI and DTU, is expected to enroll 25-30 patients from three cancer indications (basket trial), including metastatic melanoma, urothelial cancer of the bladder or non-small cell lung cancer (NSCLC) with good performance status (ECOG 0-1), in early 2019.