



Swedish cell therapy candidate CellProtect has received orphan drug designation for the treatment of multiple myeloma

CellProtect Nordic Pharmaceuticals AB ('CPNP') has been notified by the European Commission that its cell therapy candidate CellProtect has received orphan drug designation for the treatment of multiple myeloma. CellProtect is manufactured from the patient's own blood and is the first drug candidate, consisting of autologous *ex vivo* activated and expanded natural killer (NK) cells, which has received such designation in Europe.

CPNP has carried out a clinical phase I/II trial in patients with multiple myeloma where CellProtect has been studied as a supplemental treatment to autologous stem cell transplantation. The results are very promising since CellProtect in the clinical trial shows a good safety profile and signals of effect. The work on a clinical trial report to the Swedish Medical Products Agency is on-going and the plan is to publish the results in 2018.

"Today, multiple myeloma is an incurable disease where new treatments are greatly needed. Our hope is that CellProtect shall offer an effective and tolerable adjunct treatment for these severely sick patients" says Hareth Nahi, chief physician at the Hematology Centre, Karolinska University Hospital, and principal investigator for the trial.

CellProtect is considered to have a major advantage since treatment is carried out with the patient's own NK cells. By giving back cells, which have not been genetically modified or changed in any other way than having been activated and expanded, the treatment is expected to be well tolerated. Furthermore, the treatment will likely not be associated with the same risks as, e.g., treatments with CAR-T or allogeneic cell therapies.

"The decision from the commission is based on a recommendation from the European Medicines Agency's Committee for Orphan Medicinal Products and confirms that a future product is considered to be of significant benefit to those suffering from multiple myeloma. It also entails ten years of exclusivity upon marketing approval. We can now proceed and plan for additional clinical trials in order to receive approval to market CellProtect" says Karin Mellström, CEO CellProtect Nordic Pharmaceuticals AB.

"Cell therapies will become very important for treatment of cancer in the future. The treatment that CellProtect Nordic Pharmaceuticals develops is the result of a long-term and dedicated effort from engaged researchers. I am extremely enthusiastic about the milestone that the receipt of orphan drug designation means" says professor Gösta Gahrton, the Karolinska Institute and one of the members of CPNP's scientific advisory board.

Gösta Gahrton performed in 1983 one of the first stem cell transplants in the world on a patient with multiple myeloma. Stem cell transplantation is now well established in the treatment of multiple myeloma.

About CellProtect

CellProtect consists of the patient's own NK cells which through CPNP's patented method have been activated and expanded so that they can recognize and attack cancer cells. The research behind CellProtect has been performed at the Karolinska Institute in close collaboration with the Karolinska University Hospital Huddinge.

About the company

CellProtect Nordic Pharmaceuticals AB (CPNP) develops groundbreaking cell therapies for the treatment of serious diseases. The company is focusing on development of CellProtect, autologous ex vivo activated and expanded NK cells for the treatment of multiple myeloma, a form of cancer. CPNP has established a patented process to activate and expand NK cells which offers patients a new, potentially curing, treatment of their disease.

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