



VCN Biosciences obtains Orphan Drug Designation from European Medicines Agency (EMA) to their candidate VCN-01 in the treatment of human exocrine pancreatic tumors.

L'Hospitalet de Llobregat, June 15th, 2011. VCN Biosciences, a catalan biotech company focused in the development of new antitumoral agents for the treatment of human tumors that lack effective therapy, has recently obtained the granting for Orphan Medicinal Product for its more advanced clinical candidate VCN-01 in the treatment of human pancreatic carcinoma by the Committee for Orphan Medicinal Products (COMB) from EMA (European Medicines Agency). The company will take advantage of its participation in the forthcoming edition of the *Bio International Convention* to be held in Washington D.C. from June 27th to 30th, 2011, to present preclinical results obtained with VCN-01, a replication-selective virus specifically designed to selectively destroy highly desmoplastic and chemoresistant tumors.

Orphan drug (ODD) qualification refers to pharmaceuticals that have been developed for the treatment of rare diseases that affects less than 5 patients in 10,000 habitants, and constitutes a significant incentive for the onset of therapies for these pathologies. To obtain such qualification VCN Biosciences has established the severe condition of the pancreatic cancer in a context of low prevalence, together with the significant benefit that the treatment with VCN-01 provides with respect to current therapies. Orphan Drug designation allows VCN a simplified clinical development for VCN-01 with significant economic advantages, including reduced taxation and a longer period of marketing exclusivity. Manel Cascalló, Chief executive Officer of VCN Biosciences explains the relevance of ODD for VCN-01: "This designation clearly facilitates clinical development of a new therapy for one of the most aggressive and lethal human tumors. The acknowledgement of the significant benefit conferred by VCN-01 in pancreatic cancer according to European Medicines Agency highlights that this agent can represent real therapeutic alternative that must be explored, and that can expanded to other tumor targets in the future".

VCN-01 is a potent tumor-selective replication-competent adenovirus that expands selectively in tumors, which provokes simultaneously the death of tumor cells and the amplification of the therapeutic effect to neighboring cells. In addition, VCN-01 expresses PH20 hyaluronidase that acts degrading hyaluronan (HA), an important structural element of tumor extracellular matrix. Expression of hyaluronidase from VCN-01 facilitates penetration and decreases intratumoral fluid pressure, enhancing intratumoral virus spread. Extensive preclinical studies with VCN-01 in animal models demonstrate a good toxicology



profile of the virus. Moreover VCN-01 displays a remarkable antitumoral activity when tested by intravenous or intratumoral administration in different tumor models. VCN is planning to initiate a clinical program with VCN-01 in pancreatic cancer by intravenous and by intratumoral administration by the ending of 2012.

About VCN Biosciences

VCN Biosciences is a biotechnological spin-off from Institut Català d'Oncologia / IDIBELL founded in 2009 by Gabriel Capellà, Ramon Alemany and Manel Cascalló. VCN Biosciences is currently located at Bioincubadora 1 of Parc Tecnològic del BioPoL'H in l'Hospitalet de Llobregat. VCN's mission is the development of new agents for the treatment of cancer based on the use of oncolytic adenoviruses, which are viruses able to selectively recognize and destroy malignant cells. This biotechnological approach has demonstrated high potency and selectivity against cancer. The company develops new candidate viruses from its design, preclinical studies, and early efficacy studies in humans (Phase I and II clinical trials). After a recent funding round of about 1,1M€, VCN Biosciences is planning a second investment round by the ending of 2011.