



In-Cell-Art Announces Successful Completion of GMP fill/finish of Nanotaxi® and regulatory-enabling GLP safety evaluation of Nanotaxi® alone and Hepavac

Nantes – France, 18th of September 2017 – In-Cell-Art (ICA), a biotechnology company specialized in nanocarrier technologies named Nanotaxi® designed to unlock the promise of nucleic acids to treat acquired or inherited diseases, announces today successful completion of GMP fill and finish of Nanotaxi® vials and regulatory-enabling GLP safety evaluation (repeated dose toxicity, local tolerance and biodistribution) of their Nanotaxi® alone and Nanotaxi® formulated DNA immunotherapeutic candidate to treat hepatocellular carcinoma (“Hepavac”).

For these crucial steps of its development and based on the demonstrated efficacy of Hepavac in a highly relevant animal model of hepatocellular carcinoma, ICA had scientific advisory meetings with European Medicine Agency (EMA) and Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) to discuss data to support the rationale for testing Hepavac in humans including the design of nonclinical studies addressing pharmacology, biological activity and in vivo safety/biodistribution studies. Most importantly, results of the regulatory-enabling GLP safety studies (repeated dose toxicity, local tolerance and biodistribution) shows that Nanotaxi® alone and Nanotaxi®/DNA formulation are well tolerated and do not induce mortality nor toxicity when compared to control animals injected with saline solution.

Bruno Pitard, a founder of In-Cell-Art says: “it is a key achievement to fast track the development of Hepavac toward first-in-man studies to unlock the treatment of hepatocellular carcinoma that is the third leading cause of cancer deaths worldwide with more than 500,000 people affected. In addition, the absence of toxicity of Nanotaxi® demonstrates that this new class of synthetic delivery system represents not only a breakthrough technology to induce dramatic enhancement of nucleic acid expression and immunogenicity to fight cancers but also an ideal synthetic vector to develop efficient and safe prophylactic vaccines.

About In-Cell-Art

In-Cell-Art (ICA), which is headquartered in Nantes (France) is a biopharmaceutical company specializing in the preclinical and pharmaceutical development of nanocarriers named Nanotaxi® for macromolecular drugs. Its founder and research team, which includes a Nobel Laureate, have designed new classes of vectors that are organized on a nanometric scale, which enables them to cross the cell barrier efficiently and safely. In-Cell-Art offers a range of reagents and biotechnology development services:

1. ICANTibodies™

In the absence of recombinant antigen, ICANTibodies™ allows, from an in silico DNA antigenic sequence, the production of the most ambitious functional antibodies against any natively expressed nuclear, cytoplasmic, secreted or membrane proteins. ICANTibodies™ has allowed, in less than 3 years, the production of more than 300 different functional antibodies. In-Cell-Art has worked with a number of pharmaceutical firms (Sanofi, GlaxoSmithKline, Geneuro etc.) and public research institutions and universities (Institut Cochin, Cancer Research UK, Institute of Neurology UK etc).

2. ICA Nanotaxi®

•DNA Vaccine

ICA614 Nanotaxi®, an innovative DNA synthetic formulation, offers unique efficient and industrial features such as the dramatic enhancement of the immunogenicity of plasmid DNA-encoding tumours or pathogen-derived antigens, a reduction in the dose of plasmid DNA, as well as an excellent safety profile. ICA614 Nanotaxi® represents a crucial step in DNA vaccine development, and is currently being tested by major vaccine companies.

•mRNA Vaccine

Some other ICA Nanotaxi® are also being assessed in \$33.1 million RN-ARMORVAX consortium, co-funded by US Defense Advanced Research Projects Agency (DARPA). The consortium would validate the new application of ICA Nanotaxi® for mRNA-based vaccines for infectious diseases in collaboration with CureVac and Sanofi-Pasteur.

•mRNA Replacement Therapy

Some other ICA Nanotaxi® are also developed to improve the limited efficacy and stability of mRNA therapeutics, leading to the dramatic increase in therapeutic protein expression without DNA-encoded gene.

3. ICAFectin® transfection reagents

ICAFectin® transfection reagents are innovative breakthrough synthetic vectors for in vitro nucleic acid delivery. They are becoming the reagents of choice for efficient DNA and siRNA transfections as demonstrated by their increasing use in numerous studies published in high impact factor journals including Journal of Biological Chemistry, Nucleic Acids Research, PLOS ONE, PLOS Pathogen, Human Gene Therapy, Cell reports, EMBO J and more.

In-Cell-Art is a privately held company, which was founded in 2005, laureate in 2013 and 2013 of the Fast 50 Deloitte award. It is a member of the Atlanpole Biotherapies high-tech cluster of biotechnology companies in western France.

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