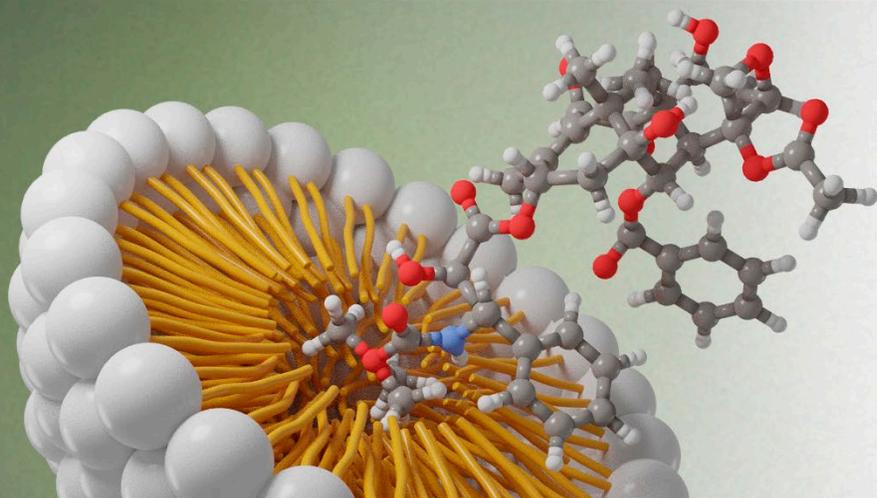


Nanotechnology Characterization Laboratory



August 2019

Twice per year the NCL accepts the most promising cancer nanomedicine candidates into its Assay Cascade characterization and testing program. Nanomedicines accepted into the program will undergo a rigorous evaluation that may include sterility and endotoxin testing, physicochemical characterization, in vitro hemato- and immunotoxicity, and in vivo studies to evaluate safety, efficacy and pharmacokinetics. The studies are tailored to each individual nanomedicine and are designed to promote the clinical translation of these novel therapies. **All studies are conducted free of charge for Awardees.**

Congratulations to the Following Awardees

Avidea Technologies, Inc.

Avidea Technologies, Inc. (Baltimore, MD) is developing self-assembling nanoparticles based on amphiphilic polymers (SNAP) as a platform for improving the manufacturing, safety and efficacy of immunotherapies for the prevention and treatment of infectious diseases and cancer. Avidea's lead product is a personalized cancer vaccine ("SNAP-7/8a") comprising peptide-based neoantigens linked to polymer-Toll-like receptor-7/8 agonist conjugates that are chemically programmed to self-assemble into nanoparticles of a defined size (~20 nm) irrespective of the underlying neoantigen composition. Avidea has validated a process for manufacturing SNAP-7/8a as a personalized therapy under cGMP and demonstrated that SNAP-7/8a safely induces robust neoantigen-specific T cell responses in mice and primates. Avidea will be working closely with NCL over the next year to undertake key studies to support an Investigational New Drug (IND) application filing in advance of clinical testing planned for mid-2020.

www.avideatechnologies.com

Prof. William H. Gmeiner, Wake Forest School of Medicine

We are developing nanoscale fluoropyrimidine DNA-based polymers (e.g. CF10) that display improved anti-cancer activity and markedly reduced systemic toxicities relative to conventional fluoropyrimidine drugs, such as 5-fluorouracil (5-FU). FP polymers differ from monomeric drugs in molecular weight, biodistribution, plasma protein binding, metabolism and other characteristics in a manner that both improves efficacy and decreases systemic toxicities. CF10 is on average more than 300-fold more potent than 5-FU in the NCI60 cell line screen and CF10 significantly improves survival relative to 5-FU in an orthotopic model of colon cancer and other pre-clinical cancer models. The cytotoxic mechanism of CF10 is unique and involves efficient conversion to FdUMP to inhibit thymidylate synthase, which promotes FdUTP incorporation into DNA and generates DNA

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for Cancer Research**

Congratulations to the Following Awardees (continued)

topoisomerase 1-cleavage complexes. CF10 is also less toxic than 5-FU and produces reduced levels of ribonucleotide metabolites that cause neutropenia and GI-tract toxicities. In collaboration with NCL, our goal is to characterize CF10's physico-chemical properties and perform key studies that will enable filing of an Investigational New Drug application (IND) and advance CF10 into clinical trials.

<https://school.wakehealth.edu/Faculty/G/William-Henry-Gmeiner>

Dr. Chuong D. Hoang, National Cancer Institute

Malignant pleural mesothelioma is an aggressive surface cancer in the thoracic cavity without long term survival. A common shortcoming of treatment among all surface cancers is the inability to achieve complete tumor removal during surgical resection, which is one of the pillars of multi-modality oncologic therapy. Residual small and/ or microscopic tumor foci hiding on exposed tortuous tissues inevitably lead to disease recurrence. We have developed an adjuvant, materials-based tumor targeting therapeutic approach that leverages surgical access. Via this locoregional route, a biodegradable peptide hydrogel can be sprayed as a thin film to evenly coat complex anatomic surfaces, functioning as a drug delivery depot. The hydrogel film can be engineered to carry a variety of nanoparticle-encapsulated payloads including small nucleic acids exerting anti-cancer effects. Our animal studies with mesothelioma suggest great therapeutic potential for this nanoparticle composite material to improve clinical outcome, as well as applicability to effectively treat other surface cancers (e.g. ovarian carcinoma, etc.).

<https://ccr.cancer.gov/thoracic-surgery-branch/chuong-dinh-hoang>

If you are interested in learning more about the NCL's services, please visit our website, <https://ncl.cancer.gov>, or contact us for more information, ncl@mail.nih.gov. **The next application deadline is September 3, 2019.**