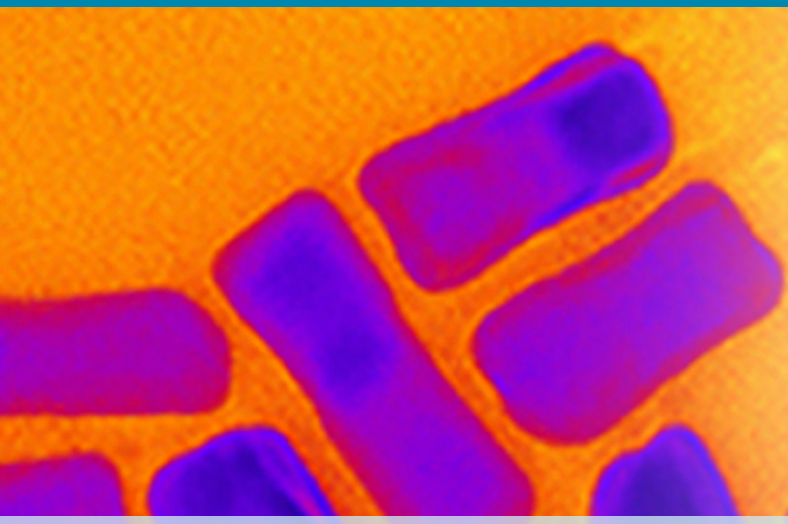
Nanotechnology Characterization Laboratory



NCL
Nanotechnology
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September 2020

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

James Adair, Penn State University
Calcium phosphosilicate nanocomposite particles for diagnostic and drug delivery to human cancer: Calcium phosphosilicate hydrate nanoparticles, or NanoJackets (NJs), are a new material system invented in the Jim Adair Penn State lab that overcomes many of the deficiencies in other inorganic (including pure calcium phosphate) and organic (nanoliposomes, polyoids, polymers, etc.) drug delivery systems. Many drugs and imaging agents fail because of either systemic toxicity and/or low solubility in physiological solutions. Encapsulation of small molecules within the biologically resorbable and biocompatible inorganic calcium phosphosilicate hydrate nanoparticles protects active agents from metabolism or degradation, protects against phase separation in biological fluids, enhances biological half-life, improves pharmacokinetic properties, dramatically improves the dispersion and delivery of drugs systemically delivered to targeted tissue and improves membrane permeability even for drug resistant cancers. Furthermore, the target molecules for breast, pancreatic, and chronic myeloid leukemia show that uptake of the NJs can be directed to specific tumor cell surface proteins. The development of the drug and imaging agent encapsulation in the NJs grew directly out of our earlier work around developing well-dispersed composite nanoparticles using reverse micelle synthetic approaches. Current research is focused on developing theranostic NJ formulations for human pancreatic cancer and acute myeloid leukemia.

MonTa Biosciences, Copenhagen, Denmark
MonTa Biosciences is a biotech company spun out of The Danish Technical University (DTU), and works with cancer immunotherapy nanoparticles. Our lead product is a micelle formulation termed MBS8, which incorporates a TLR7 agonist. The MBS8 micelles were developed in the group of Professor Thomas L Andresen at DTU Health, using a novel TLR7 agonist developed by Professor Dennis Carson at the University of California San Diego. MBS8 has shown superior antitumor activity in mouse models of cancer, and a favorable safety profile.

The Nanotechnology Characterization Laboratory is operated by Leidos Biomedical Research, Inc. in support of the Frederick National Laboratory for Cancer Research under Contract 75N91019D00024.

Frederick National Laboratory
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Congratulations to the Following Awardees (continued)

MBS8 is unique compared to other innate immune stimulators through the micelle formulation that targets specific immune cells after intravenous administration, but with reduced risk of systemic cytokine release. The MBS8 formulation activates certain immune cells that migrate into the tumor tissue shortly after treatment, leading to tumor cell death. This is followed on a longer timescale by invasion of cells from the adaptive immune system, leading to protective immunity. Furthermore, MBS8 has a favorable kinetic profile after multiple administrations, with similar PK parameters at multiple injections. MonTa Biosciences plans to start clinical phase I in Q1, 2021 at clinical sites in Europe, in cancer patients with advanced solid tumors.

Read more about MonTa Biosciences at https://montabiosciences.com

BW Therapeutics, Inc.
Read more about BW Therapeutics at https://www.bwtherapeutics.com

Tyndall Formulation Services, LLC
Read more about Tyndall Formulation Services at https://www.tyndallformulationservices.com

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 December 1, 2020**.

The company and nanoparticle descriptions herein were supplied by the Awardee.
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