Nanotechnology Characterization Laboratory



June 2021

Each quarter 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 this Quarter's Awardees

Haima Therapeutics

Haima Therapeutics is a pre-clinical stage biotechnology company focused on the development of platelet-inspired therapeutics to control bleeding and treat other blood-related disorders where platelets play a key role, such as thrombosis, inflammation, and cancer. Common treatments for cancer include chemotherapy, radiation therapy, and bone marrow transplantation. A frequent complication of these treatments is induced thrombocytopenia (low platelet counts), resulting from increased platelet damage or sequestration from circulation and impaired platelet production in the bone marrow. Thrombocytopenia puts cancer patients at high risk of uncontrolled and life-threatening bleeding. Haima is developing a platelet-inspired hemostatic nanoparticle, called SynthoPlate™, that mitigates bleeding by amplifying and accelerating the body's natural clotting mechanisms at the bleeding site. Haima's collaboration with NCI Nanotechnology Characterization Laboratory (NCL) will leverage the Assay Cascade to better characterize the physicochemical properties and to evaluate the safety profile of SynthoPlate™; bringing the technology closer to the clinic for mitigation of bleeding in cancer patients with induced thrombocytopenia.

http://www.haimatherapeutics.com

Frederick National Laboratory for Cancer Research

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Congratulations to this Quarter's Awardees (continued)

Salvacion USA Inc.

SALVACION USA Inc., Englewood Cliffs NJ, is developing nasal spray technology (Trade name: COVIXYL-V) for reducing SARS-CoV-2 in nasal passages, a main point of entry for the virus in humans. Our unique virus blocking product, optimized in collaboration with NCL, contains agents which block the virus from attaching to tissue and reducing the viral load in the tissue milieu. The nasal spray to prevent COVID-19 infection is undergoing human clinical trials to validate the in vitro and in vivo studies performed by SALVACION.

www.salvacion-usa.com

SignaBlok, Inc.

SignaBlok is a Massachusetts-based biotechnology company developing a breakthrough nanotherapy with applications ranging from pancreatic cancer to non-small cell lung cancer to acute respiratory distress syndrome (ARDS), a main cause of COVID-19-related deaths. The technology targets the <u>Triggering Receptor Expressed on Myeloid cells 1 (TREM-1)</u>, a receptor that amplifies inflammation and the upregulation of which during disease progression correlates strongly with reduced patient survival. With no known TREM-1 ligands, SignaBlok has developed a first-in-class, ligand-independent TREM-1 therapy along with a macrophage-targeted lipopeptide nanoparticle technology. This combination specifically inhibits TREM-1 in a manner that increases circulatory half-life and effectively delivers the therapeutic to its intended target while minimizing the off-target risk. SignaBlok's TREM-1 nanotherapy has been found to be well tolerated in vivo and shows great promise in preclinical models of pancreatic cancer as well as non-small cell lung cancer. The NCL collaboration will be critical in elucidating the unique properties for this technology that will facilitate a future IND application.

https://signablok.com

TanoMed

Prof. Ronit Satchi-Fainaro, Prof. Helena Florindo, Efi Cohen-Arazi, TanoMed Ltd.

Gastrointestinal (GI) cancers account for 26% of the global cancer incidence and is liable for more than 3.5 million deaths per year globally, representing 35% of all cancer-related deaths. The number of new GI cases and deaths are expected to increase by 59% and 73%, respectively, by 2040. TanoMed presents an enormous opportunity to revolutionize the therapeutic outcome for GI cancer patients. To that end, TanoMed is creating new products around the concept of immune cell-targeted nano-delivery solutions to improve therapeutic efficacy in order to trigger tumor destruction following T- and B-cell priming.

TanoMed precision immuno-oncology therapy is based on a novel Dendritic Cell-Targeted Nano-immunoModulator (TNM) platform that combines antigen carrying capacity with *in vivo* targeting and modulation of DC function, presenting the unique ability to expand host anti-tumor specific T-effector phenotype, improving sensitivity and long-term tumor recognition. Based on the preliminary studies which demonstrated TNM platform's efficacy and safety in treating cancer, the collaboration with the Nanotechnology Characterization Laboratory (NCL) team will involve re-assessing the technology in-depth and validating its feasibility for clinical translation and commercialization.

Congratulations to this Quarter's Awardees (continued)

Westwood Bioscience

Westwood Bioscience is a drug delivery platform company developing an encapsulated drug delivery nanoparticle based on lipid coated mesoporous silica particles, called Silicasomes[™], developed at UCLA. Silicasomes are comprised of a mesoporous silica core that, under optimized conditions, contain a multitude of hollow spiral "tubes"—a bit like a sponge. Size and particle distribution of this "bare mesoporous nanoparticle" ("MNSP") can be carefully and reproducibly controlled. A protonating agent is added to the MNSP which are then coated with a single lipid bilayer. The lipid bilayer protects the MNSP while in the circulation and helps prevent leakage of the drug payload. One or more drugs can then be added to the MNSP, to the lipid bilayer or to both, in a very controlled ratiometric manner. All components of the Silicasome are bio-degradable or absorbable and are non-toxic. In animal models, irinotecan-loaded Silicasomes demonstrated increased efficacy and virtually no toxicity as compared to free irinotecan or a marketed liposome-delivered formulation, including in challenging orthotopic mouse models bearing human tumors. This collaboration with the Nanotechnology Characterization Laboratory (NCL) will establish a solid foundation towards preparation of a successful IND application.

https://westwoodbioscience.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 September 1, 2021**.

