

**03/16/2023:** Oncotherapy Solutions LLC has filed a PCT patent application to expand the protection of the drug conjugates to countries outside the US. The company is looking forward to the completion of its IND-enabling studies of the drug conjugate for the treatment of metastatic TNBC, ovarian and endometrial cancers and the filing of its IND application to the FDA. Upon approval, Oncotherapy Solutions LLC with its partners will initiate Phase 1/2a clinical trial of the lead drug conjugate as monotherapy or combination therapy with Keytruda on patients with metastatic TNBC, ovarian and endometrial cancers.

**11/12/2021:** Oncotherapy Solutions LLC has filed a US Non-Provisional patent application covering the drug conjugates.

**11/23/2020:** Oncotherapy Solutions LLC has filed a US Provisional patent application covering the method of making and using the drug conjugates.

**10/3/2019:** We have successfully completed our Phase I SBIR grant studies and looking forward to Phase II SBIR grant studies. Our new lead drug conjugate showed a dramatic tumor growth inhibition of multiple triple-negative breast cancer models. A single intravenous injection of 1.4 mg/kg animal weight of the new lead drug conjugate caused a 100% tumor growth inhibition of HCC1806 TNBC model with the majority of mice showing complete response. Toxicology studies showed no effect on animal weight, white blood cells or normal organs suggesting the safety of our new drug conjugate at the single intravenous dose of 1.4 mg/kg. We have also found that a suboptimal dose of our initial drug conjugate enhances the antitumor activity of anti-PD<sub>1</sub> Keytruda using humanized mice bearing BR1126 TNBC patient-derived tumor model. We are looking forward to perform additional oncology and immuno-oncology studies of our novel lead drug conjugate alone or in combination with Keytruda using metastatic TNBC, ovarian and endometrial patient-derived tumor models expressing the target receptor.

**5/20/2018:** The National Cancer Institute has awarded Oncotherapy Solutions a Phase I SBIR grant to perform further oncology and immuno-oncology preclinical studies on its novel drug conjugates as monotherapy and as combination therapy for the treatment of Triple-Negative Breast Cancer (TNBC). We are looking forward to the successful completion of the Phase I SBIR studies and the submission of Phase II SBIR grant applications to conduct further IND-enabling studies with the goal to start clinical trials in the near future.

**6/28/2016:** We are extremely delighted to announce that our initial lead drug conjugate showed a dramatic and highly significant tumor growth inhibition of triple-negative breast cancer using the MDA-MB-231 orthotopic mouse model. The majority of treated mice had no detectable tumors (complete response) after 3 weekly injections of 1.5 mg/kg of the initial drug conjugate while animal weight remained unchanged. We are looking forward to the completion of the efficacy and toxicology studies and select a lead drug conjugate.

**6/26/2014:** Oncotherapy Solutions is pleased to announce that it was able with its partners to successfully manufacture highly potent drug conjugates. The new drug conjugates caused a dramatic killing of ovarian cancer cells expressing the target biomarker *in-vitro* while the carrier molecule alone showed no effect whatsoever. Our current goal is to introduce several modifications to the new drug conjugates in order to enhance their stability, specificity and potency against drug-resistant cancers *in-vivo*. So far the company has been operating and conducting its research activities in a virtual status where all research projects and experimental protocols have been developed by Dr. Najib Lamharzi and all manufacturing and testing of drug candidates have been outsourced to contract research organizations. The virtual business model allowed our company to operate on a small budget and save tremendous amounts of resources by working on carefully-designed research projects and through outsourcing. Upon availability of additional adequate funds, we will be leasing laboratory space at IcoGenex (our biotech incubator in Seattle WA) and perform the majority of our preclinical studies in-house according to a previous agreed upon arrangement.