FY 2020 Significant Product Development Milestones

- **Salarius Pharmaceuticals, Inc.** announced in September 2019 that the Safety Review Committees overseeing the Phase 1/2 clinical study of the company's lead investigation drug candidate, Seclidemstat, in Ewing sarcoma and the Phase 2 study of Seclidemstat in patients with advanced solid tumors have approved each study to progress to the fourth level dosing cohort. Houston-based Salarius also announced the addition of Memorial Sloan Kettering Cancer Center and Nationwide Children's Hospital as clinical sites for their Phase 1/2 trial of Seclidemstat in Ewing's sarcoma. These additions bring the total number of active clinical trial sites to eight.

  On December 16, 2019, the U.S. Food and Drug Administration granted Seclidemstat a "Fast Track Designation" to treat patients with Ewing sarcoma who have relapsed or are refractory to standard-of-care therapy. Seclidemstat has already received the FDA's Orphan Drug and Rare Pediatric Disease designations. Fast Track is an FDA-designed process to expedite the development and review of new drugs with the potential to treat serious or life-threatening conditions and fill unmet medical needs. The process streamlines regulatory submissions and enables more frequent communications with the agency to resolve questions quickly which often leads to earlier drug approval and access by patients.

  Salarius, a clinical-stage biotechnology company targeting cancers caused by mis-regulated gene expression, received a Product Development Award of up to $18.7 million in 2016 (DP160014) to support their Ewing sarcoma clinical trial.

- **Medicenna Therapeutics, Inc.** presented updated clinical results from its then-ongoing Phase 2b clinical trial of MDNA55, an IL4-guided toxin, in patients with recurrent glioblastoma (rGBM), the most common and uniformly fatal form of brain cancer, at the Inaugural Targeting Innate Immunity Congress (September 2019), the Society for Neuro-Oncology Annual Meeting (November 2019), and the Inaugural Glioblastoma Drug Development Annual Summit (December 2019).

  On May 29, 2020, the Houston and Toronto-based company presented data from its completed Phase 2b trial of MDNA55 at the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. Highlights from the ASCO presentation included a comparison of MDNA55 with an eligibility-matched Synthetic Control Arm, which demonstrated an improvement in median overall survival of 61%. When stratified by IL4R status, IL4R High subjects in the MDNA55 arm demonstrated improved median overall survival by 155%.

Medicenna announced October 15, 2020, that the FDA advised the company to proceed with an open-label hybrid control design for a Phase 3 registration trial of MDNA55 in rGBM patients with no mutation in 1DH1/1DH2 genes. The company received a $14.1 million Product Development award in 2015 (DP150031) to develop MDNA55, a novel immunotherapy to treat recurrent glioblastoma and other brain cancers.

- **Formation Biologics, Inc.** (formerly Armada Pharmaceuticals), with its U.S. headquarters in Austin, presented the first clinical data from its Phase 2 trial of AVID100 on October 10, 2019, at the 10th Annual World Antibody Drug Conjugate conference. On October 27, 2019, the company also presented at the annual International Conference on Molecular Targets and Cancer Therapeutics hosted by American Association for Cancer Research, the National Cancer Institute, and the European Organization for Research and Treatment of Cancer.

  Formation completed patient enrollment in its Phase 1a solid tumor trial of AVID200, a TGF-beta 1 and 3 inhibitor, in October 2019. The trial focuses on demonstrating the safety and tolerability of this drug as a monotherapy in patients with advanced or metastatic solid tumor malignancies with no treatment options. There are 15 patients participating in the study. Formation presented the first fibrosis clinical data with AVID200 at the Annual European Congress of Rheumatology in June 2020. CPRIT made two CPRIT Product Development awards to Formation in 2015 ($12.8 million) and 2018 ($18.9 million) to develop their lead therapeutic AVID100 and other candidates.

- In September 2019, **Aravive, Inc.** presented positive data from the first 12 patients in its then ongoing Phase 1b portion of the Phase 1b/Phase 2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer patients at the European Society for Medical Oncology Congress. Platinum-resistant ovarian cancer is one of the most difficult diseases to treat, not only because of the poor prognosis, but because of the toxicities associated with chemotherapies. The company reported in November 2019 that new positive data from the first 31 patients treated affirm earlier findings on the relationship between AVB-500 and anti-tumor response. Following its February 2020 review of the open-label data from the first 28-day treatment cycle for the three patients in each of the two dosing cohorts of the Phase 1b clinical trial of AVB-500, the independent Data Monitoring Committee unanimously recommended the study continue as planned with enrollment of patients into the higher dose cohorts.

  Aravive reports that AVB-500 improves anti-tumor effects in pre-clinical uterine cancer models when combined with the anti-angiogenic bevacizumab or the PARP

inhibitor olaparib. Additional research showed that inhibition of GAS6/AXL signaling with AVB-500 induces 'BRCA-ness', increasing response to platinum and PARP in a preclinical model of ovarian cancer. Taken together, these research findings reported in March 2020 suggest the potential for clinicians to use AVB-500 in combination with existing therapies to address multiple gynecologic cancers. The company planned to present the data at the Society of Gynecologic Oncology (SOGO) 2020 Annual Meeting on Women's Cancer, but SOGO cancelled the conference due to the ongoing COVID-19 pandemic.

Aravive announced on July 23, 2020, the successful completion of the 84 subject Phase 1b trial of AVB-500 in platinum resistant ovarian cancer. While the Phase 1b trial was a safety trial and not powered to demonstrate efficacy, the company reports that investigator-assessed best response to AVB-500 across all cohorts supports promising clinical activity.

Aravive is also investigating other applications for AVB-500 and received clearance from the U.S. Food and Drug Administration in January 2020 for the company's Investigational New Drug application to investigate AVB-500 to treat clear cell renal cell carcinoma. The company is currently enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgA Nephropathy (NCT04042623). CPRIT awarded Houston-based Aravive, Inc. a $20 million CPRIT Product Development award in November 2015 to develop AVB-500.

- **OncoNano Medicine, Inc.** presented two posters at the Society for the Immunotherapy of Cancer Annual meeting November 6-10, 2019. One poster showcased the company's development of cancer imaging agent ONM-500 for the indication of human papilloma virus. The second poster featured ONM-400, an injectable therapeutic delivery platform used in tandem with a wide variety of cancer therapeutics. The Southlake-based OncoNano received a $6 million CPRIT Product Development award in 2014 and a $10 million award in 2020 to advance the development of ONM-500 to detect breast, head and neck, and skin cancers. In addition, the company received a $15.4 million CPRIT Product Development award in 2019 to develop a novel T-cell activating cancer vaccine for solid tumors.

- **Molecular Templates** announced February 19, 2020, the initiation of dosing in a Phase I study investigating TAK-169 in patients with relapsed/refractory multiple myeloma. Co-developed with Takeda Pharmaceutical Company Limited, TAK-169 is a potential first-in-class CD38-targeting ETB. As a result of achieving this milestone, the Austin-based company will receive a $10 million payment from Takeda. Molecular Templates also presented new preclinical data on its pipeline programs

and technology platform at the American Association for Cancer Research Virtual Annual Meeting II held June 22-24, 2020.

Austin-based Molecular Templates, a clinical-stage biopharmaceutical company focused on the discovery and development of the company's proprietary targeted biologic therapeutics, engineered toxin bodies (ETBs), has received two CPRIT Product Development awards, including $10.6 million in 2011 to fund the development novel targeted ETBs for the treatment of lymphoma, and $15.2 million in 2016 to develop a novel compound to treat multiple myeloma.

- **Emtora Biosciences, Inc.** (formerly Rapamycin Holdings) presented Phase 1b trial results of eRapa in 14 low grade prostate cancer patients at the American Society of Clinical Oncology and Society for Immunotherapy of Cancer Clinical Immuno-Oncology Symposium held February 6 - 8, 2020. San Antonio-based Emtora received a $3 million CPRIT Product Development SEED Award in 2019 to develop eRapa, the company's core technology, to prevent the occurrence of colorectal cancer in patients with Familial Adenomatous Polyposis.

- In late January 2020, **Pulmotect Inc.** announced that experiments conducted at The University of Texas Medical Branch at Galveston showed pre-clinical efficacy in mice of the company's aerosol drug, known as PUL-042, protecting against both the lethal SARS-associated coronavirus (SARS-CoV) and the MERS-associated coronavirus (MERS-CoV). In April 2020, the Houston-based clinical-stage biotechnology company received approval from the FDA to initiate clinical trials testing PLU-042's safety and effectiveness to protect people in close contact with patients who have COVID-19 and reduce the severity of illness caused by the new coronavirus. The FDA announced approval May 5, 2020, of two Phase 2 clinical trials of PUL-042, increasing to 20 U.S. sites.

  The company's PUL-042 drug harnesses the power of the innate immune system, the front line of disease defense, to fight off a wide range of respiratory infections. Initially targeted to treat respiratory complications of cancer patient treatment, PUL-042 has demonstrated compelling protection against a broad range of respiratory pathogens. Pulmotect received a $7.1 million Product Development award from CPRIT in 2012 to develop PUL-042 to decrease the incidence of pneumonia, which can be fatal in immunosuppressed cancer patients.

- Dallas-based **Peloton Therapeutics** reports promising data from a Phase 2 study of a HIF-2α inhibitor developed by the company. The drug curbed tumor growth in 43% of patients and shrank tumors in 28% of patients with kidney cancer linked to a

genetic condition. These early results reported in May 2020 offer hope to patients with clear cell kidney cancer linked to Von Hippel-Lindau disease, a genetic disease that causes tumors and cysts to grow throughout the body, and kidney cancer patients more broadly. Peloton received a $3.2 million CPRIT Product Development award in 2010 to develop small molecule drug programs sourced from leading investigators at The University of Texas Southwestern Medical Center. Merck invested $1 billion to acquire Peloton in 2019.

- San Antonio-based **Pelican Therapeutics** treated its first patient in June 2020 in the company's Phase 1 clinical trial of PTX-35. The company's first-in-human Phase 1 trial will enroll up to 30 patients with advanced solid tumors not responding to standard-of-care treatments. PTX-35 is a novel, first-in-class drug designed to treat multiple solid tumor types. Preclinical studies demonstrate PTX-35, in combination with antigen-driven immunotherapies, helps eliminate tumors. Pelican received a $15.2 million CPRIT Product Development award in 2016 to support pre-clinical development, manufacturing, and Phase 1 clinical development for PTX-35.

- On July 28, 2020, **Iterion Therapeutics, Inc.** announced that it began enrolling patients with desmoid tumors in its multicenter Phase 2a dose expansion clinical study of Tegavivint, a novel, potent and selective nuclear β-catenin inhibitor. The Phase 2a trial builds on a recently completed open-label, non-randomized Phase 1 study that established safety and initial clinical efficacy of Tegavivint in patients with progressive desmoid tumors. The Houston-based company, formerly known as BetaCat, received a $15.9 million CPRIT Product Development award in 2014 to develop Tegavivint for desmoid tumors and acute myeloid leukemia.