

**SUMMARY**

Seasoned researcher highly experienced in the fields of cell biology and oncology. Served as both program lead and individual contributor to dedicated teams that successfully submitted several Investigational New Drug (IND) applications for both small molecules and mRNA therapeutics as well as a New Drug Application (NDA) to treat patients with relapsed/refractory multiple myeloma (R/R MM) which garnered FDA-accelerated approval (XPOVIO® / selinexor). Seeking an opportunity to discover novel targets and translational biomarkers to move pipelines forward and improve patient selection and care.

**WORK EXPERIENCE**

BIOTARGETED SOLUTIONS LLC, Biotechnology Consultant, Newton MA 2025-present

**Founder and Principal Consultant**

- Provide expert consulting in translational medicine, biomarker strategy, and drug development for biotech and pharmaceutical companies.
- Advise clients on biomarker discovery, validation, and integration in clinical trials to support precision medicine initiatives.
- Guide clients through regulatory strategy including IND, NDA, and BLA submissions, ensuring alignment with FDA and EMA requirements.
- Support early-stage biotech startups with scientific strategy, team mentorship, and investor communications.
- Develop scientific and medical communications including manuscripts, white papers, and regulatory documentation.
- Offer strategic advisory services to optimize drug development pipelines, leveraging 20+ years of research expertise.
- Engage in high-impact collaborations with leading biotech firms, research institutions, and venture capital groups.

OMEGA THERAPEUTICS INC., Oncology Discovery, Cambridge MA 2020 – 2025

**Senior Director, Cancer Biology (2023 – 2025), Director, Cancer Biology (2020 – 2023)**

- Established, recruited, managed and mentored the oncology discovery team including scientists and research associates.
- Led several oncology target programs using novel mRNA Epigenomic Therapeutics delivered via lipid nanoparticles, including Omega's first clinical candidate, OTX-2002, for the treatment of patients with MYC-associated advanced solid tumors (focused on hepatocellular carcinoma), which successfully completed the escalation phase (24 patients total) of a global Phase 1/2 clinical trial (November 2024).
  - Planned and executed robust mechanism of action and non-clinical pharmacology studies targeting oncogenic MYC using internal resources and Contract Research Organizations (CROs) to support and compose INTERACT (December 2020) and pre-IND (May 2021) Briefing Books that led to the submission of an IND application (June 2022) and initiation of Phase 1/2 clinical trial.
  - Wrote, reviewed and updated modules for IND application and contributed to Information Requests (IR), the clinical protocol, annual updates to Investigational Brochure (IB) and Development Safety Update Report (DSUR) as well as biomarker reports for the final Clinical Study Report (CSR).
- Developed the translational research program for OTX-2002 global clinical trial with applications across the Omega platform.
  - Developed novel epigenetic pharmacodynamic (PD) target engagement biomarkers both internally and in collaboration with CROs.
  - Determined time points and pharmacokinetic (PK) / PD samples to collect from patients for retrospective biomarker analysis.
  - Selected vendors for clinical sample management/logistics and bioanalysis through consensus building across departments.
- Prepared and presented non-clinical and clinical data on OTX-2002 at major conferences (e.g., AACR, ASCO, and ESMO GI).
- Published a research article based on non-clinical OTX-2002 data in *Nature Communications* as first author (September 2024).

RESTORBIO, INC., Research Group, Boston MA 2019 – 2020

**Senior Director, Research**

- Initiated drug discovery programs for treating advanced age-related diseases including osteoarthritis, sarcopenia, and neurodegeneration (e.g., Parkinson's disease).
- Established novel target pipeline programs through CROs.

KARYOPHARM THERAPEUTICS INC., Biology Department, Newton MA 2011 – 2020

**Clinical Research Scientist Consultant (2020), Director, Research and Clinical Development (2017 – 2019), Associate Director, Biology (2016 – 2017), Senior Scientist, Biology (2012 – 2015), Scientist, Biology (2011)**

- Managed/mentored groups of scientists and made individual contributions to novel oncology and non-oncology research projects.
- Co-led programs that discovered the second-generation Selective Inhibitor of Nuclear Export (SINE) compound KPT-8602 / eltanexor and the novel oral dual inhibitor of PAK4 and NAMPT, KPT-9274 / ATG-019 / padnarsertib.

- Co-led clinical candidate selection, IND applications, and initiation of Phase I clinical trials for eltanexor and padnarsertib.
- Contributed to clinical protocols and amendments, IBs, and DSURs.
- Prepared material for and trained clinical personnel during Site Initiation Visits.
- Determined time points and type of samples to collect from patients for prospective and retrospective biomarker determination.
- Managed the Phase I clinical trial data including daily tracking of efficacy and safety to support and understand the translational research of SINE compounds and padnarsertib.
- Shared translational data and maintained site engagement through weekly investigator meetings.
- Initiated and contributed to the padnarsertib clinical trials in companion dogs with spontaneous solid and hematological malignancies.
- Supported drug discovery efforts and established non-clinical mechanism of action research for the first-in-class SINE compound KPT-330 / selinexor / XPOVIO®.
- Prepared, wrote, and reviewed non-clinical pharmacology reports and summary documents for IND applications, IBs, and the NDAs for XPOVIO® (FDA-approved to treat relapsed/refractory multiple myeloma [R/R MM] on July 3, 2019, R/R diffuse large B-cell lymphoma on June 22, 2020, and R/R MM in combination with bortezomib and dexamethasone on December 18, 2020).
- Prepared and presented non-clinical and preliminary clinical data at internal Scientific Advisor Board meetings and major conferences (e.g., AACR, ASH, ESMO, ASCO GI, and others).

FOX CHASE CANCER CENTER, Department of Medical Oncology, Philadelphia PA. Sci. Tech. Mentoring with Dr. Elizabeth Henske

## EDUCATION

**Doctor of Philosophy**, Cell Biology, Harvard Medical School, Boston, MA

**Bachelor of Science**, *with Distinction*, Biology, Minor in Chemistry, Pennsylvania State University, University Park, PA

HARVARD MEDICAL SCHOOL, Boston, MA

### **Ph.D. Candidate Mentoring with Dr. Pamela Silver, Department of Systems Biology**

- Executed a high-throughput RNA interference (RNAi) screen to determine how a set of genes, when reduced, influence Akt signaling and FOXO1a localization.
- Dissertation: *Forkhead at the Crossroads of Cancer and Healthy Lifespan*.

### **Rotating Ph.D. Candidate, Biological and Biomedical Sciences Program**

- Worked with Dr. Alex Toker at Beth Israel Deaconess Medical Center, Boston MA and Dr. Robert Kingston at Massachusetts General Hospital, Boston MA

## MENTORING EXPERIENCE

OMEGA THERAPEUTICS INC.

- Led a multi-disciplinary cancer discovery project team (2-5 researchers) for Omega's first IND.
- Managed/mentored research associates and scientists within the oncology group transitioning from discovery to translational team through projects, individual goal development and three successful promotions.
- Established external collaborations with CROs for analysis of non-clinical and clinical samples.

KARYOPHARM THERAPEUTICS INC.

- Managed a multi-disciplinary team (2-5 researchers) as the head of biology in matrix model environment.
- Supervised technicians and post-doctoral level scientists within the biology group, supporting multiple clinical programs through projects and individual goal development.
- Set up and maintained over 50 academic and biotechnology external collaborations and CROs.

HARVARD MEDICAL SCHOOL

- Mentored undergraduate and Master's-level research scientists in the Silver laboratory.
- Taught BCMP/MCB 234: Cellular Metabolism and Human Disease.
- Served as teaching fellow for the 2007 Harvard iGEM (International Genetically Engineered Machine) team.

## ADDENDUM

### ORAL PRESENTATIONS

- In silico-designed covalent peptidomimetic inhibitors (KPT-SINE) of CRM1 modulate tumor suppressor protein nuclear export and induce apoptosis in cancer cells. AACR Chemical Systems Biology, June 28, 2012; Boston, Massachusetts, USA
- KPT-SINE (Selective Inhibitors of Nuclear Export) induce apoptosis in colon cancer cells in vitro and in vivo through nuclear localization of Tumor Suppressor Proteins (TSPs). AACR Annual Meeting, April 2, 2012; Chicago, Illinois, USA
- A nuclear localization switchable device reveals a regulatory network. Conference on Systems Biology in Mammalian Cells, June 3rd, 2010; Freiburg, Germany

### PUBLICATIONS

- **Senapedis W**, Gallagher KM, Figueroa E, Farelli JD, Lyng R, Hodgson JG, O'Donnell CW, Newman JV, Pacaro M, Siecinski SK, Chen J, McCauley TG. "Targeted transcriptional downregulation of MYC using epigenomic controllers demonstrates antitumor activity in hepatocellular carcinoma models." *Nat Commun.* 16 Sept. 2024, Vol 15, Article number: 7875.
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## PATENTS

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- Formulations for modulating myc expression. Witt, AW; Farelli, JD; Scheidegger, AW; **Senapedis, W**; Kennedy, JM; Belaghzal, H; Ansell, SM; Du, X; Lin, PJC; Tam, YK. (2023), WO2023250427A3.
- Combination therapies comprising myc modulation. Witt, AE; Farelli, JD; Scheidegger, AW; **Senapedis, W**; Kennedy, JM; Belaghzal, H; Yarar, D; Lee, E; Gallagher, K. (2023), WO2023250429A2.
- Compositions and methods for modulation myc expression. Witt, A; Farelli, J; Scheidegger, A; **Senapedis, W**; Kennedy, J; Belaghzal, H; Yarar, D; Lee, E.. (2021) WO2022132195A2.
- Preparation of (S,E)-3-(6-aminopyridin-3-yl)-N-((5-(4-(3-fluoro-3-methylpyrrolidine-1-carbonyl)phenyl)-7-(4-fluorophenyl)benzofuran-2-yl)methyl)acrylamide for the treatment of cancer. Baloglu, E; Shacham, S; **Senapedis, W**. From PCT Int. Appl. (2017), WO 2017031323 A1 20170223.
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