

Duo Oncology

Category:

Best Startup

Company Name:

Duo Oncology

Turnover and/or Funding:

2021 \$1.1M SAFE led by clinical oncologists focused on jumpstarting development of potent yet patient-centric cancer medicines.

2023 \$3M Priced Seed led by professional VCs and included BeiGene Pharma as an institutional invest.

2024 \$1.8M Non-dilutive awards from NIH including two Phase I SBIR grants and selection for the National Cancer Institute's Nanocharacterization Program.

2025 \$3M Convertible Note Seed+ lead by Prevail Partners (Operational VC investor) to jumpstart phase 1 trial.

2026 (Future) \$22M Series A/B with \$8M committed from Prevail Partners pending Phase 1 trial results.

Sub-Category:

Biotechnology

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

Corporate History

Founded in 2021, Duo Oncology was born from a grassroots effort by frontline oncologists determined to modernize chemotherapy-a cornerstone of cancer treatment that has lagged behind advances in immunotherapies and targeted therapies. The company launched with \$1.1M in initial investment from its founding clinicians and swiftly achieved major milestones: a favorable Pre-IND meeting with the FDA in 2022, kilogram-scale production of its lead compound, and successful GLP toxicology studies. Since then, Duo secured five NIH small business awards and raised an additional \$5M in preferred investment from BeiGene Pharmaceuticals and professional venture investors.

Duo's mission has attracted a distinguished leadership team. CEO and co-founder Dr. Sam Rothstein, a nanomedicine entrepreneur with 20 years of experience, was joined in

2023 by Drs. Iglesias and Manax, renowned for their work on Abraxane-the most commercially successful cancer nanomedicine-and for leading Precision Promise, the largest pancreatic cancer trial globally. Key opinion leaders, including Dr. Dan Von Hoff, Dr. Manuel Hidalgo, and Dr. Diane Simeone, have shaped Duo's first clinical program. This program aims to replace paclitaxel and gemcitabine-mainstays of chemotherapy for pancreatic, biliary, breast, and lung cancers-and is slated to begin in Fall 2025.

Disease Burden and Need for a New Standard of Care

Pancreatic cancer is among the deadliest diagnoses, marked by rapid tumor progression, late detection, and dismal outcomes-fewer than 10% of patients survive beyond five years. Even with aggressive treatment, average progression-free survival is only 7.2 months, and overall survival is 12.8 months. This pattern of poor outcomes and high burden extends to other aggressive cancers, including lung, ovarian, breast, and advanced colorectal cancers, where chemotherapy remains the backbone of care. Yet chemotherapy brings substantial toxicity and cost. Patients commonly endure neuropathy, anemia, gastrointestinal complications, chronic fatigue, and emotional distress, all while facing significant financial hardship. Standard regimens like FOLFIRINOX can cost up to \$420,000 for six cycles, not including indirect costs or supportive care. In low- and middle-income countries, where chemotherapy dominates cancer care due to limited access to novel therapies, out-of-pocket expenses can consume up to 50% of household health spending.

Despite their widespread use, many chemotherapies fail to meet modern benchmarks for meaningful benefit. According to the WHO, essential cancer medicines should deliver at least a 4-6 month survival improvement over standard treatment without harming quality of life. Much of today's chemotherapy does not meet this bar, while imposing high toxicity and financial strain.

Duo Oncology's nanomedicine platform directly addresses these shortcomings. By delivering potent chemotherapeutics with precision to tumor tissue, Duo aims to minimize systemic toxicity, enhance survival outcomes, and reduce the physical and economic toll of treatment. This patient-centered innovation aligns with global calls for high-value cancer care that truly improves both longevity and quality of life.

History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):

Duo Oncology's nanomedicine platform traces its origins to over a decade of pioneering research at the University of Pittsburgh led by Drs. Jingjing Sun and Song Li. Their work began with advanced computer simulations that guided the design of a novel gemcitabine-conjugated polymer, POEG-co-PVDGEM (PGEM). This polymer self-assembles into ultrasmall (~13 nm) nanoparticles-about one-tenth the size of

conventional carriers-capable of penetrating dense tumor tissues that resist larger drug particles. The elegant and straightforward chemical synthesis links gemcitabine to a polymer backbone, creating a biocompatible prodrug carrier that also achieves high loading of additional chemotherapeutics like paclitaxel with remarkable stability.

Preclinical studies by Sun and Li's team demonstrated that PGEM nanoparticles achieve superior tumor accumulation and deep penetration in multiple cancer models, including patient-derived xenografts of pancreatic and colon cancers. Beyond effective chemotherapy delivery, PGEM activates the cGAS-STING innate immune pathway, enhancing antitumor immune responses and synergizing with modern immune checkpoint inhibitors.

Building on this strong academic foundation, Duo Oncology took leadership to translate the technology into a clinical candidate. The company secured exclusive licenses to core intellectual property protecting the polymer chemistry and prodrug design, with patents covering the U.S. and key international markets through 2040. Manufacturing was scaled to kilogram batches under clinical-grade conditions. Toxicology and pharmacology programs, designed and supported by expert faculties at the Sidney Kimmel Comprehensive Cancer Center and UPMC Hillman Cancer Center, demonstrated a favorable safety profile, wider therapeutic window, and improved tolerability with noteworthy weight-gain compared to standard chemotherapy in rat and dog models.

Duo Oncology further optimized preclinical development through NIH grants supporting detailed pharmacokinetic and biodistribution studies to refine dosing and indications. The company assembled a clinical development team including Dr. Victoria Manax, former Chief Medical Officer at PanCAN, and Dr. Jose Iglesias, formerly CMO at Abraxis, who bring deep expertise in oncology nanomedicine trial design and execution. Statistical rigor and trial design benefit from collaboration with Dr. Don Berry, a renowned Bayesian biostatistician, while clinical data management and regulatory support come from Prevail Partners, a bespoke clinical research team pioneering real-time data analysis.

Strategic product roadmap and commercialization guidance are provided by BeiGene Pharmaceuticals, a global oncology leader and significant investor in Duo Oncology's seed round, reinforcing confidence in the platform's market potential.

Duo Oncology is initiating a Phase 1 clinical trial based on an innovative Bayesian adaptive continuous reassessment method to rapidly identify optimal dosing balancing safety and efficacy in patients with pancreatic, biliary, breast, and lung cancers. To enhance immune activity from STING activation, Duo Oncology, in collaboration with Sun and Li's lab, developed a next-generation combination therapy incorporating a CCR2 antagonist within the PGEM carrier. This dual-action immunochemotherapy reverses tumor immune resistance, enhances innate and adaptive immune responses, and synergizes with immune checkpoint inhibitors like anti-PD-1 antibodies, showing

compelling preclinical efficacy.

Together, this integrated approach-combining academic innovation, clinical expertise, regulatory and data management, and industry partnerships-positions Duo Oncology to transform the essential active moieties of chemotherapy into patient-centric medicines through in silico chemistry with lean, virtual best-in-world team.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Impact on the Human Condition

Duo Oncology's nanomedicine platform directly addresses critical unmet needs in cancer treatment, particularly for patients with aggressive tumors such as pancreatic cancer, which has a 5-year survival rate under 10%. Conventional chemotherapy regimens like gemcitabine plus nab-paclitaxel often cause severe side effects-including neuropathy, blood disorders, and gastrointestinal toxicity-that drastically reduce patient quality of life and generate healthcare costs six to ten times higher than the cost of the drugs themselves (JAMA Network Open, 2023;

DOI:10.1001/jamanetworkopen.2023.50756). Duo's ultrasmall (~13 nm) polymeric nanoparticles (PGEM) enable targeted delivery and prolonged retention of chemotherapy drugs directly inside tumors, minimizing systemic exposure. Preclinical studies in rats and dogs demonstrated improved safety and well-being, evidenced by maintained or increased body weight, unlike animals treated with standard chemotherapy who suffered significant weight loss. This safety profile supports less frequent dosing schedules, reducing the physical and economic burden on patients by lowering clinic visits and adverse event management costs, thus substantially improving patient quality of life and long-term outcomes.

Influence on Medicinal Chemistry and Research

The foundational work by Drs. Sun and Li has been recognized as seminal in advancing nanomedicine design. Their publication in Theranostics (Sun et al., 2020;

DOI:10.7150/thno.38287) describes a novel gemcitabine-conjugated polymer (PGEM) that self-assembles into ultrasmall, highly stable nanoparticles capable of co-delivering both hydrophilic and hydrophobic drugs at high loading capacities (up to 24wt% paclitaxel). This contrasts with conventional larger nanoparticles (~100-150 nm) that suffer from poor tumor penetration. The use of advanced computational modeling to rationally design polymer-drug interactions and optimize nanoparticle size exemplifies a shift towards more predictive, integrated medicinal chemistry approaches that accelerate drug development.

Building on this platform, Duo Oncology's integration of immunomodulatory agents-such as CCR2 antagonists embedded within PGEM nanoparticles-has further expanded the therapeutic potential, as highlighted in Materials Today (Wan et al., 2023; DOI:10.1016/j.mattod.2022.11.008). This approach simultaneously activates antitumor immunity via the STING pathway while counteracting immune resistance, representing cutting-edge translational research in oncology nanomedicine. The versatility of this

platform opens new frontiers for drug delivery beyond cancer, addressing challenges in autoimmune, neurodegenerative, and infectious diseases where potent drugs are limited by systemic toxicity. Duo's technology thus serves as a blueprint for next-generation medicines that prioritize patient-centric efficacy and safety.

Conclusion

Duo Oncology's nanomedicine platform is a transformative advance that combines rigorous academic innovation with clinical and industrial expertise. By overcoming biological and pharmacological barriers, it offers safer, more effective cancer treatments that improve patient outcomes and quality of life. The platform's broad applicability and strong research impact position it as a catalyst for future innovation across medicine, heralding a new era of patient-centric drug design.

Please provide appropriate references (PubMed, Abstract, Website):

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