

SURGE Therapeutics

Category:

Best Startup

Company Name:

SURGE Therapeutics

Turnover and/or Funding:

\$64,000,000

Sub-Category:

Biotechnology

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

SURGE Therapeutics (SURGE) seeks to transform the standard of care for patients with solid tumors by reimagining surgery from being a physical intervention only to being a therapeutic intervention as well. To this end, our mission is to create a world where nobody grieves the loss of a loved one to preventable post-surgical cancer recurrence and metastasis.

Recurrence and metastasis represent the greatest unmet medical need in oncology, accounting for 90% of cancer-related deaths. Nine million patients undergo surgical tumor resection every single year, and nearly half of them will experience recurrence within five years. Innovative solutions are clearly required.

Surgery is the standard of care for every major solid tumor, but the current intervention is insufficient. The procedure presently involves a surgeon cutting out the tumor, closing up the patient, and sending the patient home. SURGE believes that the empty space where the tumor had resided should not be left empty; rather, it should be filled with an immunotherapy-loaded hydrogel that can reprogram the immune system to both prevent local recurrence and eradicate disseminated disease - just as a vaccine in your arm against polio can lead to life-long immune protection throughout your body. SURGE's approach involves supplementing the standard of care rather than competing with it, and the additional therapy is expected to have a substantial positive impact on survival outcomes.

SURGE was founded in 2016, based on research conducted in founder and CEO Michael Goldberg's lab at Harvard Medical School / Dana-Farber Cancer Institute. In addition to a seed round, SURGE raised \$26 M in a Series A in 2021 and \$36 M in a Series B in 2023, the same year that it initiated a first-in-category clinical trial. SURGE has since initiated two additional Phase 1 proof-of-principle studies and is on track to advance all three programs into Phase 2 proof-of-concept studies in early 2026.

Leveraging clinically de-risked assets, SURGE is a clinical-stage company that is striving to dramatically enhance patient survival by improving how, when, and where cancer immunotherapy is deployed. Immunotherapies should work better if given in a preferred context: at the right place and at the right time, namely at the site and time of surgery. SURGE is the only company developing intraoperative immunotherapy, and its innovation allows the immune system to clear microscopic residual disease - both local and distal - rather than having to address macroscopic advanced disease, which is very hard to eradicate completely.

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

The work underlying intraoperative immunotherapy was published by Dr. Goldberg's lab in 2018 in the prestigious journal Science Translational Medicine. Its relevance in the context of the burgeoning field of immunoengineering was described in Nature Reviews Cancer in 2019. The novelty of the approach was validated by the issuance of multiple patents (in the United States, in Europe, and in Asia) filed in relation to this work. SURGE's thermosensitive hydrogel loaded with immunotherapy can be injected at any tumor resection site and extends the release of the immunotherapy locally, enabling reprogramming of the post-resection milieu from immunosuppressive to immunostimulatory.

The preclinical evidence demonstrated not-seen-before efficacy in highly aggressive mouse models of spontaneous metastasis. The data revealed that the survival benefit was agnostic to several key features of cancer: the underlying genetic lesions, the cell of origin, and the anatomical location. Extended localized release of immunotherapy enables the immune system to overcome surgery-induced immune suppression and is superior to traditional routes of administration, whether systemic delivery or even local bolus delivery in solution, which diffuses away rapidly. GLP-toxicology studies in larger animals confirmed that the approach is incredibly safe, paving the way for clinical trials, which are underway to address three indications: bladder cancer, breast cancer, and prostate cancer.

While specific details are confidential, the clinical data acquired to date support the utility of intraoperative immunotherapy in human patients. Specifically, the safety

profile, pharmacokinetics, and pharmacodynamics across multiple dose levels are all highly desirable. SURGE is excited to transition from the Phase 1 proof-of-principle studies to Phase 2 proof-of-concept studies in the relatively near future.

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

This is not simply a drug or device but is rather a paradigm shift in oncology with hopefully broad implications for cancer patient survival outcomes. As noted above, recurrence and metastasis are the principal causes of cancer-related deaths, yet most oncology companies are focused on treating cancer once it has achieved an advanced state. There is a need to move immunotherapy into early clinical settings, as the Oncology Center of Excellence at FDA has recognized through their initiation of Project FrontRunner, which seeks to incentivize such drug development, as there is evidence that immunotherapy leads to improved survival if given as an earlier line of therapy and/or against less bulky disease.

Most people would agree that it should be easier to clear a small number of residual cells immediately following surgical resection than to clear billions of cancer cells in the advanced setting -- and the data support this. This benefit is particularly true when the modality is immunotherapy, as later-stage disease has several features that restrict responses to immunotherapy: 1) many cancer cells, 2) a dysfunctional immune system, and 3) a concentrated immunosuppressive microenvironment. Intraoperative immunotherapy has none of these limitations and simply leverages the fact that a surgeon has often removed ~99% of the offending cancer cells with a scalpel. Eliminating the remaining ~1% of cancer cells - whether at the site of surgery or those already escaped to other parts of the body and therefore inaccessible to the surgeon - would lead to a functional cure for cancer, and this should be our goal.

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

<https://surgetx.com>

<https://www.businesswire.com/news/home/20230719921865/en/SURGE-Therapeutics-Raises-2432M-Series-B-Financing-to-Advance-Intraoperative-Immunotherapy-to-Improve-Cancer-Patient-Survival-Outcomes-Post-Surgery>

<https://www.forbes.com/sites/indiarice/2023/07/19/this-startup-just-raised-32-million-to-keep-cancers-from-recurring-after-surgery/?sh=6d7ec3196ef3>

<https://endpts.com/surge-therapeutics-raises-32m-after-dosing-first-patients-with-immunotherapy-during-surgery/>

<https://youtu.be/izBhKesjzaA>

<https://youtu.be/sVO2cojUA5s>

<https://www.science.org/doi/10.1126/scitranslmed.aar1916>

<https://www.nature.com/articles/s41568-019-0186-9>

References File Document upload:

N/A