Local Postsurgical Targeted Therapy (LPTT)

If breast cancer is localized and not spread to other organs, surgical removal is generally the most effective treatment. However, breast cancer may recur because some tumor cells were not removed completely during surgery. Currently, many hospitals in the U.S. use radiation therapy as a standard procedure after lumpectomy (breast-conserving procedure) to reduce the rate of cancer recurrence. However, radiation therapy is expensive ($6,000 – 12,000), cumbersome (4–5 week treatment regimen) and has side effects including nausea, hair loss, skin burns, and fatigue. Following radiation therapy, hormone therapy is often used for hormone positive and HER-2 negative breast cancer patients to reduce cancer recurrence. This hormone therapy is recommended for up to 5 years for early stage hormone positive breast cancer patients after surgery.

Our Approach

Postsurgical Therapeutics, Inc. ("PTI") is developing local postsurgical targeted therapy ("LPTT"), which can be applied to the surgical site as a powder prior to suturing to eliminate residual tumor cells. The LPTT is a sustained and controlled release drug delivery system based on microspheres consisting of PLGA and targeted drug(s). Postsurgical currently focuses on the targeted drug(s) for treating hormone receptor positive and HER-2 negative breast cancer patients after surgery. This targeted drug(s) may be co-administered with hormone therapy. Generally targeted drugs are more selective to cancer cells compared to normal cells and thus reduce side effects. By contrast conventional chemo drugs kill both cancer cells and normal cells. The hormone therapy includes selective estrogen receptor modulator, selective estrogen receptor degrader and aromatase inhibitor. Generally, a combination of targeted drug(s) and hormone therapy causes some serious systemic side effects if taken orally over a long period of time. The hormone therapy can be taken orally while LPTT can be sprayed to the resected lesion by a simple hand-held delivery system. This powder formulation releases targeted drug(s) over 3 months.

There is a very large opportunity for a product that can reduce cancer recurrence after surgical removal of a tumor. PTI's first application of LPTT is for post-surgical treatment of breast cancer. There are approximately 200,000 lumpectomies performed annually in the U.S. and similar numbers in Europe. Up to 80% of breast cancer patients are hormone positive and HER-2 negative. PTI believes its LPTT will be cost-effective and can eliminate the need for expensive and cumbersome radiation therapy. The potential opportunity for treatment of hormone positive breast cancer patients after lumpectomy is substantial in the U.S and other developed countries (>$2 – 3 billion).

Product Development

PTI and Upex-Med have developed everolimus-PLGA and paclitaxel-PLGA microsphere formulations and have performed animal test. We are currently forcusing on a combination of local everolimus-PLGA microspheres and oral exemestane or tamoxifen hormone therapy as our

first product. A combination of everolimus and exemestane (both drugs are taken orally) was approved by the FDA and commercially available currently.

First we inoculated MCF-7 cell onto the back of mice and grew tumor to a size of approximately 200 mm^3. Since MCF-7 cell grew slow, we supplemented orally with estradiol to help tumor grow faster. Once tumor volume became about 200 mm^3, we performed a surgery to remove about 95% of tumor. Then, we treated with everolimus-PLGA or paclitaxel-PLGA microspheres before closing the resected area. Both groups were co-treated with oral tamoxifen. Third group was without any treatment as a control. We found that both everolimus and paclitaxel group had 2 out of 7 mice with recurring cancer (29%) while the control group had all 7 out of 7 mice with recurring cancer after 15 days (100%). This study demonstrates that local postsurgical chemo or targeted therapy may reduce the recurrence rate of hormone positive breast cancer. LPTT may replace expensive and cumbersome current standard radiation therapy after lumpectomy.

PTI also performed a test which treated locally with everolimus-PLGA or paclitaxel-PLGA microspheres plus oral exemestane. This study was completed with a similar outcome using oral tamoxifen.

Regulatory Approval in the U.S.

PTI believes LPTT product will be eligible for the FDA's 505(b)(2) regulatory path in the U.S. ("repurposed drug") rather than the 505(b)(1) regulatory path required for new drugs. The 505(b)(2) regulatory path allows the developer of a new formulation of an approved therapeutic agent to reference the safety and efficacy data on which the therapeutic agent was approved. Product development and approval using the 505(b)(2) regulatory path should take no more than 6 – 8 years. This path can lead to approval in a fraction of the time and cost expected with the 505(b)(1) regulatory path.

Intellectual Property

PTI filed a continuation-in-part (CIP) in September, 2021 to strengthen the original application.

Commercialization Strategy

We are currently seeking for a corporate partnership to complete development, obtain regulatory approvals and commercialize worldwide. We expect the partnership to provide near term cash, including an upfront license fee, and milestone payments.