Greenwich LifeSciences

COMPANY PROFILE

Business Description: Greenwich LifeSciences (the "Company") is a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery. GP2 is a 9 amino acid transmembrane peptide of the HER2/*neu* (human epidermal growth factor receptor 2) protein, a cell surface receptor protein that is expressed in a variety of common cancers, including in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or "over-expressor") levels.

Substantial Unmet Need: One in 8 U.S. women will develop invasive breast cancer over her lifetime, with approximately 266,000 new breast cancer patients and 3.1 million breast cancer survivors in 2018. In the adjuvant setting, a HER2/*neu* 3+ patient typically receives Herceptin in the first year following breast cancer surgery, with the hope that their breast cancer will not recur, and with the odds of recurrence slowly decreasing over the first 5 years following surgery. Herceptin has been shown to reduce recurrence rates by 50%, from 25% to 12%, in the adjuvant setting. In the neoadjuvant setting, a HER2/*neu* 3+ patient receives treatment before surgery and based on the results of a biopsy at surgery, will receive Herceptin or Kadcyla, a more potent form of Herceptin, following surgery. Kadcyla has been shown to reduce recurrence rates by 50%, from 22% to 11%, in the neoadjuvant setting. Accordingly, the Company believes that GP2 immunotherapy may be effective in safely addressing the 50% of recurring patients who do not respond to either Herceptin or Kadcyla.

Statistically Significant Phase IIb Clinical Data in HER2/*neu* 3+ Over- Expressors: In a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) Phase IIb clinical trial led by MD Anderson and completed in 2018, no recurrences were observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$). Furthermore, the GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays. Of the 138 patients who have been treated with GP2 immunotherapy to date over 4 clinical trials, no serious adverse events were reported related to GP2 immunotherapy, and GP2 immunotherapy was well tolerated. The Phase IIb clinical trial results can be summarized as:

- No cancer recurrences over 5 years, if fully immunized
- No reported serious adverse events
- A well tolerated safety profile

Upcoming Phase III Clinical Trial: Greenwich LifeSciences is currently preparing the cGMP manufacturing of GP2, selecting clinical trial partners, and finalizing a protocol towards commencing a Phase III clinical trial that is conservatively designed to reproduce the Phase IIb clinical trial results.

BOARD OF DIRECTORS

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Jaye Thompson, Ph.D.
VP Clinical & Regulatory Affairs

CONTACT

Investor & Public Relations Team
T: 832-819-3232
info@greenwichlifesciences.com

DISCLAIMER

Greenwich LifeSciences Reports Robust Immune Response Phase IIb Data Supporting GP2 Clinical Outcome of 0% Metastatic Breast Cancer Recurrences Over 5 Years of Follow-up
Apr 9 2021, 5:00 AM EDT

Greenwich LifeSciences CEO to Participate on Cancer Panel and to Present at Benzinga Biotech Conference
Mar 23 2021, 6:00 AM EDT

Greenwich LifeSciences Updates 2021 Timeline & Announces Two Upcoming Presentations at the American Association for Cancer Research Annual Meeting
Mar 11 2021, 6:00 AM EST