Novelos revives failed drug as potential breast cancer treatment

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Novelos Therapeutics Inc., the biotechnology company that suffered a heavy blow when its promising lung cancer drug target failed in a late stage trial [1], is advancing the same candidate as a potential breast cancer therapy.

The Newton-based biotech has announced positive Phase 2 results for NOV-002 in combination with neoadjuvant chemotherapy treatment in patients with certain types of breast cancer.

The study was conducted by the Braman Family Breast Cancer Institute at Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine.

The goal of the study is to show that the addition of Novelos' drug target doubles the so-called complete response rate for breast cancer patients taking three other chemotherapy drugs. The endpoint called for 12 patients to achieve this response, and that goal has been achieved. The number of successful outcomes may rise, as some of the 39 patients in the study are still being treated.

The study was a so-called single arm study, meaning it did not involve a group of patients on placebo. Such trials are sometimes insufficient for U.S. Food and Drug Administration. However, they are often employed in disease areas where there is a significant unmet need, and it would be unethical not to treat all patients with the experimental therapy.

"We are excited about this proof-of-concept trial, and we are excited to have NOV-002 back in the game," Harry Palmin, president and CEO of Novelos, said Monday. Palmin said the company plans to consult with the FDA on designing a larger placebo-controlled study.

Novelos suffered a setback in February, when it announced that its Phase 3 lung cancer trial for the same drug candidate failed. The failure surprised analysts [2], who predicted that the trial had been extended due to longer-than-expected survival rates.

SOURCE [3]

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