Non-hormonal therapy reduces hot flashes and night sweats in women who have been diagnosed with breast cancer

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A Monash University-led trial of a new drug known as Q-122 therapy significantly reduced the number and severity of hot flashes and night

sweats in women who have been diagnosed with breast cancer. It also improved their sleep and had no serious adverse effects.

QUE Oncology's Phase II trial of Q-122, a novel non-hormonal oral therapy for the treatment of vasomotor symptoms (commonly known as hot flashes/flushes and night sweats) in women taking endocrine therapy for breast cancer, have been published in *The Lancet*.

The Phase II study was a multi-center, randomized, double-blind, placebo-control trial involving 131 women taking endocrine therapy (tamoxifen or an aromatase inhibitor) following breast cancer. More than 75% of breast cancers are hormone-sensitive, with endocrine therapy being the standard treatment option.

Q-122 therapy significantly reduced the frequency and severity of moderate and severe vasomotor symptoms, with associated improvement in quality of life, compared with placebo. Q-122 was well tolerated with no serious adverse effects.

Endocrine therapy is recommended for 5–10 years for women with hormone-sensitive breast cancer to prevent disease recurrence. However, approximately 70% of women taking endocrine therapy have vasomotor symptoms which contribute to over one third of women prematurely stopping endocrine therapy.

"Our research findings published in *The Lancet* demonstrate efficacy of Q-122 as a non-hormonal oral treatment for vasomotor symptoms in women taking oral adjuvant endocrine therapy after breast cancer, with no evidence of treatment side-effects," said Principal Investigator and Senior Author, Professor Susan Davis Director, of the Monash University Women's Health Research Program.

"In addition to a reduction in flushes and sweats, women who received

Q-122 in the study reported a significantly lower likelihood of their hot flushes and sweats interfering with their sleep, and social and leisure activities, compared with placebo. If Q-122 can provide relief from these symptoms, it holds great potential for reducing discontinuation of endocrine therapy, enabling ongoing protection against breast cancer recurrence. This is an extremely important potential benefit of Q-122 beyond symptom relief alone," Professor Davis added.

QUE Oncology was formed through a joint venture between Emory University in Atlanta and the University of Queensland (UQ) research commercialization company, UniQuest. The company has been supported by leading life science investors, including the Brandon Capital-managed Brandon BioCatalyst and Uniseed.

"It's great to see extremely positive results from QUE Oncology's Phase II trials published in the world's leading independent general medical journal. The research highlights the need for a therapy for patients undergoing endocrine therapy for breast cancer who are experiencing vasomotor symptoms, but also for a broader scope beyond this patient group including postmenopausal women, of which 70–80% experience vasomotor symptoms," says Dr. Chris Nave, Chairman of QUE Oncology and CEO of Brandon BioCatalyst.

The results of QUE Oncology's Phase II study support the conduct of larger and longer studies of Q-122, with potential use extending to postmenopausal women who require an alternative to estrogen therapy for vasomotor symptoms.

More information: Amanda Vrselja et al, Q-122 as a novel, non-hormonal, oral treatment for vasomotor symptoms in women taking tamoxifen or an aromatase inhibitor after breast cancer: a phase 2, randomised, double-blind, placebo-controlled trial, *The Lancet* (2022). DOI: 10.1016/S0140-6736(22)01977-8

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