Major trial shows targeted drug extends breast cancer survival

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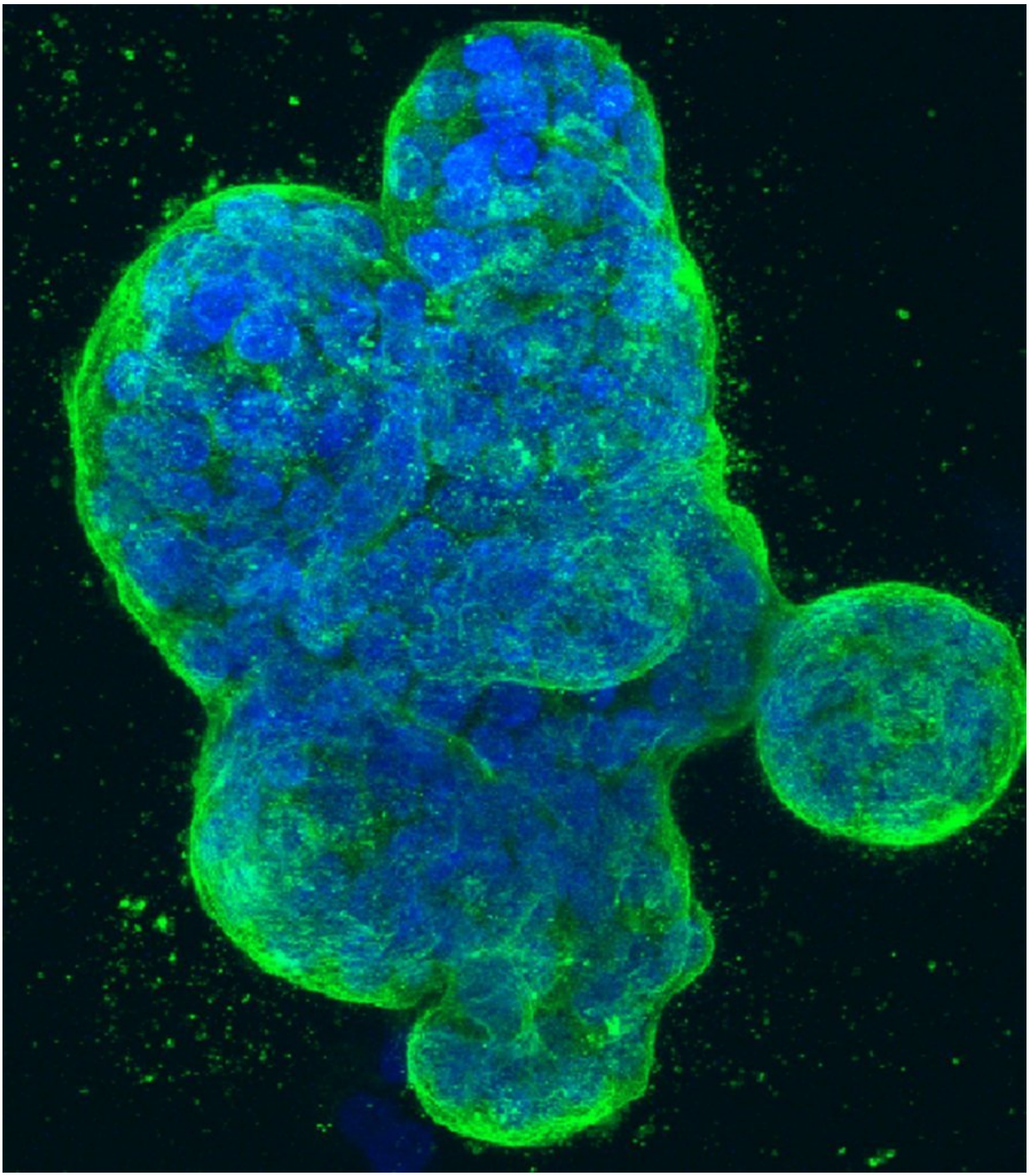

Three-dimensional culture of human breast cancer cells, with DNA stained blue and a protein in the cell surface membrane stained green. Image created in 2014 by Tom Misteli, Ph.D., and Karen Meaburn, Ph.D. at the NIH IRP.

Combining a targeted drug with hormone therapy substantially extends survival for women with advanced breast cancer, a major clinical trial has found.

Women taking palbociclib together with hormone therapy lived seven months longer than those on hormone treatment alone – adding to previous data showing the combination could delay the disease's progression.

The drug's benefit was stronger in women who had previously responded to hormone therapy – who lived 10 months longer with the combination treatment.

The international PALOMA-3 clinical trial was led by researchers at The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust, and involved 144 research centres in 17 countries.

The study was funded by the drug's manufacturer, Pfizer. It is published in the *New England Journal of Medicine*, and is being presented simultaneously at the European Society of Medical Oncology congress in Munich, Germany.

The clinical trial tested the benefit of adding palbociclib to the hormone therapy fulvestrant in 521 women with advanced, hormone-sensitive breast cancer whose tumours did not have a protein called HER2.

When women with advanced breast cancer stop responding to other treatments, the only option available is chemotherapy, which can have debilitating side-effects.

The trial examined what effect palbociclib had on women's overall survival and whether it could delay their having to receive chemotherapy.

In the new analysis, the researchers found that women who received the combination treatment survived for an average of 34.9 months – 6.9 months longer than those who received fulvestrant and a dummy pill.

Three years after they were enrolled in the study, 49.6 per cent of women who received both palbociclib and fulvestrant were still alive, compared with 40.8 per cent of women who were treated with fulvestrant alone.

In women whose tumours had previously been sensitive to hormone therapy, the benefit of palbociclib was even clearer – with the combination treatment extending survival by 10 months.

In these women, those who were given the combination treatment survived for an average of 39.7 months, compared with 29.7 months in women who received fulvestrant alone.

The group of women given the combination treatment also saw a longer delay until the start of chemotherapy.

For these women, the average time between enrolment in the trial and the start of chemotherapy increased to 17.6 months compared with 8.8 months in women who received fulvestrant alone.

The trial was led by Professor Nicholas Turner, who works within the Breast Cancer Research Division and Breast Cancer Now Research Centre at The Institute of Cancer Research (ICR), and is a Consultant Medical Oncologist at The Royal Marsden.

Researchers at the ICR – a research institute and charity – believe the findings strengthen the case for making palbociclib available to women whose cancer has progressed on prior hormone therapy. It was approved by NICE for women with previously untreated advanced breast cancer in

November last year.

Professor Nicholas Turner, Professor of Molecular Oncology at The Institute of Cancer Research, London, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust, said:

"The development of palbociclib is one of the biggest advances in treatment for women with advanced breast cancer in the last two decades.

"It's incredibly rewarding that the benefits we had previously seen for palbociclib are now translating into such significant extensions in survival. This drug can offer women more precious time with their loved ones and because it is a targeted treatment it is much kinder than chemotherapy, and enables many women to carry on with their lives normally.

"I'm keen to see it available on the NHS for women with breast cancer who have been treated previously with hormone therapy, as well as those with newly diagnosed advanced disease, as soon as possible."

Professor Paul Workman, Chief Executive of The Institute of Cancer Research, London, said:

"Palbociclib is an innovative new drug that targets specific weaknesses in cancer cells, treating breast cancer in a smarter, kinder way than anything that had been available for these women before.

"This important trial provides further evidence that precision therapies for cancer, based on our scientific understanding of tumours, can offer real survival benefits over traditional treatments. It is an illustration too of the way that targeted drugs can be given together in innovative combinations, as a way of tackling cancer's ability to adapt and evolve,

and slowing down development of resistance to treatment."

Christine O'Connell, 45, from London, who is being treated with palbociclib and hormone therapy for advanced breast cancer, said:

"My treatment with palbociclib and hormone therapy has been much more manageable than the chemotherapy I received when I was first diagnosed with breast cancer in 2012, with all the unpleasant side-effects.

"Without palbociclib, my breast cancer would probably progress sooner. At some point I might need to move on to chemotherapy, but for the moment, palbociclib is doing the job.

"Palbociclib has allowed me to lead a relatively normal life. I'm able to work part-time, and I can keep up my cycling, which I could never have done had I been on conventional therapy."

More information: Nicholas C. Turner et al. Overall Survival with Palbociclib and Fulvestrant in Advanced Breast Cancer, *New England Journal of Medicine* (2018). DOI: 10.1056/NEJMoa1810527

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