

Life-extending drug for ovarian cancer made available in Europe

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Cancer patients in Europe can now receive a life-extending drug invented and developed by scientists at Newcastle University.

Women with recurrent <u>ovarian cancer</u> have been given access to the pioneering treatment, Rubraca, following approval of the <u>drug</u> by the European Medicines Agency (EMA). This allows the drug to be available on the European market.

Rubraca has been approved for ovarian cancer patients with a faulty BRCA gene. First discovered approximately 20 years ago, it came out of research initiated at Newcastle University, UK, by Cancer Research UK-funded scientists.

If approved by the National Institute for Health and Care Excellence and the Scottish Medicines Consortium, it will allow ovarian cancer patients in the UK with a BRCA gene mutation to access the new treatment.

Success of treatment

Studies have shown that the oral medication has a high success rate as 54% of women on clinical trials had complete or partial shrinkage of their tumour for an average of 9.2 months.

Ruth Plummer, Clinical Professor of Experimental Medicine at the Northern Institute for Cancer Research, Newcastle University, was the



first clinician to prescribe Rubraca.

Professor Plummer, who is also Consultant Medical Oncologist at Newcastle upon Tyne Hospitals NHS Foundation Trust, said: "It is very exciting and the culmination of many years of research from a team here in Newcastle, and in collaborations with others, that Rubraca has been licensed by the EMA.

"It means this drug, which prolongs patients' lives, will become available to patients across Europe."

Rubraca, also known as rucaparib, is a class of drug called a PARP inhibitor which exploits a defect in the cancer cell's ability to repair normal wear and tear to its DNA to kill the tumour cells without unduly harming healthy cells.

The EMA has approved the use of the drug for women with ovarian cancer who have been treated with two or more chemotherapies and whose tumours have a BRCA mutation. This follows last year's approval in the USA by the Food and Drug Administration.

Ovarian cancer diagnosis

Each year, around 7,000 women are diagnosed with ovarian cancer across the UK and one in 50 women will develop the disease at some point in their life.

Around 15% to 20% of women with ovarian cancer will have a BRCA gene mutation, putting them at increased risk of developing other cancers and a 50% risk of passing the faulty gene to their children.

Dr. Yvette Drew, Senior Lecturer at Newcastle University and Honorary Consultant in Medical Oncology at Newcastle upon Tyne Hospitals NHS



Foundation Trust, has led the clinical development of Rubraca in ovarian cancer in the North East.

She said: "Rubraca is a well-tolerated oral drug, allowing women to have a better quality of life for longer without debilitating side-effects that are often seen with chemotherapy.

"The approval of this medication is a great testament to the work of the Newcastle University team and is an example of what can be achieved when scientists and oncologists work together to target a specific type of cancer at the molecular level."

Newcastle University researchers—Professors Hilary Calvert, Nicola Curtin, Barbara Durkacz, Bernard Golding, Roger Griffin, Herbie Newell and Ruth Plummer—were part of a multi-disciplinary team that discovered and developed Rubraca.

Sir Harpal Kumar, Cancer Research UK's chief executive, said: "We're delighted that Rubraca has been licensed for use by the EMA, particularly when Cancer Research UK-funded scientists working at Newcastle University discovered and developed the drug in the early 1990s in collaboration with industry partners.

"The drug—one of an exciting group of drugs that exploit the weaknesses cancer cells have in repairing damaged DNA—will offer new hope to women with advanced ovarian cancer.

"We hope it could one day treat other cancer types and clinical trials are underway to discover its potential. Our partnerships with academia and industry are helping us bring more new treatments to patients, accelerating our efforts to beat cancer sooner."

Patient's story



Susan Ross has been on Rubraca under Dr. Drew's care at the Freeman Hospital's Northern Centre for Cancer Care in Newcastle for more than two years and is living life to the full.

The 60-year-old, of Whitley Bay, was diagnosed with ovarian cancer with a BRCA gene mutation over 10 years ago and says she feels great after being given the drug as part of a clinical trial.

Susan has been on Rubraca since December 2015 when her ovarian cancer returned and was not operable. Her tumour has shrunk completely and she continues to receive the treatment as part of a clinical trial.

She said: "It is wonderful that Rubraca has been given EMA approval and women in Europe eligible for this treatment will be able to receive it.

"I feel the best I've felt since before my ovarian cancer diagnosis in 2007. I have my life back and I've been to far afield countries like Australia and Japan.

"The team at Newcastle University should be very proud of what they have achieved as Rubraca is offering hope to ovarian cancer patients with the BRCA gene mutation that they can live their life well.

"I would like to thank all those who have been involved in Rubraca's development and to the clinical team who have looked after me so well."

Susan underwent four operations and three rounds of chemotherapy before being enrolled on the clinical trial. She continues to be closely monitored with regular CT scans.

History of Rubraca



Newcastle University has been instrumental in the development of Rubraca.

The project that led to its discovery was among the first of Newcastle Cancer Drug Discovery Group that started at the University, involving the Northern Institute for Cancer Research and School of Chemistry.

A team of Cancer Research UK-funded scientists at the University contributed to the discovery of the treatment from an idea of a <u>cancer</u> drug target, which moved through chemistry and laboratory science and finally clinical trials of Rubraca began.

Scientists at the School of Chemistry and Northern Institute for Cancer Research started their research on inhibitors of DNA repair enzymes, including an enzyme called poly(ADP-ribose) polymerase (PARP-1).

It was later established that inhibiting PARP-1 was particularly effective in treating tumours with a mutated BRCA gene.

Finding an inhibitor of this enzyme relied on finding a molecule that would displace PARP-1's natural chemical substrate. A key step in this process was established at the School of Chemistry, where a way to mimic the natural substrate leading to compounds that inhibited the enzyme was found.

Experts at the Northern Institute for Cancer Research helped to develop the drug and the first clinical trial of Rubraca was conducted in Newcastle in 2003, and further <u>clinical trials</u> followed.

Provided by Newcastle University

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