Dear (your local MP,)

As a constituent of yours and someone who has been affected by metastatic breast cancer (first-hand), I wanted to get in touch to ask for your help around unacceptably slow access to cutting-edge treatments for metastatic breast cancer. Namely, I would like to ask for your help in raising the issue of the urgent need for MHRA approval and NICE funding of the drug **Sacituzumab Govitecan** (brand: Trodelvy) for metastatic Triple Negative Breast Cancer.

\*( I've been/am a friend/family of someone living with primary/secondary breast cancer for….. and I will be on treatment for life.)

Of all the subtypes of metastatic breast cancer, metastatic Triple Negative Breast Cancer (TNBC) is the hardest to treat with the worst prognosis. The average life expectancy for someone with metastatic TNBC is just 12-18 months. In the UK every year, around 1650 women die of metastatic TNBC. Given the aggressive nature of the disease, most of them die months, not years, after their advanced diagnosis. Triple Negative breast cancer also disproportionately affects **young women** and **women of colour**.

Given this reality, it is no surprise that there has been enormous excitement in the patient and oncology communities over the development of a new, targeted therapy for TNBC called **Sacituzumab Govitecan** (drug name Trodelvy). Trodelvy was given accelerated approval by the Federal Drugs Administration (FDA) in the United States on April 22 2020. It received this on the basis of remarkable clinical trial results that showed that Trodelvy can work to shrink cancer in patients who are otherwise resistant to chemotherapy. It reduces the risk of a metastatic TNBC patient dying by 49% compared with standard chemotherapy treatments.

With all this promise, we would assume that the government in the UK would be keen to ensure British patients have access to Trodelvy in a timely manner. **Unfortunately, nothing seems to be further from the truth.** Gilead, the drug company that owns and markets Trodelvy, applied for MHRA licensing in January 2021. They did so via the new, post-Brexit system called [Project Orbis](https://www.gov.uk/guidance/guidance-on-project-orbis) which has been hyped by the government as a way that British patients will get **faster access to vital cancer drugs.** In this system, which involves a consortium of countries including the UK, USA, Australia and Switzerland, drugs which have already been approved by the FDA undergo a faster approval process in other consortium countries. Trodelvy would seem the perfect test case for this new system, and as such constitutes a test case for **the new, post-Brexit cancer drug approvals environment.**

If Trodelvy is anything to go by, Project Orbis has not lived up to its promise. When the Trodelvy application was made in January 2021,t he oncology community hoped that licensing would be complete by June 2021 (thus matching the 150-day deadline the MHRA sets out for [its regular accelerated approval](https://www.gov.uk/guidance/guidance-on-150-day-assessment-for-national-applications-for-medicines) process). However, recent signals have indicated that a decision on approval will not meet this deadline and may even take until the end of 2021.In other words, the new post-Brexit approval system may still see it take **up to a year** for a licensing decision on Trodelvy. A year in which 1650 women will die of metastatic TNBC, women whose lives could have been extended and vastly improved by access to this life-saving drug.

Even if licensing is completed by the end of 2021, the drug may be approved **but not yet funded** on the NHS. The timeline NICE is currently offering for a funding decision is **Spring 2022** - potentially another full year away. There is a strong possibility that the drug may be approved in 2021 but not funded for another year, which would mean that desperate metastatic Triple Negative breast cancer patients would need to self-fund access to Trodelvy, something that not all will be able to do. Women will die while the ‘promise’ of faster, post-Brexit access to drugs withers on the vine.

Therefore, I would be extremely grateful to have your support, by kindly asking you to raise the issue of access to Trodelvy, and the efficacy of the Project Orbis system more widely, in parliament. I also ask that you request that the Secretary of State for Health and Social Care, the Rt. Hon. Sajid Javid MP, raise this issue with MHRA and NICE and ensure that the promise of Project Orbis be met with faster approval of Trodelvy.

This would mean so much to me and the thousands of other women (and men) who are invisible and living with secondary Triple Negative breast cancer in the UK.

Yours Sincerely,

\*optional. Amend as required.