Sam Roberts
Chief Executive
NICE

Fiona Bride
Director of Medicines Value and Access
NHS England

Haran Maheson
Head of Oncology UK/ Vice President Oncology
Daiichi Sankyo

18 January 2024

RE: Access to Enhertu

Dear Mr Roberts, Ms bride, and Mr Maheson,

As Chair of the Health and Social Care Select Committee, I am writing to ask you for an update regarding the current situation and plans for access to trastuzumab deruxtecan (Enhertu) for certain patients with breast cancer in England.

I was disappointed to hear in September 2023 that Enhertu was provisionally rejected by NICE for use on the NHS in England for treating HER2-low secondary (metastatic) or unresectable breast cancer after chemotherapy.

Despite a second committee meeting in early November 2023, there is still no final decision and I hear the NICE appraisal process has now been paused to enable commercial discussions between NHS England and Daiichi Sankyo. Yet the Scottish Medicines Consortium (SMC) approved Enhertu for use on the NHS in Scotland in December 2023.

Enhertu is the first treatment licensed for HER2-low breast cancer, and it is estimated that around 1,000 people in England every year would be eligible for the treatment. For eligible patients, Enhertu can both slow the spread of the cancer and increase survival compared to chemotherapy.

It is important that these commercial discussions happen as quickly as possible, as right now patients in England are facing an agonising wait to see if they will be able to access this effective treatment that could bring them hope of more time to spend with their loved ones.

This is of course not the first breast cancer treatment to have its approval delayed in recent years. Concerns about the end-of-life criteria being removed and replaced with a severity modifier were also raised during the 2022 Health and Social Care Committee inquiry into Cancer Services. I am aware that, historically, the end-of-life criteria has contributed to several important breast cancer medicines being recommended for use. I'm also aware that patient communities were concerned that this change could have unintended consequences for some medicines for incurable cancers.

While I appreciate much of your discussions will be in confidence, I would welcome an update from you all regarding the current situation and some initial insight into how we can avoid this situation in the future.

- **Is there any progress in negotiations that can be shared and when may we expect an update?**
- **What assessment has been undertaken of what role the new NICE methods could have had in impacting this appraisal, in particular the introduction of the severity modifier and the removal of the end-of-life criteria?**
- **What more can be done to enable timely commercial discussions to ensure guidance is produced as quickly as possible allowing faster patient access to cost-effective medicines as set out in the NICE manual?**

I look forward to hearing from you about this critical issue and would welcome the opportunity to meet with you to discuss this further.

Yours sincerely,

Steve Brine MP

Chair of the Health and Social Care Select Committee