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Eisai Co., Ltd.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE): FINAL APPRAISAL DETERMINATION FOR HALAVEN[®] (ERIBULIN)

The National Institute for Health and Clinical Excellence (NICE) has issued its final appraisal determination (FAD) on Halaven[®] (eribulin) on 17 November, 2011. Eisai Europe Ltd., (European subsidiary of Eisai Co., Ltd.) has issued a statement regarding the draft. For your convenience, the body text of release is copied below.

(Eisai Europe Ltd., Release on 17 November, 2011)

WOMEN WITH ADVANCED BREAST CANCER DENIED LIFE-EXTENDING TREATMENT HALAVEN[®] ▼ (ERIBULIN) *Eisai plans to appeal NICE's decision*

Hatfield, UK, 17 November 2011 – The National Institute for Health and Clinical Excellence (NICE) today published its final appraisal determination (FAD) on Halaven[®] (eribulin). This final appraisal does not recommend NHS funding of eribulin in England and Wales.¹ Eribulin is a new treatment approved for the treatment of patients with locally advanced or metastatic breast cancer whose disease has progressed after at least two chemotherapeutic regimens for advanced disease.² Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.

There is a clear unmet need for new treatment options for women with heavily pre-treated metastatic breast cancer whose disease has continued to progress despite receiving several lines of chemotherapy. Eribulin is the first single agent chemotherapy to demonstrate a prolongation of overall survival.³ It has an expected and manageable safety profile which is in line with other single agent drug treatments for advanced breast cancer.³ Despite the need for new treatment options and the proven benefits of eribulin, NICE has issued a negative recommendation for the use of eribulin on the NHS and Eisai intends to appeal this decision.

Professor Chris Twelves, Deputy Director, Cancer Research UK Clinical Centre in Leeds commented; "Eribulin has challenged the notion that improved overall survival is an unrealistic outcome for women with heavily pre-treated advanced breast cancer. The EMBRACE trial not only demonstrated that eribulin provides an improvement in median overall survival compared to single agent treatments, but that this survival benefit is not outweighed by any unexpected or unmanageable side effects, an important aspect for any treatment in this setting."

Nick Burgin, European Director of Market Access, Eisai said; "We are dismayed with this final NICE appraisal as it denies women access to a treatment that is proven to prolong life and provides an opportunity for the NHS to improve cancer outcomes in metastatic breast cancer patients. Eribulin is an innovative agent currently being offered to the NHS at the lowest price in the world. Eisai has tried to make eribulin affordable in England and Wales and has offered a discount on the price of the new drug. We feel that patients should not be unable to access a life-prolonging drug like eribulin on the basis of an arbitrary threshold of cost per quality adjusted life year (QALY) used by NICE and we plan to appeal this decision."

Eribulin is already available and reimbursed in a number of countries throughout Europe and this negative NICE decision further demonstrates the inequality for patients in the UK compared to other countries. The NICE decision means that eribulin can only be accessed on the NHS in England via the Cancer Drugs Fund. Currently, only four of the 10 Cancer Drugs Fund regions have approved funding for eribulin, denying access to those outside these regions or in parts of the UK where the Cancer Drugs Fund does not exist.

Results of the pivotal Phase III research study, EMBRACE, showed that patients treated with eribulin survived on average 2.7 months longer than patients who received 'treatment of physician's choice' (TPC), (eribulin 13.2 months vs. TPC 10.5 months, nominal $p=0.014$).² TPC represents active treatment options currently used by doctors in real world clinical practice.

A further pre-planned analysis of region 1 (North America/Australia/Western Europe) of the Phase III EMBRACE clinical trial was also carried out. The results showed a significant overall survival benefit of eribulin over TPC of 3.0 months (nominal $p=0.031$).³ Ten UK trial centres were included within region 1 and this further analysis was carried out as the patients in this region were felt to best represent how patients in the UK are managed.

Eribulin is approved in the European Union, USA, Switzerland, Japan, and Singapore. Eribulin is currently commercially available in Austria, Denmark, Finland, Germany, Japan, Netherlands, Norway, Portugal, Spain, Sweden, Singapore, Switzerland, United Kingdom, and the USA.

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References

¹ National Institute for Health and Clinical Excellence, Final appraisal determination, Eribulin for the treatment of locally advanced or metastatic breast cancer, November 2011.

² Summary of Product Characteristics Halaven (updated March 2011), Available at:

<http://www.medicines.org.uk/EMC/medicine/24382/SPC/Halaven+0.44+mg+ml+solution+for+injection/>

³ Cortes J, O'Shaughnessy J, Loesch D, et al. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. *The Lancet*. 2011; 377: 914 -923