

## **PRESS RELEASE FOR EU MEDICAL MEDIA ONLY**

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## **Eisai and MedSIR announce initiation of new study investigating Halaven<sup>®</sup> (eribulin) treatment efficacy in metastatic breast cancer**

***REVERT study is a multicenter, randomised, phase II trial evaluating the efficacy of Halaven<sup>®</sup> (eribulin) monotherapy and eribulin plus endocrine therapy in locally-recurrent or metastatic breast cancer patients (MBC) after progression on endocrine therapy.<sup>1</sup>***

**Hatfield, UK, 31 May 2019** – Eisai Europe Ltd and MedSIR today announced the initiation of the REVERT study to investigate the clinical activity of Halaven<sup>®</sup> (eribulin) in MBC.<sup>1</sup> The trial aims to investigate the efficacy of a combined endocrine-chemotherapy therapeutic approach in MBC.<sup>1</sup>

MBC currently remains incurable for the majority of those affected, with a five-year survival rate of just 25 percent.<sup>2</sup> For the last decade aromatase inhibitors (a type of endocrine therapy) have been shown to be efficacious for post-menopausal ER-positive/HER2-negative MBC patients.<sup>3</sup> Clinical trial data showed that they have a good overall response rate (ORR) and can increase progression-free survival (PFS).<sup>4</sup> However, the majority of these patients eventually experience resistance to endocrine therapies, speeding up the progression of metastasis.<sup>5</sup>

The primary endpoint of the REVERT study is the overall response rate (ORR) in patients treated with the combination of eribulin and endocrine therapy, defined as the proportion of patients with complete response or partial response based on the local investigator's assessment, according to the Response Evaluation Criteria in Solid Tumours (RECIST V.1.11) criteria. The secondary endpoints of the study include investigating progression-free survival (PFS), duration of response, clinical benefit rate, overall survival (OS), and the change in maximum tumour shrinkage in response to eribulin in monotherapy and combined with endocrine therapy as well as ORR in response to eribulin monotherapy only.<sup>1</sup>

"Endocrine resistance is one of the most important clinical issues within the treatment landscape of metastatic breast cancer," commented Dr Javier Cortés, Head of Breast Cancer Programme at the IOB Institute of Oncology in Madrid & Barcelona, Spain. "The REVERT study will look at the possibility of a combined endocrine-chemotherapy therapeutic approach, which could benefit a significant number of patients across Europe."

"The REVERT Study has the potential to unlock some interesting properties that we did not previously know about eribulin," said Maria Campos, Strategy Director in MedSIR. "We hope that the findings from this trial will ultimately benefit many patients across Europe who currently are faced with such treatment challenges."

Eribulin is a single chemotherapeutic agent, currently indicated for the treatment of adult patients with locally advanced breast cancer or MBC who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.<sup>6</sup> Working as a microtubule-dynamics inhibitor, which binds to a limited number of high affinity sites on the growing positive ends of microtubules to inhibit growth,<sup>7</sup> eribulin is the only single cytotoxic chemotherapeutic agent that has demonstrated a significant prolongation in OS in MBC patients previously treated with an anthracycline/taxane.<sup>8,9</sup>

The most reported adverse events related to eribulin (reported in ≥10% of patients) include neutropenia, leukopenia, anaemia, decreased appetite, peripheral neuropathy, headache, dyspnoea, cough, nausea, constipation, diarrhoea, vomiting, alopecia, arthralgia and myalgia, back pain, pain in extremity, fatigue, pyrexia and weight loss.<sup>6</sup>

The first data readout from the REVERT study is estimated to be in late 2021.<sup>1</sup>

## Notes to Editors

### About metastatic breast cancer

Metastatic breast cancer is an advanced stage of the disease that occurs when cancer spreads beyond the breast to other parts of the body. Each year, approximately 138,000 women in Europe will die from breast cancer.<sup>10</sup> It is estimated that approximately 30% of breast cancer patients will develop metastatic breast cancer and approximately 6% of women will have metastatic disease at the time of diagnosis.<sup>11</sup> Of these women, only an estimated one in four is expected to survive beyond five years.<sup>2</sup>

### About Halaven® (eribulin)

Eribulin is a chemotherapy indicated by the European Medicines Agency for the treatment of adult patients with:

- Locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.<sup>6</sup>
- Unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.<sup>6</sup>

Discovered and developed by Eisai, eribulin is a microtubule-dynamics inhibitor which binds to a limited number of high affinity sites on the growing positive ends of microtubules to inhibit their growth.<sup>7</sup>

Eribulin is licensed for the treatment of advanced breast cancer based on results from two pivotal Phase III studies, The EMBRACE trial (Study 305) and Study 301. The EMBRACE trial included 762 women with locally recurrent or metastatic breast cancer and received between two and five previous chemotherapy regimens (two or more for advanced disease), including an anthracycline and a taxane, unless contraindicated. Overall survival was significantly improved in women assigned to eribulin (n=508) (median 13.2 months) compared with treatment of physician's choice (TPC) (n=254) (median 10.5 months; HR 0.81, 95% CI: 0.68–0.96; nominal p=0.014).<sup>6</sup> The most common (reported in >50%) adverse events in both groups were asthenia or fatigue (270 [54%] of 503 patients on eribulin and 98 [40%] of 247 patients on TPC at all grades) and neutropenia (260 [52%] patients receiving eribulin and 73 [30%] of those on TPC at all grades). Peripheral neuropathy was the most common adverse event leading to discontinuation from eribulin, occurring in 24 (5%) of 503 patients.<sup>8</sup>

Study 301 included 1,102 women with locally advanced or metastatic breast cancer in earlier line metastatic breast cancer, and demonstrated a trend favouring improved overall survival with eribulin compared to capecitabine in the intent to treat population, although the improvement was not statistically significant. Women treated with eribulin (n=554) had a median overall survival of 15.9 months (HR 0.88; 95% CI: 0.77–1.00; p=0.056) versus 14.5 months with capecitabine (n=548). The trial did not meet the pre-specified endpoint for median progression-free survival, with 4.1 and 4.2 months for eribulin and capecitabine, respectively (HR 1.08; 95% CI: 0.93–1.25; p=0.30). Adverse events in Study 301 were consistent with the known profile of both drugs and most of them were grade 1 or 2.<sup>12</sup>

### About Eisai

Eisai is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realise our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of oncology and neurology.

For further information on Eisai, please visit [www.eisai.com](http://www.eisai.com).

### About MedSIR

Founded in 2012 and with offices in Europe and US, MedSIR is committed to bringing innovative and cutting-edge cancer treatments to patients around the world.

MedSIR identifies strategies for oncological research and transform them into coherent and relevant clinical trials. Their international network of oncology experts understands current disease treatment complexities, anticipating the evolution and future changes in this dynamic field, and enabling for the design of clinical trials that will help not only the patients of today but also cancer patients tomorrow.

The MedSIR approach is both flexible and agile, allowing us to adapt our trials to the changing world of global oncology, preserving scientific integrity while delivering meaningful data on time. We have been responsible for developing over 20 international projects ranging from small proof-of-concept studies all the way to randomized phase 3 studies in over 11 countries and collaborating with more than 150 brilliant and talented investigators.

Please, visit us at [www.medsir.org](http://www.medsir.org).

## References

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