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## **CAPRELSA? (vandetanib) Receives Positive CHMP Opinion in the European Union for Treating Advanced Medullary Thyroid Cancer**

18 (ots/PRNewswire) -

AstraZeneca today announced that the Marketing Authorisation Application for CAPRELSA (vandetanib) received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. The proposed indication also states that for patients in whom Rearranged during Transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decisions.

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Clinical data show that patients benefit from treatment with CAPRELSA regardless of their RET status. In line with the CHMP's requirement, AstraZeneca will conduct a further study to generate additional data to confirm the benefits in patients who are RET negative.

The opinion was reached after the CHMP reviewed data from the Phase III CAPRELSA clinical trial programme, including the ZETA study. This study, a double-blind trial of 331 patients with advanced MTC that has progressed and spread to other parts of the body, showed a 54 per cent reduction in risk for disease progression compared to placebo.

In Europe, thyroid cancer affects approximately 48,000 people annually with an estimated mortality rate of 6,300 of which 5 to 10 per cent have medullary thyroid cancer. Advanced MTC has a poor prognosis and clinical outcomes for patients with this disease have not changed substantially in the past 20 years. Currently there are no approved therapies in Europe for this advanced stage of the disease.

The CHMP positive opinion for CAPRELSA will now be reviewed by the European Commission, which has the authority to approve medicines for use in the European Union. CAPRELSA was approved by the US Food and Drug Administration in April 2011 and is also under review in Canada and Switzerland.

CAPRELSA is an oral kinase inhibitor using two distinctive mechanisms of action - blocking the blood supply to the tumour by slowing the VEGF (vascular endothelial growth factor receptor) pathway and reducing the growth and survival of the tumour through EGFR (epidermal growth factor receptor) and RET (rearranged during transfection) pathways.

### NOTES TO EDITORS

#### CHMP opinion

A positive opinion has been granted by the CHMP regarding the following proposed indication:

'Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. For patients in whom Rearranged during Transfection (RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision (see important information in sections 4.4 and 5.1 in the Product Information).'

#### About medullary thyroid cancer

There are four types of thyroid cancer. Papillary and follicular are the most common with anaplastic and medullary being less common. Medullary thyroid cancer (MTC) differs from papillary and follicular types as it does not arise from the thyroid cells themselves, but rather from the specialised "C-cells" that are in between the thyroid cells. These C-cells are found mostly in the upper and middle parts of the thyroid and produce a substance called calcitonin which can serve as a marker for the progression of MTC.

Approximately 25 per cent of all MTC cases are genetic in nature, caused by a mutation in the RET proto-oncogene [[http://en.wikipedia.org/wiki/RET\\_proto-oncogene](http://en.wikipedia.org/wiki/RET_proto-oncogene)]. This is referred to as familial MTC and is likely to be diagnosed and treated in patients earlier. When there is no family history, MTC occurs by itself and is referred to as sporadic MTC. Patients who develop sporadic MTC tend to be older and present with more advanced stages of cancer at the time of initial diagnosis, compared to those with family history.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: <http://www.astrazeneca.com>

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#### Contact:

CONTACTS: Media Enquiries: Esra Erkal-Paler, +44-20-7604-8030 (24 hours); Abigail Baron, +44-20-7604-8034 (24 hours); Isabelle Jouin, +44-20-7604-8031 (24 hours). Investor Enquiries UK: Karl Hård, +44-20-7604-8123, mob: +44-7789-654364; Nicklas Westerholm, +44-20-7604-8124, mob: +44-7585-404950. Investor Enquiries US: Ed Seage, +1-302-886-4065, mob: +1-302-373-1361; Jorgen Winroth, +1-212-579-0506, mob: +1-917-612-4043.

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