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***Herzuma*[®] (trastuzumab), a biosimilar for the treatment of breast cancer, now available in Europe**

- *Herzuma, biosimilar trastuzumab, that is delivered intravenously, is now available in Europe for the treatment of patients with early breast cancer, metastatic breast cancer, or metastatic gastric cancer whose tumours have either HER2 overexpression or HER2 gene amplification.^{1,2}*
- *Herzuma is the third biosimilar to be marketed and distributed by the Mundipharma network in Europe, which is a testament to Mundipharma's leadership and expertise in biosimilars.*
- *Overall, biosimilars like Herzuma have the potential to save European and US healthcare systems approximately €50 billion to €100 billion before 2020.³*

Cambridge, UK, 2 May 2018 – The Mundipharma global network of independent associated companies today announced that Herzuma, biosimilar trastuzumab, is now available in Europe, with the product now launched in both the UK and Germany and further launches across European countries anticipated in the coming months. The Mundipharma network has exclusive distribution rights to Herzuma in the UK, Germany, Italy, Ireland, Belgium, Luxembourg and the Netherlands.

Richard Trollope, Head of Oncology and Biosimilars at Mundipharma International Limited, said: “Building on our partnership with Celltrion Healthcare, we are pleased to announce that biosimilar trastuzumab is now available in Europe with national launches commencing in both the UK and Germany. The availability of biosimilar trastuzumab will provide an alternative treatment option to the thousands of eligible patients across Europe with early breast cancer, metastatic breast cancer or metastatic gastric cancer.”

Herzuma, a biosimilar of i.v. Herceptin[®], was granted marketing authorisation on 9th February 2018 for the treatment of patients with early breast cancer, metastatic breast cancer or metastatic gastric cancer whose tumours have either HER2 overexpression or HER2 gene amplification, following positive opinion and recommendation for approval by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in December 2017. Biosimilar trastuzumab has the potential to make significant cost savings for healthcare organisations, releasing healthcare resource for other innovative medicines.³

Alberto Martinez, President and CEO, Mundipharma International Limited, said: “Mundipharma has a proven track record of launching biosimilars successfully in Europe, which is illustrated by Celltrion Healthcare entrusting us once again with the launch of biosimilar trastuzumab across key European markets. As biosimilar trastuzumab continues to launch in additional countries, we look forward to assisting healthcare economies across Europe wanting to deliver better value to patients.”

Herzuma is the third biosimilar to be marketed and distributed by the Mundipharma network in Europe, having launched Remsima® (infliximab), the first biosimilar monoclonal antibody, in 2015, and Truxima® (rituximab), the first biosimilar monoclonal antibody for the treatment of cancer, in 2017.

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Notes to editors:

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies, including Napp Pharmaceuticals Ltd in the UK, was founded in 1956 by doctors and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information please visit: www.mundipharma.com.

About trastuzumab

Trastuzumab is a monoclonal antibody designed to target the HER2 receptor. When it binds to the receptor, trastuzumab reduces HER2 signalling that otherwise increases tumour stimulation, and also enables the immune system to target the cancerous tumour.⁴

It is administered on its own as monotherapy, as well as in combination with or following standard chemotherapy. Trastuzumab has changed the prognosis of patients with HER2 positive breast cancer, both in advanced and early stage disease.⁵

About biosimilars

Biosimilar is a term used to describe officially approved subsequent versions of biopharmaceutical medicines that are made available by a different company following patent and exclusivity expiry on the original product. Biosimilars are classed as biologic medical products, which mean they contain an active drug substance that is comprised of, or derived from, a living organism. Biosimilars are strictly regulated and need to demonstrate comparability to the previously approved reference product via a thorough development programme including quality assurance, pre-clinical and clinical programmes.

®Herzuma is a registered trade mark of Celltrion, Inc. and is used under licence.

®Herceptin is a registered trade mark of Genentech, Inc.

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References

¹Herceptin (trastuzumab) Summary of Product Characteristics. Available online at: <https://www.medicines.org.uk/emc/medicine/3567>. Accessed April 2018

²Herzuma (trastuzumab) Summary of Product Characteristics. Available at: https://ec.europa.eu/health/documents/community-register/2018/20180209139854/anx_139854_en.pdf - Accessed April 2018

³ Delivering on the Potential of Biosimilar Medicines. March 2016. Available online at: <https://www.coursehero.com/file/20466083/IMS-Institute-Biosimilar-Brief-March-2016/>. Accessed April 2018

⁴ Gajria D, et al. HER2-amplified breast cancer: mechanisms of trastuzumab resistance and novel targeted therapies. *Expert Rev Anticancer ther.* 2011 Fe; 11 (2): 263-275

⁵Bartsch, R et al. Trastuzumab in the management of early and advanced stage breast cancer. *Biologics* 2007; 1(1): 19-31