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Mundipharma expands biosimilar portfolio with exclusive partnership deal across seven European countries for trastuzumab biosimilar, Herzuma®

- Exclusive distribution and marketing rights granted in seven European countries including Germany, Italy and UK
- Third biosimilar deal with Celltrion Healthcare cements Mundipharma's leadership position in the biosimilar market and is testament to Mundipharma's commercialization expertise
- Biosimilars are projected to save stretched European healthcare systems between €11.8bn and €33.4bn between 2007 and 2020[1]

Cambridge, UK, 19 March 2018 – The Mundipharma global network of independent associated companies today strengthened its partnership with biopharmaceutical company Celltrion Healthcare Hungary Kft, by securing exclusive distribution rights to its trastuzumab biosimilar, Herzuma® in seven EU markets including Germany, Italy and the UK.

Man Hoon Kim, President and CEO of Celltrion Healthcare commented, "*We are pleased to be partnering once again with Mundipharma on the commercialization of our trastuzumab biosimilar. They have a proven track record of launching biosimilars in Europe, working effectively across multiple healthcare systems and demonstrating local in-market expertise. This alliance enables us to continue to pursue our commitment to delivering effective and affordable medicines which benefit healthcare systems, healthcare professionals and patients.*"

Herzuma®, which is a biosimilar of the reference biologic i.v. Herceptin®, was granted marketing authorisation on 9th February 2018 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[2] for HER2-positive early breast cancer in the neo-adjuvant and adjuvant setting, metastatic breast cancer, and metastatic gastric cancer in adults[3]. Breast cancer remains the most prevalent form of cancer in women in Europe, affecting an estimated 362,000 women and causing around 92,000 deaths in 2012, with a five-year prevalence of over 1.4 million[4]. 15–20% of primary breast cancers are HER2-positive[5], which can be more aggressive than other types of breast cancer.

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Trastuzumab is recommended by European guidelines throughout the treatment pathway for HER2-positive breast cancer due to clinical benefit shown in a number of studies[6,7]. Gastric cancer lead to around 58,000 annual deaths across Europe in 2012[8] and studies have found that a range of 4.4% to 53.4%, with a mean of 17.9% of such cancers show increased levels of HER2[9].

Richard Trollope, Commercial Head of Oncology and Biosimilars at Mundipharma commented, "*We are delighted to strengthen our partnership with Celltrion Healthcare and add an important medicine to our already successful biosimilar commercial platform.*

"Celltrion Healthcare's decision to entrust us with a third biosimilar from their portfolio is testament to the insight and experience we have developed from successfully launching two previous monoclonal antibody biosimilars. With Remsima® (infliximab) we achieved market leading status in the majority of our markets, and we are already seeing strong market uptake with our newest biosimilar medicine Truxima® (rituximab) across those markets where we have distribution rights.

"We look forward to, once again, using our expertise in biosimilars to navigate the complex European environment and enable Herzuma® to help healthcare economies deliver better value to patients."

-Ends-

Notes to editors:

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, nonclinical and clinical data.

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.[10]

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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.[11]

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies 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

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