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Mundipharma announces exclusive license and supply agreement with Prestige Biopharma for Tuznue® (HD201)

- The Mundipharma network has acquired the right to launch Tuznue®, a trastuzumab biosimilar treatment, from Prestige BioPharma, in selected European markets
- This long-term partnership reinforces Mundipharma's leadership in the biosimilars marketplace
- With agreements in place with three companies to deliver biosimilars, Mundipharma is fast becoming the partner of choice in Europe for companies seeking local commercial expertise

Cambridge, UK, 2 July 2019 – Mundipharma has entered into an exclusive license and supply agreement with Prestige Biopharma for Tuznue, a trastuzumab biosimilar treatment. The agreement will enable the Mundipharma network to distribute, market and sell Tuznue in selected European countries following marketing authorisation, including France, Spain, Norway, Sweden, Denmark, Finland, Portugal, Switzerland and Austria.

Tuznue is a trastuzumab biosimilar treatment to Roche's Herceptin® which is used to treat patients with HER2-overexpressing breast cancer, HER2-overexpressing metastatic gastric cancer or gastroesophageal junction adenocarcinoma.[1] The European Medicines Agency (EMA) recently accepted a Marketing Authorisation Application for Tuznue.[2] This application was based on positive top-line results from global clinical trials of Tuznue, which confirmed that it is biosimilar to Herceptin in terms of clinical response and pharmacokinetics, in addition to having a comparable safety profile to the range previously observed in other trastuzumab biosimilar trials.[3]

Alberto Martinez, CEO, Mundipharma Europe, commented, "Across Europe, we now partner with three different companies to deliver market leading biosimilar medicines to patients, in addition to our own in-house development, regulatory, IP and commercialisation capabilities.

Today's announcement cements our position as the biosimilar partner of choice for companies looking to bring their biosimilar medicines to the European market.

By partnering with Prestige, we can continue to move medicine forward. Using our collective expertise, Prestige in development, and us in commercialisation we can continue to reduce the

financial burden for even more healthcare systems, while widening access to this important treatment for cancer patients."

Prestige Biopharma CEO, Dr Lisa S. Park commented, "We are very pleased to partner with Mundipharma to commercialise our lead biosimilar in the selected European markets. This partnership is an important milestone for Prestige BioPharma, which will further increase the global availability of our Trastuzumab biosimilar so that more patients can benefit from its quality and accessibility. We envisage the partnership with Mundipharma to grow strong to encompass more programs in the future"

Prestige BioPharma is a Singapore-based biopharmaceutical company focusing on the development of biosimilars and new antibody therapeutics and has several additional biosimilars currently in development.

Notes to editors:

About Tuznue®

Tuznue, trastuzumab biosimilar treatment to Roche's Herceptin®, is a monoclonal antibody that interferes with the human epidermal growth factor receptor 2 (HER2). In some cancers, notably certain types of breast cancer, HER2 is over-expressed, and causes cancer cells to reproduce uncontrollably. A biosimilar is defined by the EMA as a biological medicine highly similar to another already approved biological medicine (the reference medicine). Approved biosimilars have been through rigorous testing to show that they have no clinically meaningful differences from their reference medicines. They are also manufactured to the same meticulous standards to ensure consistent quality, often at a significantly reduced price to healthcare systems.

About HER2-overexpressing breast cancer and gastric cancer

The introduction of Herceptin (trastuzumab) revolutionised the treatment of breast cancer. Prior to its introduction there were few treatment options available to women with HER2-overexpressing breast cancer. HER2-overexpressing means that a protein called HER2 is produced in large quantities, making the cancer cells grow quickly. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.[1]

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About the Mundipharma network

Mundipharma is a network of privately-owned independent associated companies whose purpose is to move medicine forward.

With a high performing and learning organisation that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

About Prestige BioPharma

Prestige BioPharma is a Singapore-based biopharmaceutical company focusing on the development of biosimilars and new antibody therapeutics. Its lead program, HD201 Trastuzumab biosimilar, is under Phase 3 clinical development and has been filed with EMA while USFDA filing is in progress. Prestige BioPharma´s next products in line include a Bevacizumab biosimilar (HD204) in Phase 3, an Adalimumab biosimilar (PBP1502) and an innovative anti-PAUF mAb (PBP1510) for the treatment of pancreatic cancer ready for clinical development. Manufacturing facilities for global commercial supply are located in Osong, South Korea. For more information, please visit www.prestigebiopharma.com or contact:

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