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ASIA EDITION

FDA approves arthritis drug by Samsung Bioepis

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Samsung Bioepis secures third FDA approval in the past seven months

Samsung Bioepis becomes the first company to receive FDA approvals for biosimilars referencing all three first-generation anti-TNF medicines.

Samsung Bioepis Co., Ltd. has announced that the US Food and Drug Administration (FDA) has approved HADLIMA™ (adalimumab-bwwd), a biosimilar referencing HUMIRA® i (adalimumab), for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis. Please see below the full indications and Boxed Warning for HADLIMA™.

HADLIMA™ is Samsung Bioepis' third anti-TNF biosimilar approved for marketing in the United States (US). HADLIMA™ is also Samsung Bioepis' fourth biosimilar approved in the US, following the approvals for RENFLEXIS™ (infliximab-abda) in April 2017, ONTRUZANT™ (trastuzumab-dttb) in January 2019 and ETICOVO™ (etanercept-ykro) in April 2019.

HADLIMA™ was developed by Samsung Bioepis, and will be commercialized in the US by Merck, also known as MSD outside of the US and Canada. HADLIMA™ is expected to launch in the US after June 30, 2023, in accordance with a licensing agreement signed with AbbVie Inc.

Hee Kyung Kim, Senior Vice President and Head of Regulatory Affairs, Samsung Bioepis said, "With the approval of HADLIMA, we are proud to have three anti-TNF biosimilars approved in the US. We believe the US healthcare system can benefit from biosimilars, as they could play an important role in broadening access to treatment options for patients with autoimmune conditions. We remain committed to advancing our strong pipeline of biosimilar candidates, so that more patients and healthcare systems can benefit from biosimilars."

In addition to the US, Samsung Bioepis' adalimumab biosimilar has been approved for marketing in over 30 countries, including 28 European Union (EU) member states, Canada, Australia and Korea.

The FDA approval was based on data derived from a randomized, double-blind 52-week Phase 3 study, in which 544 patients with moderate to severe rheumatoid arthritis despite methotrexate (MTX) therapy were randomized to receive either

HADLIMA™ or the adalimumab reference product (ADL).