

Mylan, Fujifilm receive European marketing authorization for Hulio Biosimilar

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Hulio is a biosimilar to AbbVie's Humira, which is the world's best-selling biologic medication



Mylan and Fujifilm Kyowa Kirin Biologics recently announced that the European Commission (EC) has granted marketing authorization for Hulio (Product Code: FKB327), a biosimilar to AbbVie's Humira® (adalimumab), for all indications.

The authorization follows the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP), which concluded that the development program including analytical, functional, clinical and immunogenic

ity data demonstrated biosimilarity with the reference product, Humira. The EC approval of Hulio applies to all 28 European Union (EU) member countries and European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein. Mylan plans to launch Hulio across various markets in Europe on or after Oct. 16.

Mylan and Fujifilm Kyowa Kirin Biologics partnered earlier this year. Fujifilm Kyowa Kirin Biologics has a nonexclusive royalty bearing license with AbbVie (Mylan has a sublicense) for the use and sale of Hulio in European countries.

Mylan President Rajiv Malik commented, "We're very pleased with the decision of the European Commission to grant marketing authorization for Hulio. This is the fourth product that Mylan will be bringing to market in the area of complex generics and biosimilars, and we're proud to be a leader in the market formation. We've made great progress with Fujifilm Kyowa Kirin Biologics and look forward to continuing this important collaboration."

"We are delighted that Hulio has received approval from the European Commission," said Dr. Yoshifumi Torii, Fujifilm Kyowa Kirin Biologics President and CEO. "The EC's approval of Hulio marks a significant milestone. In cooperating with Mylan, we continue to commit all efforts to bring high quality and affordable biosimilars to patients throughout European countries."

Mylan Europe President Jacek Glinka added, "Biosimilars represent a huge opportunity in Europe to drive better patient access through high quality, value medications that support healthcare systems across the region to deliver ongoing excellent care in the face of aging populations and increasingly stretched resources."

Humira is the world's best-selling biologic medication. It had brand sales of approximately \$4.4 billion in Europe for the 12

months ending June 30, 2018, according to IQVIA.