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Mylan, Fujifilm Kyowa Kirin Biologics declares positive CHMP opinion for Hulio

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CHMP has recommended approval of Hulio for multiple chronic inflammatory diseases in adults, including Rheumatoid arthritis, Ankylosing spondylitis, Axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,Psoriatic arthritis, Psoriasis, Hidradenitis suppurativa, Crohn's disease, Ulcerative colitis, Uveitis

Mylan N.V. and Fujifilm Kyowa Kirin Biologics Co., Ltd. announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the Marketing Authorization Application of HulioTM, the companies' biosimilar to Humira® (adalimumab), for all indications.

The decision of the European Commission (EC) on the approval is expected in October 2018, which would grant marketing authorization in the 28 European Union (EU) member countries and European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.

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CHMP also recommended approval of Hulio for the treatment of pediatric inflammatory diseases, including polyarticular juvenile idiopathic arthritis (age 2 and older), enthesitis-related arthritis (age 6 and older), plaque psoriasis (age 4 and older), Crohn's disease (age 6 and older), hidradenitis suppurativa (age 12 and older) and uveitis (age 2 and older).

Data submitted as part of the Marketing Authorization Application included similarity assessment in analytical testing, preclinical and clinical studies that demonstrated biosimilarity to the adalimumab reference product, Humira.

The Phase III clinical study, ARABESC, conducted by Fujifilm Kyowa Kirin Biologics, demonstrated no clinically meaningful differences in terms of safety, efficacy and immunogenicity compared with the reference product, Humira, in rheumatoid arthritis patients.

Fujifilm Kyowa Kirin Biologics granted an exclusive license to Mylan for commercializing biosimilar adalimumab in Europe.