

Centus Biotherapeutics Receives European Marketing Authorization for Equidacent[®], Biosimilar Avastin[®]

LONDON and TOKYO, Sep. 29th, 2020— Centus Biotherapeutics Ltd., a joint venture between Fujifilm Kyowa Kirin Biologics Co., Ltd. and AstraZeneca, today announced that the European Commission (EC) has granted the marketing authorization for Equidacent[®] (Product Code: FKB238), the company's biosimilar to Avastin[®] (bevacizumab).

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 immunogenicity data demonstrated biosimilarity with the reference product, Avastin[®].

The EC approval of Equidacent[®] applies to 27 European Union (EU) member states, the United Kingdom (UK) and the European Economic Area (EEA) member states of Norway, Iceland, and Liechtenstein.

Equidacent[®] is indicated for the following indications:

- metastatic carcinoma of the colon or rectum
- metastatic breast cancer
- unresectable advanced, metastatic, or recurrent non-small cell lung cancer
- advanced and/or metastatic renal cell cancer
- epithelial ovarian, fallopian tube, or primary peritoneal cancer
- persistent, recurrent, or metastatic carcinoma of the cervix

Fujifilm Kyowa Kirin Biologics President and CEO Atsushi Matsumoto, Ph.D. commented, "We are proud that Centus received the approval of Equidacent[®] from the European Commission. This demonstrates that Fujifilm Kyowa Kirin Biologics successfully utilized its deep scientific expertise needed to develop biosimilars in collaboration with AstraZeneca."

Centus was established in 2015 as a joint venture between Fujifilm Kyowa Kirin Biologics and AstraZeneca. Fujifilm Kyowa Kirin Biologics has granted an exclusive license to Centus for the development, manufacture, and commercialization of Equidacent[®] on a worldwide basis. Centus has been proceeding with clinical development of Equidacent[®].

Data submitted to obtain the marketing authorization for Equidacent[®] included similarity assessment in analytical testing, preclinical and clinical studies that demonstrated biosimilarity to the bevacizumab reference product, Avastin[®]. The phase 3 clinical study, AVANA, conducted by Centus, demonstrated no clinically meaningful differences in terms of safety, efficacy, and immunogenicity compared with the reference product, Avastin[®], in non-small cell lung cancer patients.

About Bevacizumab

Bevacizumab is a recombinant humanized monoclonal antibody that blocks angiogenesis by inhibiting vascular endothelial growth factor A (VEGF-A). It reduces growth and metastasis of several solid tumors.

About Centus

Centus Biotherapeutics (Centus) founded in 2015 is a joint venture between AstraZeneca, a global pharmaceutical leader, and Fujifilm Kyowa Kirin Biologics, a Japanese biopharmaceutical company focused on biosimilar development.

With the unique coupling of world class biologics expertise, global commercial infrastructure and deep biosimilar development experience, Centus is well positioned to win the trust of doctors and serve the needs of patients worldwide.

For more information please visit: <https://www.centusbiotherapeutics.com>

About Fujifilm Kyowa Kirin Biologics

Fujifilm Kyowa Kirin Biologics was established by FUJIFILM Corporation (President: Kenji Sueno; “Fujifilm”) and Kyowa Kirin Co., Ltd. (President and CEO: Masashi Miyamoto, “Kyowa Kirin”) on March 27, 2012 as a company for developing, manufacturing, and marketing biosimilars. Its pipeline includes Equidacent[®] and Hulio[®], an adalimumab biosimilar (Product Code: FKB327), a drug to treat a range of inflammatory diseases.

By merging the technologies in advanced production, quality control, and analysis which Fujifilm has developed over many years through its photographic film business, with the proprietary technologies and know-how which Kyowa Kirin has accumulated through its biopharmaceutical R&D and manufacturing, Fujifilm Kyowa Kirin Biologics creates revolutionary production processes and reduces costs for the production of biosimilars. Through this partnership, the company will develop and manufacture reliable, high quality, and cost-competitive biosimilar products, and will commercialize these products in a timely manner. With this strategy, Fujifilm Kyowa Kirin Biologics aims to hold a leading position in the expanding biosimilar market.

You can learn more about the business at: fujifilmkyowakirin-biologics.com

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