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ASIA EDITION

Samsung BioLogics Receives the first FDA DP approval

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Samsung BioLogics has 16 total global approvals for manufacturing Drug Substance in Plant 1 and 2



Samsung BioLogics announced that it has been licensed by the US FDA to manufacture a monoclonal antibody Drug Product at its first plant. Samsung BioLogics Co., a biopharmaceutical business arm of South Korea's top conglomerate Samsung Group. The company did not disclose the name of the product.

Samsung BioLogics has 16 total global approvals for manufacturing Drug Substance in Plant 1 and 2, and Drug Products in Plant 1 including 2 EMA DP approvals and one PMDA DP approval. Samsung BioLogics is expecting additional global Drug Substance and Drug Product approvals for both Plant 1 and Plant 2 during the second half of 2018.

TH Kim, CEO and President of Samsung BioLogics, said "Samsung BioLogics continues to prove that it possesses the capability to provide End-to-End service from cell line development to fill/finish DP service" and he added that "Samsung BioLogics will keep innovating ourselves to manufacture high quality biologics products for clients all over the world in timely manner".