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DHA approves clinical trial application for JHL's new biosimilar

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Dornase alfa is sold under the brand name Pulmozyme in the European Union (EU) and in the United States (US).

Dutch Healthcare Authority (DHA) has approved a Clinical Trial Application for JHL Biotech's dornase alfa biosimilar, JHL1922, to improve pulmonary function of cystic fibrosis patients. The Phase I clinical trial will be conducted in the Netherlands.

JHL1922 would provide patients with an affordable alternative to dornase alfa, which is indicated for daily administration to improve pulmonary function in cystic fibrosis patients in conjunction with other standard therapies. Dornase alfa is sold under the brand name Pulmozyme in the European Union (EU) and in the United States (US).

It is a recombinant human deoxyribonuclease I (rhDNase I), an enzyme which selectively cleaves deoxyribonucleic acid (DNA). Dornase alfa was first approved for treatment of cystic fibrosis in the U.S. in 1993 and in Europe in 1994.

JHL has several biosimilars currently in or expected to be in clinical trials including Rituximab biosimilar, JHL1101, to treat rheumatoid arthritis; Trastuzumab biosimilar, JHL1188, to treat breast cancer; and Bevacizumab biosimilar, JHL1149 to treat metastatic colorectal cancer, lung cancer, and ovarian cancer.