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FDA approves PARIâ??s innovative eFlow technology to treat COPD

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LONHALA MAGNAIR is the first nebulized long-acting muscarinic antagonist (LAMA) approved for the treatment of COPD in the U.S



PARI Pharma announces the approval of its first innovative eFlow closed system nebulizer Magnair together with Sunovion's Lonhala (glycopyrrolate) Inhalation Solution.

MAGNAIR, designed, optimized, and developed by PARI Pharma, is intended only for use with LONHALA (glycopyrrolate) Inhalation Solution vials in patients with COPD.

The drug/device combination product received FDA approval on December 5th, 2017 under a New Drug Application (NDA).

MAGNAIR is the first product to be commercialized using PARI Pharma's innovative eFlow closed system nebulizer technology which does not have a traditional open medication reservoir in which patients manually transfer the liquid drug product from a vial.

MAGNAIR features a proprietary blow-fill-seal ampule which is inserted into the cap of MAGNAIR and pierced open once the cap of the MAGNAIR handset is closed, without the need for a manual filling step.

This feature is designed to reduce risk of spilling of the medication when the vial is emptied. As with all eFlow Technology nebulizers, MAGNAIR allows the patient to breathe naturally without any special breathing technique. The patient inhales and exhales as they normally do at rest.

"With the approval of LONHALA MAGNAIR for COPD, we are bringing a new advancement in nebulizers that are designed to be efficient, silent and fast to people with COPD. It is great to see our technology addressing an unmet medical need for a nebulized LAMA," states Dr. Martin Knoch, President of PARI Pharma.

"MAGNAIR is a great example of the flexibility of development and optimization using the eFlow Technology platform," added Geoff Hunziker, President of PARI Pharma's US sister company eFlow LLC.

"Sunovion is pleased that the FDA has approved LONHALA MAGNAIR as the first nebulized long-acting muscarinic antagonist treatment option for people in the U.S. living with COPD," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion.

According to him, LONHALA MAGNAIR is an important advancement for patients who may prefer nebulized medications and a therapy that fits into their everyday lives.

LONHALA MAGNAIR is approved for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.