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Novartis gets FDA filing acceptance of Xolair® to treat nasal polyps

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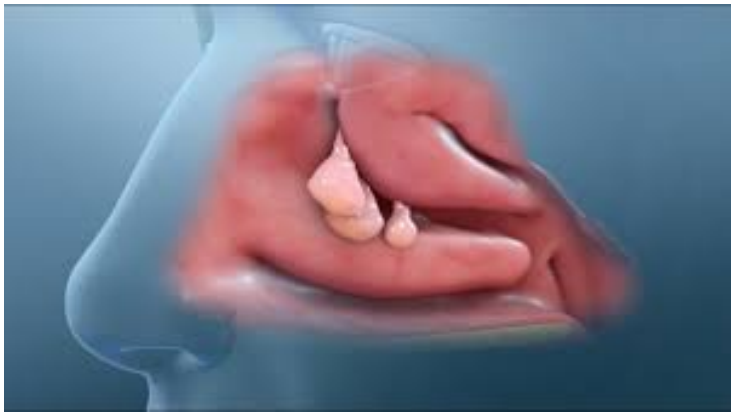

Novartis announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Xolair® (omalizumab) for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to intranasal corticosteroids. If approved, Xolair would become the first antibody to help reduce the size of nasal polyps and help improve symptoms through targeting and blocking immunoglobulin E (IgE). The FDA is expected to make a decision on approval for this indication by Q3 2020.

"With millions of Americans living with this serious respiratory condition, there is a significant unmet need for additional treatment options for patients who do not respond to intranasal corticosteroids," said Victor Bultó, President, Novartis Pharmaceuticals Corporation. "The FDA's acceptance of this sBLA is an important step on our path to continually reimagining medicine and understanding the full potential of Xolair across allergic, respiratory and inflammatory conditions and associated comorbidities."

Xolair is an injectable biologic medicine designed to target and block IgE. Xolair is currently approved for the treatment of moderate to severe persistent allergic asthma in people six years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids, and for chronic idiopathic urticaria (CIU) in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. In the US, Novartis Pharmaceuticals Corporation and Genentech work together to develop and co-promote Xolair.

In November 2019, Novartis submitted to the European Medicines Agency a Type II variation application for Xolair for the treatment of nasal polyps. A decision is expected in 2020.