

MEDIA & INVESTOR RELEASE

Novartis provides update on FDA review of ofatumumab, a self-administered, targeted B-cell therapy for patients with relapsing multiple sclerosis

Basel, June 2, 2020 — Novartis today announced that it has received notice from the US Food and Drug Administration (FDA) that the agency has extended its review of the Supplemental Biologics License Application (sBLA) for ofatumumab (OMB 157), a self-administered, targeted B-cell therapy for patients with relapsing multiple sclerosis. Regulatory action is now expected in September 2020.

“Novartis will continue to work with the FDA to complete the review as soon as possible,” said Marie-France Tschudin, President, Novartis Pharmaceuticals. “We are well prepared and ready to launch ofatumumab upon approval. We are committed to the MS community and look forward to bringing this important advancement to patients with MS.”

Additional regulatory filings are currently underway and regulatory approval for ofatumumab in Europe is expected by Q2 2021.

About ofatumumab

Ofatumumab (OMB 157) is a fully human anti-CD20 monoclonal antibody (mAb) in development for RMS that is self-administered by a once-monthly injection, delivered subcutaneously^{1,2,7}. As shown in preclinical studies, ofatumumab is thought to work by binding to a distinct epitope on the CD20 molecule inducing potent B-cell lysis and depletion³. The selective mechanism of action and subcutaneous administration of ofatumumab allows precise delivery to the lymph nodes, where B-cell depletion in MS is needed, and may preserve the B-cells in the spleen, as shown in preclinical studies⁴. Once-monthly dosing of ofatumumab also allows fast repletion of B-cells and offers more flexibility⁵. Ofatumumab was originated by Genmab and licensed to GlaxoSmithKline; Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015⁶.

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About Novartis

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