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. 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 depletion. 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 studies. Once-monthly dosing of ofatumumab also allows fast repletion of B-cells and offers more flexibility. Ofatumumab was originated by Genmab and licensed to GlaxoSmithKline; Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015.

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guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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