Novartis announces Complete Response Resubmission for inclisiran New Drug Application " >

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Novartis today announced the Complete Response resubmission to the US Food and Drug Administration (FDA) for the inclisiran New Drug Application (NDA). Novartis is listing its own site in Schaftenau, Austria, as the manufacturing location for the final finished product within the resubmission.

- The inclisiran Complete Response resubmission addresses the FDA Complete Response Letter (CRL) issued in December 2020, stating unresolved facility inspection-related conditions at a third-party manufacturing facility. The FDA did not raise any concerns related to the efficacy or safety of inclisiran.
- The transfer of the manufacturing of inclisiran to the Novartis-owned facility at Schaftenau, Austria, was planned and initiated in 2020, prior to the receipt of the CRL.

Novartis will provide an update after the FDA has determined that the response resubmission is complete.

Disclaimer:

This investor update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this media update 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, payor 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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

application

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