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FDA accelerates review of Novartis STAMP inhibitor asciminib (ABL001) for patients with chronic myeloid leukemia (CML) >

Aug 25, 2021

Novartis today announced that the US Food and Drug Administration (FDA) accepted and granted Priority Review to the company’s New Drug Application (NDA) for asciminib (ABL001) in chronic myeloid leukemia (CML), following its submission under the FDA's Real-Time Oncology Review (RTOR) program. Priority Review is granted to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions, as determined by the FDA. This designation could shorten the FDA review period to eight months compared to the 12 months under Standard Review.

- Priority Review granted based on positive data from the pivotal, Phase III ASCEMBL trial, where asciminib was compared to Bosulif® (bosutinib)* in patients with Philadelphia chromosome-positive CML in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine-kinase inhibitors (TKIs), and data from a Phase I trial that included patients with Ph+ CML-CP harboring the T315I mutation.
- Despite available treatments, many patients with CML remain at risk of disease progression, and sequential therapy with currently available TKIs may be associated with increased resistance and/or intolerance.
- Asciminib, a novel investigational therapy specifically targeting the ABL myristoyl pocket – also known as a STAMP inhibitor –, is in development across multiple treatment lines for CML.

Novartis has previously received Orphan Drug, Fast Track and two Breakthrough Therapy designations for asciminib. Breakthrough Therapy designations were granted for asciminib for the treatment of adult patients with Ph+ CML-CP previously treated with two or more TKIs, as well as adult patients with Ph+ CML-CP harboring the T315I mutation.

16. Mauro MJ, et al. Combination of Asciminib Plus Nilotinib (NIL) or Dasatinib (DAS) in Patients (PTS) with Chronic Myeloid Leukemia (CML): Results from a Phase 1 Study. EHA Library. 06/15/19; 267467; S884.
17. Cortes JE, et al. Combination Therapy Using Asciminib Plus Imatinib (IMA) in Patients (PTS) with Chronic Myeloid Leukemia (CML): Results from a Phase 1 Study. EHA Library. 06/15/19; 267466; S883.

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.

*Bosulif is a registered trademark of Pfizer.


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