# Novartis announces FDA approval for Jadenu™ to simplify treatment administration for patients with chronic iron overload

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- - Jadenu (deferasirox), a new formulation of Exjade (deferasirox), is the only once-daily oral tablet for iron chelation
- - Jadenu, taken with or without food, simplifies daily treatment administration for patients with chronic iron overload
- - Chronic iron overload is a serious condition that can affect people with sickle cell disease, thalassemia and myelodysplastic syndromes

EAST HANOVER, N.J., March 30, 2015 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved Jadenu™ (deferasirox) tablets, a new oral formulation of Exjade® (deferasirox) tablets for oral suspension, for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older, and chronic iron overload in non-transfusion-dependent thalassemia syndromes (NTDT) in patients 10 years of age and older. Jadenu is the only once-daily oral iron chelator that can be swallowed whole.

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Many patients with myelodysplastic syndromes, sickle cell disease or thalassemia need repeated blood transfusions and consequently, long-term daily chelation therapy. Jadenu oral tablets can be taken in a single step, with or without a light meal, simplifying administration of treatment for chronic iron overload. Exjade is a dispersible tablet that must be mixed in liquid and taken on an empty stomach. Jadenu is approved under accelerated approval based on a reduction of liver iron concentrations and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

"Novartis has had a long-term commitment to improving the lives of patients with chronic iron overload," said Bruno Strigini, President, Novartis Oncology. "Exjade transformed iron chelation therapy. We responded to feedback from patients and their physicians, and now Jadenu, by simplifying treatment administration, offers an important new option to help meet these patients' needs."

Chronic iron overload is a life-threatening cumulative toxicity that results from blood transfusions required to treat sickle cell disease, myelodysplastic syndromes, thalassemia and other conditions. Chronic iron overload also can occur in patients with NTDT due to increased iron absorption in the stomach and intestines[1,2]. If left untreated, chronic iron overload can damage the liver and heart[3,4].

Jadenu contains deferasirox, the same active ingredient that is in Exjade, a medicine that has been used by patients with chronic iron overload for almost 10 years. Exjade currently is the most-prescribed chelator in the United States[5].

"Jadenu is an exciting development for patients with chronic iron overload who have been eager for alternative treatment options," said Dr. Elliott Vichinsky, Director of Hematology and Oncology at the University of California, San Francisco (UCSF) Benioff Children's Hospital Oakland and Professor, UCSF School of Medicine. "Taking iron chelation therapy every day has sometimes been a challenge for them. The administration of Jadenu oral tablets once a day is simple."

Novartis has submitted additional regulatory applications for Jadenu in other countries worldwide.

Please visit http://www.pharma.us.novartis.com/info/products/brands/Jadenu.jsp for Jadenu full Prescribing Information.

About Jadenu (deferasirox) Tablets for Oral Use
Jadenu is an iron chelator indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients ages 2 years and older. Jadenu is also indicated to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT). These indications are approved under accelerated approval based on a reduction of iron levels in the liver (measured by liver iron concentration) and blood (measured by serum ferritin levels). Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. There are ongoing studies to find out how Jadenu works over a longer period of time.

It is not known if Jadenu is safe or effective when taken with other iron chelation therapy. Controlled clinical trials of deferasirox in patients with myelodysplastic syndromes (a serious blood disorder) and chronic iron overload due to blood transfusions have not been performed.

In the United States, Jadenu is available by prescription only.

Important Safety Information about Jadenu (deferasirox) Tablets for Oral Use
Jadenu contains deferasirox, the same active ingredient in Exjade (deferasirox) tablets for oral suspension. Deferasirox may cause serious kidney problems, liver problems, and bleeding in the stomach or intestines. In some cases, these problems were fatal. Kidney problems occurred particularly in patients with multiple medical conditions and those who were very ill because of their disease. Bleeding in the stomach or intestines occurred more often in elderly patients. Liver problems were more likely to happen in patients older than 55 years.

Jadenu should not be taken by patients with pre-existing severe kidney and liver problems; high-risk myelodysplastic syndromes; advanced cancer; low platelet counts; or an allergy to Jadenu.

Since deferasirox has been on the market, there have been reports of serious reactions, sometimes leading to death. Severe blood disorders (including neutropenia, agranulocytosis, worsening anemia and thrombocytopenia), serious allergic reactions (including swelling of the throat), severe skin reactions (including Stevens Johnson syndrome and erythema multiforme), decreased hearing and vision changes have been reported. These serious reactions and deaths have happened most often when deferasirox was taken by elderly patients. The most commonly reported side effects related to deferasirox in clinical trials were nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash.

Please see full Prescribing Information including Boxed WARNING available at www.jadenu.com.

About Exjade (deferasirox) Tablets for Oral Suspension
Exjade is an iron chelator indicated for the treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions (transfusional hemosiderosis) in patients ages 2 years and older. Exjade is

also indicated to treat patients ages 10 years and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT). In patients Exjade lowered the levels of iron in the blood (measured by serum ferritin levels) and liver (measured by liver iron concentration). An improvement in survival or disease symptoms resulting from reduction in elevated iron levels, however, has not been proven.

It is not known if deferasirox is safe or effective when taken with other iron chelation therapy. Controlled clinical trials of Exjade in patients with myelodysplastic syndromes (a serious blood disorder) and chronic iron overload due to blood transfusions have not been performed.

In the United States, Exjade is available by prescription only.

Important Safety Information about Exjade (deferasirox) Tablets for Oral Suspension
Exjade may cause serious kidney problems, liver problems, and bleeding in the stomach or intestines. In some cases, these problems were fatal. Kidney problems occurred particularly in patients with multiple medical conditions and those who were very ill because of their disease. Bleeding in the stomach or intestines occurred more often in elderly patients. Liver problems were more likely to happen in patients older than 55 years.

Exjade should not be taken by patients with pre-existing severe kidney and liver problems; high-risk myelodysplastic syndromes; advanced cancer; low platelet counts; or an allergy to Exjade.

Since Exjade has been on the market, there have been reports of serious reactions, sometimes leading to death. Severe blood disorders (including neutropenia, agranulocytosis, worsening anemia and thrombocytopenia), serious allergic reactions (including swelling of the throat), severe skin reactions (including Stevens Johnson syndrome and erythema multiforme), decreased hearing and vision changes have been reported. These serious reactions and deaths have happened most often when Exjade was taken by elderly patients. The most commonly reported side effects related to Exjade in clinical trials were nausea, vomiting, diarrhea, stomach pain, increases in kidney laboratory values, and skin rash.

Please see full Prescribing Information including Boxed WARNING available at www.exjade.com.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "long-term," "may be contingent," "commitment," "exciting," "ongoing," or similar terms, or by express or implied discussions regarding potential marketing approvals for Jadenu, or regarding potential future revenues from Jadenu or Exjade. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Jadenu or Exjade will be submitted or approved for sale in any additional markets, or at any particular time. Neither can there be any guarantee that Jadenu or Exjade will be commercially successful in the future. In particular, management's expectations regarding Jadenu and Exjade could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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.

About Novartis
Located in East Hanover, N.J., Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). As of December 31, 2014 Novartis Group companies employed approximately 133,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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References


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