Novartis expands transplant portfolio with Hecoria®, the first generic tacrolimus that can be prescribed by brand name

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- Now available in US pharmacies, Hecoria (tacrolimus) capsules are approved for the prevention of organ rejection in certain kidney and liver transplant patients
- Hecoria, a branded generic, complements the Novartis portfolio by offering an option for physicians who seek to have the same brand of tacrolimus dispensed at every refill
- Novartis is dedicated to improving access to medications and is offering the same level of patient support services for Hecoria as for its other branded transplant products

East Hanover, N.J., April 2, 2012 — Novartis today announced the US introduction and availability of Hecoria® (tacrolimus) capsules, the first generic tacrolimus that can be prescribed by its brand name. Now available in pharmacies, Hecoria is an AB-rated generic therapeutic bioequivalent to Prograf® (tacrolimus capsules). Hecoria is approved by the US Food and Drug Administration (FDA) for the prevention of organ rejection in patients receiving liver or kidney transplants.

Following organ transplantation, patients require lifelong treatment with immunosuppressants.1 Many transplant patients are faced with complicated post-transplant medication regimens and significant financial burden. As a branded generic, Hecoria offers an option for healthcare providers who seek to have their patients receive the same brand of tacrolimus at every prescription refill, at the affordable price of a generic. Available in 0.5 mg, 1 mg and 5 mg capsules, Hecoria is the only tacrolimus that has its brand name printed on the capsule. Patients can identify Hecoria when dispensed at a pharmacy.

Currently, there are more than 112,000 patients awaiting an organ transplant.2 In 2010, nearly 17,000 patients received a kidney transplant, and more than 6,000 received a liver transplant, all of whom will need lifelong treatment with immunosuppressants.2

“Novartis pioneered medicines to facilitate transplantation with the introduction of cyclosporine more than 25 years ago. Today, Novartis is proud to offer the broadest portfolio of transplant immunosuppressants on the market,” said Usman Azam, MD, head of US Medical & Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation. “Hecoria complements our extensive portfolio of transplant immunosuppressant medications, and underscores our ongoing commitment to delivering a broad range of treatment options to our customers and their patients.”

The FDA approval of Hecoria was based on the approved Sandoz Abbreviated New Drug Application (ANDA) and comparative, randomized, single-dose, 2-way crossover, bioavailability studies of Prograf and tacrolimus 5 mg capsules performed in healthy
volunteers following a standard meal and under fasting conditions. Results demonstrated that tacrolimus and Prograf capsules are bioequivalent under fed and fasting conditions.

Health plans will generally reimburse Hecoria as an AB-rated generic and will generally make the medication available to patients at a generic price. Novartis is committed to improving access to medications for those most in need through its Patient Assistance Program, and is offering the same level of financial support for Hecoria as for other branded Novartis products. Patients experiencing financial hardship who have no third-party coverage may be eligible to receive financial support for Hecoria through the Novartis Patient Assistance Program. For information about the Novartis Patient Assistance Program, visit http://www.patientassistancenow.com.

Hecoria is marketed and distributed by Novartis Pharmaceuticals Corporation and manufactured by Sandoz, the generic pharmaceuticals division within the Novartis group of companies.

About Hecoria® (tacrolimus) capsules
Hecoria (tacrolimus) capsules are calcineurin-inhibitor immunosuppressants indicated for the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants. It is recommended that Hecoria be used concomitantly with adrenal corticosteroids. In kidney transplant recipients, it is recommended that Hecoria be used in conjunction with azathioprine or mycophenolate mofetil. Careful and frequent monitoring of tacrolimus trough concentrations is recommended for all patients receiving this product.

Hecoria should not be used simultaneously with cyclosporine. Use with sirolimus is not recommended in liver transplant. The safety and efficacy of Hecoria with sirolimus has not been established in kidney transplant. Tacrolimus injection should be reserved for patients unable to take Hecoria orally. It is not known if Hecoria is safe and effective in children who have had a kidney transplant.

Important Safety Information for Hecoria® (tacrolimus) capsules

Patients receiving Hecoria are at increased risk of development of lymphoma and other malignancies, particularly of the skin, due to immunosuppression. Patients receiving Hecoria are at increased susceptibility to bacterial, viral, fungal and protozoal infections, including opportunistic infections. Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Hecoria.

Potential serious adverse events associated with Hecoria include lymphoma and other malignancies, serious infections, polyoma virus infections, cytomegalovirus (CMV) infections, new onset diabetes after transplant, nephrotoxicity, neurotoxicity, hyperkalemia, hypertension, myocardial hypertrophy and pure red cell aplasia. Use with sirolimus is not recommended in liver transplant due to increased risk of serious adverse reactions. Immunizations with live vaccines should be avoided.

In kidney transplant, the most common adverse reactions (≥ 30%) were infection, tremor, hypertension, abnormal renal function, constipation, diarrhea, headache, abdominal pain, insomnia, nausea, hypomagnesemia, urinary tract infection, hypophosphatemia, peripheral edema, asthenia, pain, hyperlipidemia, hyperkalemia and anemia. In liver transplant, the most common adverse reactions (≥ 40%) were tremor, headache, diarrhea, hypertension, nausea, abnormal renal function, abdominal pain, insomnia, paresthesia, anemia, pain, fever, asthenia, hyperkalemia, hypomagnesemia and hyperglycemia.

Prograf® is a registered trademark of Astellas Pharma US.
Please see full Prescribing Information, including Boxed Warnings.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “dedicated,” “introduction,” “commitment,” “will,” or similar expressions, or by express or implied discussions regarding potential future revenues from Hecoria. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Hecoria to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Hecoria will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Hecoria could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group’s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

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