Gilead Files European Marketing Application for Boosting Agent Cobicistat

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FOSTER CITY, Calif.--(BUSINESS WIRE)--May. 23, 2012-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today that the Marketing Authorisation Application (MAA) for cobicistat, submitted on April 26, 2012, has been validated by the European Medicines Agency (EMA). Cobicistat is Gilead's pharmacoenhancing or "boosting" agent that increases blood levels of certain commercially available protease inhibitors, including atazanavir and darunavir, in order to enable once-daily dosing. Currently, ritonavir is the only agent used to boost HIV therapy. Review of the MAA for cobicistat will be conducted under the centralized licensing procedure, which, when finalized, provides one marketing authorization in all 27 member states of the European Union (EU).

"With today's EMA validation, we're hopeful that we may soon be able to offer an important new boosting option for patients who rely on protease inhibitors as part of their HIV therapy," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences.

The MAA for cobicistat is supported by pharmacokinetic data demonstrating that cobicistat boosts atazanavir and darunavir exposure similar to ritonavir, and by 48-week data from a pivotal Phase 3 study (Study 114) in which cobicistat met its primary objective of non-inferiority to ritonavir, when both agents were administered with a background regimen of atazanavir plus Truvada® (emtricitabine and tenofovir disoproxil fumarate). Topline results from the study were announced in December 2011, and complete data will be presented at an upcoming medical meeting.

Gilead plans to submit an application for marketing approval of cobicistat to the U.S. Food and Drug Administration (FDA) in the third quarter of 2012. Cobicistat is a component of Gilead's investigational Quad single tablet regimen, which also contains elvitegravir, emtricitabine and tenofovir disoproxil fumarate. Cobicistat enables once-daily dosing of elvitegravir within the Quad.

In June 2011, Gilead announced an agreement with Janssen R&D Ireland for the development of a fixed-dose combination of cobicistat and darunavir. Subject to regulatory approval, Janssen will be responsible for the formulation, manufacturing, registration, distribution and commercialization of the cobicistat and darunavir fixed-dose combination worldwide. Additionally, in October 2011, Gilead announced an agreement with Bristol-Myers Squibb to develop a fixed-dose combination of cobicistat and atazanavir. Bristol-Myers Squibb will be responsible for the formulation, manufacturing, development, registration, distribution and commercialization of the atazanavir and cobicistat fixed-dose combination worldwide.

About Cobicistat

Cobicistat is Gilead's proprietary mechanism-based inhibitor of cytochrome P450 3A (CYP3A), an enzyme that metabolizes drugs in the body. Unlike ritonavir, cobicistat acts only as a pharmacoenhancer and has no antiviral activity.

Cobicistat, elvitegravir and the Quad are investigational products and their safety and efficacy have not yet been established.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risk that EMA and other regulatory agencies may not approve cobicistat, any combination products containing cobicistat, elvitegravir or the Quad, and that any marketing approvals, if granted, may have significant limitations on their use. In addition, even if approved, Gilead may not be able to successfully commercialize these products, and may make a strategic decision to discontinue their development if, for example, the market for the products fails to materialize as expected. Further, Gilead may be unable to submit its New Drug Application for cobicistat to FDA in the currently anticipated timelines. These risks, uncertainties and other factors could cause actual results to differ materially

from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

Truvada is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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