BioMarin InvestorRoom

Kuvan Receives Positive Opinion From CHMP for European Approval

Decision on Marketing Authorization Expected by End of 2008

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BioMarin Pharmaceutical Inc. announced today that its partner Merck Serono, a division of Merck KGaA, Darmstadt, Germany, has received a positive opinion for Kuvan(R) (sapropterin dihydrochloride) as an oral treatment for hyperphenylalaninemia (HPA) in patients with phenylketonuria (PKU) or tetrahydrobiopterin (BH4) deficiency from the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMEA). The CHMP recommendation will be considered by the European Commission, which will deliver its final decision on the granting of marketing authorization within 67 days.

"The positive opinion from the CHMP is encouraging and bodes well for potential approval, which is on track by the end of the year, triggering a $30 million milestone payment to BioMarin," said Jean-Jacques Bienaime, Chief Executive Officer of BioMarin. "We are excited to work with our partner Merck Serono to offer the first therapeutic option to manage PKU in the European market."

About Kuvan

Kuvan(R) (sapropterin dihydrochloride) Tablets is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

The active ingredient in Kuvan, sapropterin dihydrochloride, is the synthetic form of 6R-BH4 (tetrahydrobiopterin), a naturally occurring enzyme cofactor that works in conjunction with phenylalanine hydroxylase (PAH) to metabolize Phe. BioMarin and Merck Serono estimate that Kuvan could be a potential treatment option for approximately 30 percent to 50 percent of the estimated 50,000 identified PKU patients in the developed world.

Kuvan has received orphan drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA). Kuvan has received seven years of market exclusivity in the United States. In November 2007, Merck Serono submitted a Marketing Authorization Application (MAA) to the EMEA for sapropterin dihydrochloride as an oral treatment for patients suffering from hyperphenylalaninemia (HPA) due to PKU or BH4 deficiency. If approved in the EU, it will receive 10 years of market exclusivity for this indication.

About PKU

PKU, a genetic disorder affecting approximately 50,000 diagnosed patients in the developed world, is caused by a deficiency of the enzyme phenylalanine hydroxylase. PAH is required for the metabolism of phenylalanine, an essential amino acid found in most protein-containing foods. If the active enzyme is not present in sufficient quantities, Phe accumulates to abnormally high levels in the blood and becomes toxic to the brain, resulting in a variety of complications including severe mental retardation and brain damage, mental illness, seizures, tremors, and limited cognitive ability. As a result of newborn screening efforts implemented in the 1960s and early 1970s, virtually all PKU patients under the age of 40 in developed countries have been diagnosed at birth. To learn more about PKU, please visit http://www.pku.com/. Information on this website is not incorporated by reference into this press release.

About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio comprises three approved products and multiple clinical and pre-clinical product candidates. Approved products include Naglazyme(R) (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin; Aldurazyme(R) (laronidase) for mucopolysaccharidosis I (MPS I), a product which BioMarin developed through a 50/50 joint venture with Genzyme Corporation; and Kuvan(R) (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), developed in partnership with Merck Serono, a division of Merck KGaA of Darmstadt, Germany. Other product candidates include 6R-BH4 for cardiovascular indications, which is currently in Phase 2 clinical development for the treatment of peripheral arterial disease and sickle cell disease, and PEG-PAL (PEGylated recombinant phenylalanine ammonia lyase), which is currently in Phase 1 clinical development for the treatment of PKU. For additional information, please visit http://www.bmrn.com/. Information on BioMarin's

website is not incorporated by reference into this press release.

About Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. Its North American business operates in the United States and Canada as EMD Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux(R)), multiple sclerosis (Rebif(R)), infertility (Gonal-f(R)), endocrine and cardiometabolic disorders (Glucophage(R), Concor(R), Euthyrox(R), Saizen(R), Serostim(R)), as well as psoriasis (Raptiva(R)).

With an annual R&D expenditure of around euro 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the continued development and commercialization of Kuvan and BioMarin's other products and product candidates and actions by regulatory authorities. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others: our success in the continued commercialization of Kuvan; the content and timing of decisions by the U.S. Food and Drug Administration, the European Commission and other regulatory authorities concerning each of the described products and product candidates; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Risk Factors" in BioMarin's 2007 Annual Report on Form 10-K, as amended, and the factors contained in BioMarin's reports on Form 10-Q and Form 8-K. Stockholders are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise.

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