BioMarin Announces Kuvan(R) (sapropterin dihydrochloride) Patent Challenge Settlement

SAN RAFAEL, Calif., Sept. 18, 2015 (GLOBE NEWSWIRE) -- BioMarin Pharmaceutical Inc. (NASDAQ:BMRN), today announced that it has entered into a settlement agreement with Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) that resolves patent litigation in the United States (U.S.) related to BioMarin's Kuvan® (sapropterin dihydrochloride) 100mg oral tablets.

Under the terms of the settlement, BioMarin will grant Dr. Reddy's a non-exclusive license to its patents related to Kuvan to allow Dr. Reddy to market a generic version of sapropterin dihydrochloride 100mg tablets in the U.S. for the indications approved for Kuvan beginning at a confidential date in the future, but which is more than five years from today, or earlier under certain circumstances. Additional details of the agreement remain confidential.

"This settlement agreement recognizes the strength of the intellectual property related to Kuvan and helps to ensure that patients who depend on Kuvan to manage their phenylketonuria (PKU) will continue to receive the medication and the range of support services offered to patients for years to come," said Jeff Ajer, Executive Vice President and Chief Commercial Officer of BioMarin. "This settlement is beneficial to patients, clinicians, BioMarin and our shareholders, as it removes the cost, distraction and uncertainty associated with this litigation."

BioMarin continues to vigorously enforce its intellectual property related to Kuvan. This includes continuing its suit against Par Pharmaceutical, Inc., which is not affected by this settlement.

As required by law, BioMarin and Dr. Reddy will submit the Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice.

Important Safety Information about Kuvan

It is not possible to know if Kuvan will work for you without a trial of the medicine.

Your doctor will check your blood Phe levels when you start taking Kuvan to see if the medicine is working.

Starting Kuvan does not eliminate the need for ongoing dietary management. Any change to your diet may impact your blood Phe level. Follow your doctor's instructions carefully. Your doctor and dietitian will continue to monitor your diet and blood Phe levels throughout your treatment with Kuvan **to make sure your blood Phe levels are not too high or too low**. If you have a fever, or if you are sick, your Phe level may go up. Tell your doctor and dietitian as soon as possible so they can make any necessary changes to your treatment.

Children younger than 7 years old treated with Kuvan doses of 20 mg/kg per day are at an increased risk for low levels of blood Phe compared with children 7 years and older. Frequent blood monitoring is recommended in this population to ensure that blood Phe levels do not fall too low.

Tell your doctor if you have ever had liver or kidney problems, have poor nutrition or have a loss of appetite, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Kuvan is a prescription medicine and should not be taken by people who are allergic to any of its ingredients. Kuvan and other medicines may interact with each other. Tell your doctor about **all the medicines you take**, including

prescription and over-the-counter medicines, vitamins, herbal and dietary supplements.

If you forget to take your dose of Kuvan, take it as soon as you remember that day. Do not take 2 doses in a day. If you take too much Kuvan, call your doctor for advice.

The most common side effects reported when using Kuvan are headache, runny nose and nasal congestion, sore throat, diarrhea, vomiting, and cough. Additional adverse reactions reported in connection with worldwide marketing include sore throat, heartburn or pain in the esophagus, inflammation of the lining of the stomach, indigestion, stomach pain, and nausea. These are not all the possible side effects seen with Kuvan. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Kuvan can cause serious side effects, including:

- **Severe allergic reactions**. Stop taking Kuvan and **get medical help right away** if you develop any of these symptoms of a severe allergic reaction:
    - Wheezing or trouble breathing
    - Nausea
    - Flushing
    - Lightheadedness or fainting
    - Coughing
    - Rash

- **Inflammation of the lining of the stomach (gastritis)**. Gastritis can happen with Kuvan and may be severe. **Call your doctor right away**

if you have any:

- Severe upper stomach-area discomfort or pain
- Blood in your vomit or stool
- Nausea and vomiting
- Black, tarry stools

- **Too much or constant activity (hyperactivity) can happen with Kuvan**. Tell your doctor if you have any signs of hyperactivity, including fidgeting, moving around or talking too much.

To access full Patient Information, go to http://kuvan.com/patient-information/.

About BioMarin

BioMarin is a global biotechnology company that develops and commercializes innovative therapies for patients with serious and life-threatening rare and ultra-rare genetic diseases. The company's portfolio consists of five commercialized products and multiple clinical and pre-clinical product candidates. For additional information, please visit www.BMRN.com.

Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: possible launch dates for generic versions of Kuvan and ongoing litigation related to generic versions of Kuvan. 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: the review of the settlement agreement with Dr. Reddy by the U.S. Federal Trade Commission and the U.S.

Department of Justice; the progress and outcome of the ongoing litigation with Par Pharmaceutical, Inc.; possible future ANDA filings related to Kuvan tablets or Kuvan powder for oral solution; 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 2014 Annual Report on Form 10-K, and the factors contained in BioMarin's reports on Form 10-Q. 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. For additional information, please visit www.BMRN.com. Information on BioMarin's website is not incorporated by reference into this press release.

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