BioMarin Announces Kuvan® (sapropterin dihydrochloride) Patent Challenge Settlement

Retains exclusive U.S. rights until October 1, 2020

SAN RAFAEL, Calif., April 13, 2017 /PRNewswire/ -- BioMarin Pharmaceutical Inc. (NASDAQ: BMRN), today announced that it has entered into a settlement agreement with Par Pharmaceutical that resolves patent litigation in the United States (U.S.) related to BioMarin's Kuvan® (sapropterin dihydrochloride) 100mg oral tablets and powder for oral solution in 100mg packets.

Under the terms of the settlement, BioMarin will grant Par a non-exclusive license to its patents related to Kuvan to allow Par to market a generic version of sapropterin dihydrochloride 100mg tablets and powder for oral solution in 100mg and 500 mg sachets in the U.S. for the indications approved for Kuvan beginning October 1, 2020 or earlier under certain circumstances. Additional details of the agreement remain confidential.

BioMarin continues to vigorously enforce its intellectual property related to Kuvan. BioMarin holds patents in Europe related to Kuvan that are valid until at least 2024.

As required by law, BioMarin and Par 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 in both the United States and the European Union, 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 Par Pharmaceutical by the U.S. Federal Trade Commission and the U.S. Department of Justice; the outcome of current litigation with Dr. Reddy's Laboratories, 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 2016 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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