

# BioMarin Files New Drug Application for Orapred ODT

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NOVATO, Calif.

BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) today announced that it has submitted a New Drug Application to the U.S. Food and Drug Administration for Orapred ODT(TM) (prednisolone sodium phosphate orally disintegrating tablets), a new formulation of Orapred(R) (prednisolone sodium phosphate oral solution). Prednisolone is commonly used to reduce inflammation seen in numerous medical conditions including asthma, arthritis and cancer.

"Orapred ODT holds the potential to provide individuals of all ages with a new formulation of prednisolone that is convenient and easy to administer," stated Jean-Jacques Bienaime, Chief Executive Officer of BioMarin. "We are committed to maximizing the value of our Orapred franchise and expect to have Orapred ODT on the market in mid-2006, pending regulatory approval."

Orapred ODT utilizes proprietary oral disintegrating tablet technology to provide a taste-masked, non-refrigerated and easy-to-administer formulation of prednisolone. There are currently no prednisolone oral disintegrating tablets on the market.

## About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio is comprised of three approved products and multiple clinical and preclinical product candidates. Approved products include Naglazyme(TM) (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin, Aldurazyme(R) (laronidase) for mucopolysaccharidosis I (MPS I), and Orapred(R) (prednisolone sodium phosphate oral solution) for inflammatory conditions. Investigational product candidates include Phenoptin(TM) (sapropterin hydrochloride), a Phase 3 product candidate for the treatment of phenylketonuria (PKU). For additional information, please visit [www.BMRN.com](http://www.BMRN.com).

Information on BioMarin's website, [www.BMRN.com](http://www.BMRN.com), is not incorporated by reference into this press release.

## Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the development of Orapred ODT; the continued development and commercialization of the Orapred brand; and filings with and actions by regulatory authorities; and BioMarin's Orapred operations. 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 content and timing of decisions by the FDA concerning Orapred ODT; our success in continuing commercialization of Orapred; the market for Orapred and Orapred ODT and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Factors That May Affect Future Results" in BioMarin's 2003 Annual Report on Form 10-K and the factors contained in BioMarin's reports on Forms 10-Q and 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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