Koios

Koios Pharmaceuticals Files Challenge to High-Cost Drug's Patent

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SANTA MONICA, Calif.--(BUSINESS WIRE)--Koios Pharmaceuticals LLC announced that it has filed a challenge to the validity of U.S. Patent 8,644,231, the sole Orange-Book listed patent protecting Rasuvo®—a methotrexate autoinjector product—from generic competition.

Koios further announced that it has entered into a confidential development and commercialization partnership with a leading developer of sterile injectable pharmaceutical products to introduce a generic equivalent to Rasuvo.

Rasuvo is approved for the treatment of inflammatory autoimmune diseases including rheumatoid arthritis in adults and polyarticular juvenile idiopathic arthritis in children.

Americans spent $30.2 billion on specialty autoimmune medicines like Rasuvo, Humira, and Enbrel in 2015, according to IMS Health, and spending on autoimmune treatments grew 28% from the prior year—more quickly than any other treatment category.

Koios's mission is to increase Americans' access to affordable medicines by promoting pharmaceutical price competition. The company leverages novel legal strategies at the intersection of *inter partes* review and the Hatch-Waxman Act to introduce generic equivalents to high-cost specialty pharmaceutical products before the patents protecting those products would naturally expire.

The '231 patent would not expire until 2029.

"We're thrilled to have taken this first step toward our mission," said Kayvan Noroozi, Koios's President and CEO. "Methotrexate was developed by the famed pediatric pathologist Sidney Farber and has been used since the 1950s. Medac's patent adds nothing new to the methotrexate molecule, and we strongly believe it does not make any inventive scientific contributions. The American public should have access to competitively priced methotrexate autoinjector products before the '231 patent expires."

Medac Exhibit 2009

Koios is represented by Scott Kamholz, M.D., Ph.D., and DeAnn Smith of Foley Hoag LLP. The challenge was filed as a petition for *inter partes* review before the U.S. Patent and Trademark Office under proceeding number IPR2016-01370.

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