

## **MEDIA ADVISORY**

### **Momenta Applauds FDA Denial of Citizen Petition Requesting FDA Mandate of Information Sharing in Biosimilars Review Process**

*- FDA Reaffirms Separation of Biosimilar Application Process from Biosimilar Patent Exchange Process -*

Momenta Pharmaceuticals, Inc. (NASDAQ: MNTA) today applauded the Food and Drug Administration (FDA) for its denial of Amgen's Citizen Petition asking the FDA to play a role in the patent exchange process. Amgen sought to require the FDA to force applicants to certify delivery of their application to their reference product competitor.

"We are very pleased that the FDA considered Momenta's comments in recognizing its authority under the Biologics Price Competition and Innovation Act (BPCIA)," said Craig Wheeler, President and Chief Executive Officer of Momenta. "We believe the FDA's denial of this petition is a step in the right direction toward encouraging the use of the 351(k) pathway and promoting an efficient review and approval process for biosimilars."

A copy of Momenta's comment letter is available at <http://1.usa.gov/1CSiLKw>. The FDA's Citizen Petition Denial Response is available at <http://1.usa.gov/1FNqjQM>.

#### **About Momenta**

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural and functional analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for oncology and autoimmune indications.

To receive additional information about Momenta, please visit the website at [www.momentapharma.com](http://www.momentapharma.com), which does not form a part of this press release. The company's logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

#### **Investor Relations:**

Sarah Carmody  
Momenta Pharmaceuticals  
1-617-395-5189  
[IR@momentapharma.com](mailto:IR@momentapharma.com)

#### **Media Relations:**

Karen Sharma  
MacDougall Biomedical Communications  
1-781-235-3060  
[Momenta@macbiocom.com](mailto:Momenta@macbiocom.com)