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PatientsLikeMe and the FDA Sign Research Collaboration Agreement

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WASHINGTON--(BUSINESS WIRE)--PatientsLikeMe and the U.S. Food and Drug Administration (FDA) have signed a research collaboration agreement to determine how patient-reported data can give new insights into drug safety. Under the collaboration, PatientsLikeMe and the FDA will systematically explore the potential of patient-generated data to inform regulatory review activities related to risk assessment and risk management. The announcement was made at the start of the Drug Information Association's (DIA) annual meeting in Washington D.C.

PatientsLikeMe Co-Founder and President Ben Heywood said the agreement is an unprecedented step toward enhancing post-market surveillance and informing regulatory science. "Most clinical trials only represent the experience of several hundred or at most several thousand patients, making it impossible to anticipate all the potential side effects of drugs in the real world. Patient-generated data give a more complete picture about a drug's safety by providing a window into patients' lives and healthcare experiences over time. We're very encouraged by the FDA's action to evaluate newer sources of data to help identify benefits and risks earlier."

The cornerstone of the FDA's post-approval drug safety surveillance is a spontaneous reporting system consisting of individual case safety reports. Reporting adverse events to the FDA is mandatory for drug product manufacturers but voluntary for healthcare professionals and patients. The majority of these individual case safety reports are submitted by healthcare professionals and patients to drug product manufacturers, who then have regulatory requirements to report them to the FDA. The PatientsLikeMe data are generated in a different context by patients themselves, and provide important real-time insights into the nuances inherent in patients' experiences over time, including drug tolerance, adherence and quality of life.

PatientsLikeMe is the largest and most active patient network online, with 350,000 members reporting on their real-world experiences with more than 2,500 conditions. The company's drug safety initiatives began in 2008 with a pilot program that allowed patients living with Multiple Sclerosis (MS) to report adverse events directly to the FDA. One year later the company launched the first drug safety platform on social media, enabling industry partners to meet their regulatory obligations. In all, PatientsLikeMe has collected more than 110,000 adverse event reports on 1,000 different medications, data that the FDA will now be able to access and analyze as a supplement to traditional sources, including FAERS.

While this is the first time that PatientsLikeMe has formally worked with the FDA, the collaboration adds to a foundation the company has built as an active participant in the regulatory science process. PatientsLikeMe has worked with, provided counsel to and co-authored discussion papers with a range of government groups, including the Institute of Medicine, the National Institute of Health, the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services, as well as nonprofit organizations such as the Patient Centered Outcomes Research Institute (PCORI).

About PatientsLikeMe
PatientsLikeMe® (www.patientslikeme.com) is a patient network that improves lives and a real-time research platform that advances medicine. Through the network, patients connect with others who have the same disease or condition and track and share their own experiences. In the process, they generate data about the real-world nature of disease that help researchers, pharmaceutical companies, regulators, providers, and nonprofits develop more effective products, services and care. With more than 350,000 members, PatientsLikeMe is a trusted source for real-world disease information and a clinically robust resource that has published more than 60 peer-reviewed research studies. Visit us at www.patientslikeme.com or follow us via our blog, Twitter or Facebook.

About the FDA
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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