Ashland injectable pharmaceutical excipient accepted into FDA Novel Excipient Review Pilot Program

October 31, 2022

WILMINGTON, Del., Oct. 31, 2022 (GLOBE NEWSWIRE) -- Ashland Inc. (NYSE: ASH) today announced the United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research Office of New Drugs has accepted Ashland Viatel ™ bioresorbable mPEG-PDLLA pharmaceutical excipient in the review cycle of the FDA Novel Excipient Review Pilot Program.

The voluntary program is the first time the FDA will allow excipient manufacturers to obtain review of certain novel excipients prior to their use in drug formulations*. The pilot program which offers a new pathway to evaluate excipients could hasten important public health benefits and is available for novel excipients that have not been used in FDA-approved drug products nor have an established use in food. Ashland's excipient is intended as a polymeric carrier for the delivery of therapeutic pharmaceuticals to target certain tissue sites within the body.

"We are continuing to demonstrate strong technology differentiation in new product innovations that are aligned with core markets and customer drivers to enable organic growth," said Guillermo Novo, chair and chief executive officer, Ashland.

The primary functions of Ashland's excipient could offer life-changing and transformative benefits for consumers. For customers, primary formulation formats include nanoparticles, microparticles, implants or in-situ forming drug depots.

"This prestigious opportunity to participate in the FDA pilot program shines a spotlight on Ashland's life sciences core strategy of undiluted attention to innovation in pharmaceutical ingredients," said Ashok Kalyana, senior vice president and general manager, life sciences, Ashland. "Working with pharmaceutical partners, we're addressing scenarios where manufacturers and drug developers have previously cited difficulty using existing products. Ashland's innovative excipients effectively deliver complex drug molecules where and when they're needed."

The two-stage FDA program includes the proposal and full data package. Ashland's submission will proceed to the second stage of the program.

For more information, visit Ashland.com/viatel

About Ashland
Ashland Inc. (NYSE: ASH) is a global additives and specialty ingredients company with a conscious and proactive mindset for environment, social and governance (ESG). The company serves customers in a wide range of consumer and industrial markets, including architectural coatings, automotive, construction, energy, food and beverage, nutraceuticals, personal care and pharmaceutical. Approximately 3,900 passionate, tenacious solvers – from renowned scientists and research chemists to talented engineers and plant operators – thrive on developing practical, innovative and elegant solutions to complex problems for customers in more than 100 countries. Visit ashland.com and ashland.com/ESG to learn more.

*https://www.fda.gov/drugs/development-approval-process-drugs/pilot-program-review-innovation-and-modernization-excipients-prime

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Attachment

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