News Release

P416/22
December 5, 2022

BASF Pharma Solutions excipient accepted into FDA Pilot Program for novel excipients

- **U.S. Food and Drug Administration accepts Soluplus® branded excipient in its program to evaluate safety and acceptability of excipients for use in clinical trials, independent from a specific New Drug Application.**
- **Excipients (inactive ingredients) such as the Soluplus® branded excipient play a critical role in enabling the drug development process for poorly soluble active pharmaceutical ingredients**

Florham Park, New Jersey, December 5, 2022 –

BASF Pharma Solutions, a global business unit of BASF, announces today that the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), Office of New Drugs, has accepted their excipient, Soluplus®, into the FDA's Pilot Program for the Review of Innovation and Modernization of Excipients (PRIME). The program seeks to reduce the risk and burden for pharmaceutical companies wishing to utilize novel excipients for modern drug development challenges as well as to provide a pathway for excipient manufacturers like BASF to obtain FDA review of their novel excipients prior to use in an FDA-approved drug.

The Soluplus® branded excipient has now moved into the next stage of the extensive evaluation process, and the FDA will share the results at the conclusion of this process.

Media Relations
Deb Oliveri
Phone: 551-252-3567
deborah.oliveri@basf.com

Media Relations
Rebekka-Martina Mueller
Phone: +49 151 65570069
rebekka-martina.mueller
@partners.basf.com

BASF SE
67056 Ludwigshafen
www.basf.com
presse.kontakt@basf.com

“With our long history of developing novel excipients, it is especially rewarding that BASF is selected to participate in this pilot program,” states Jeff DeAlmeida, Senior Vice President, BASF Pharma Solutions. “We chose to submit this particular excipient for the FDA’s consideration as it can be used in the development of a wide range of vital medicines.”

The Soluplus® branded excipient (polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer) was specifically designed to improve the solubility and oral bioavailability of poorly soluble active pharmaceutical ingredients, which has been an ever-increasing challenge to the industry. “The review of novel excipients is a critical step in driving innovation in new materials to meet the global health challenges of today and the future,” states Dominik Odenbach, Director of Global Quality, Regulatory Compliance and External Affairs, BASF Pharma Solutions. Soluplus® is particularly suitable as a matrix polymer in hot melt extrusion, a key enabling technology utilized in numerous modern medicines.

“We would like to thank the FDA for introducing the novel excipient Pilot Program. IPEC-Americas, the IQ Pharma Consortium, and the USP all recognize the need for excipient innovation and the challenges for the adoption of novel excipients in drug development. The collaborative efforts among these groups have supported and advocated for this initiative. As the need for novel excipients has never been greater, we are optimistic that a successful pilot program will lead to a formal novel excipient review program in the near future,” says Nigel Langley, Global Technology Director at BASF and a Chair of IPEC-Americas.

BASF is a leader in innovation and has pioneered the development of novel excipients over several decades. More information about the FDA’s PRIME program can be found here: https://www.fda.gov/drugs/development-approval-process-drugs/pilot-program-review-innovation-and-modernization-excipients-prime

About BASF

At BASF, we create chemistry for a sustainable future. We combine economic success with environmental protection and social responsibility. Around 111,000 employees in the BASF Group contribute to the success of our customers in nearly all sectors and almost every country in the world. Our portfolio comprises six segments: Chemicals, Materials, Industrial Solutions, Surface Technologies, Nutrition & Care and Agricultural Solutions. BASF generated sales of €78.6 billion in

2021. BASF shares are traded on the stock exchange in Frankfurt (BAS) and as American Depositary Receipts (BASFY) in the U.S. Further information at www.basf.com.

About BASF's Nutrition & Health division

BASF Nutrition & Health provides a comprehensive product and service range for human and animal nutrition, pharmaceutical, and flavor & fragrance industries. With our science-driven portfolio, we address customers in globally growing markets to meet the demands of an expanding world population. Together with our customers, we play an active role in enhancing the nutrition, health and wellbeing of consumers all over the world. Our products fulfill the highest safety, regulatory and sustainability standards. BASF Nutrition & Health operates sites in Europe, North America and in Asia-Pacific. For more information, go to www.basf.com.