FOR IMMEDIATE RELEASE

Noble Launches Human Factors Engineering Services to Support Product Development and US FDA Approval of Medical Devices and Combination Products

"Human Factors Plus" (HF+) is a natural extension of Noble's deep understanding of the patient experience when it comes to self-administering drug therapies

Orlando, Florida, February 2, 2021 – Noble, an Aptar Pharma company and world leader in providing drug delivery training device programs for pharmaceutical companies and original equipment manufacturers, today announces the launch of "Human Factors Plus" (HF+), an expanded service to further optimize the patient self-administration experience by supporting its customers in bringing new products to market.

HF+ combines the application of human factors engineering with Noble's expertise in developing patient-centric training solutions and onboarding platforms to advance the development and testing of new self-administered medical products that optimize safety and efficacy while minimizing use errors and the risk of adverse events. The "Plus" in Noble's HF+ program comes from their extensive research and experience in understanding the needs and concerns of patients who have self-administered drug therapies. In addition, Noble can provide clients with "one-stop shopping" through patient training devices and onboarding platforms, training utilization programs, training Instructions for Use (IFU), video programs and product launch strategy programs.

The U.S. Food & Drug Administration (FDA) considers human factors engineering an essential component of product development for drug delivery and medical devices and recommends making it a robust part of the design control process to maximize the likelihood that a new device will be safe and effective for its intended users and use environments. Device deficiencies can result in a delay in patients receiving otherwise effective treatment, and lost time and revenue for the sponsoring company. In the competitive medical healthcare environment, delays can also mean lost market share that is difficult to recover.

"Human factors engineering provides empirical and analytical evidence that a device and its labeling can be used safely and effectively by the intended patient," said Kevin Cluff, Ph.D., senior research human factors engineer for Noble, who holds a doctorate in mechanical engineering and has more than 25 years of human

factors experience. “This process involves testing the numerous touch points where patients interface with a drug product, including packaging, IFUs, prescribing information, quick reference guides and device indicators and controls.”

“Noble is proud to be the voice of the patient and to support the patient across every stage of their journey,” explained Tim McLeroy, executive director of marketing and patient services. “We understand how to leverage the application of human factors engineering and we know how to build a better patient experience. Together, HF+ engineering and building a better patient experience are a powerful combination to support product development and FDA approval for our customers and their combination products.”

Noble’s HF+ capabilities include:

- Strategic planning for regulatory approval pathways
- Contextual inquiry – observation of users in their environments
- Formative and summative studies – iterating usability testing and applying learnings to improve or demonstrate the user interface
- Heuristic evaluations – HF expert review based on experience
- Task, IFU and training analyses
- Threshold analysis – systematic comparison to approved products
- Use-related risk analysis – hazards, severity, harm, mitigations
- Design of drug delivery and medical training devices and prototypes

The benefits of human factors range from producing easier-to-use devices and better patient understanding of device use to more effective and efficient training that improves patient compliance and medical outcomes. Human factors engineering also helps reduce the risk of user errors, product complaints and recalls.

Noble’s human factors efforts broaden the existing range of value-added benefits from Aptar Pharma Services. Noble’s new services complement Noble’s expertise in conceptualization, design and development, mechanical/electrical/software engineering, project management, quality management, manufacturing, commercialization and logistics services as well.

About Noble

Noble develops robust training devices and onboarding solutions for the world’s top pharma brands and biotech companies and is focused on fostering healthy patient outcomes for those who self-administer drug therapies. Noble manufactures and commercializes training devices that mimic the exact feel, force and function of drug delivery devices such as autoinjectors, prefilled syringes, onbody, nasal and pulmonary devices in order to increase patient adherence and confidence and decrease usage errors. Noble was founded in 1994 and is based in Orlando, Florida. For more information, visit www.gonoble.com.

Noble Speaks Patient™

Noble is an Aptar Pharma Company, which is part of AptarGroup, Inc., a global leader in the design and manufacturing of a broad range of innovative drug delivery, consumer product dispensing and active packaging solutions that serve a variety of end markets including pharmaceutical, beauty, personal care, home, food and beverage. For more information, visit www.aptar.com.

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