PRESS RELEASE

Fluidda and Aptar Pharma Announce Exclusive Collaboration to Help Accelerate Regulatory Pathway for Orally Inhaled Products

Kontich, Belgium, September 22, 2022 – Fluidda, leader in the field of Functional Respiratory Imaging and developer of the medical device Broncholab®, today announced an exclusive collaboration with Nanopharm, an Aptar Pharma company and a leader in contract research and development services for orally inhaled and nasal drug products (OINDPs). The companies will leverage their respective proprietary technology platforms to help accelerate U.S. Food & Drug Administration (FDA) approvals for orally inhaled generic products (OIDPs) via the alternative bioequivalence pathway.

Fluidda's proprietary in silico platform FRI (Functional Respiratory Imaging) delivers quantitative predictions of regional drug deposition in disease state lungs using Computational Fluid Dynamics (CFD). The FRI platform provides critical information to help understand the availability and activity of the drug at the site of action in the lungs, when complemented by Nanopharm's local lung physiologically based pharmacokinetic (PBPK) model platform and it's in vitro data.

Nanopharm has pioneered the development of the alternative bioequivalence regulatory pathway for U.S. FDA approval of generic OIDPs for Asthma and Chronic Obstructive Pulmonary Disease (COPD) using its proprietary in vitro and in silico service platform, SmartTrack™.

This novel approach is intended to allow pharma companies to file Abbreviated New Drug Application (ANDA) dossiers without the need to perform time-consuming, costly and often unpredictable clinical end-point studies. Similarly, it can be used with 505(b)(2) filings, by derisking and abbreviating clinical studies.

“We are pleased to solidify our relationship with Fluidda and its world-leading FRI technology. A company would have to spend several years to achieve the current combined expertise and experience of Nanopharm and Fluidda. The collaboration between Nanopharm and Fluidda has the potential to revolutionize this arduous regulatory pathway” stated Dr. Jag Shur, Vice President, Science & Technology at Nanopharm.

Having already worked together closely for several years, Nanopharm and Fluidda have gained a unique insight into the complex and continually evolving regulatory requirements. This exclusive collaboration deepens the relationship between Fluidda and Nanopharm, benefiting both patients and customers with an uncompromised and holistic approach in developing the scientific rationale to demonstrate bioequivalence using only in vitro and in silico methodologies. The first potential approval of an OIDP using the alternative bioequivalence approach is pending, and, when approved, will further validate Nanopharm’s SmartTrack™ as the go-to solution for alternative bioequivalence studies and should accelerate demand for the companies’ collective services.

With momentum building for the transition to new lower global warming potential (GWP) propellants for pMDI’s, SmartTrack™ will also help companies to understand and modulate the impact of these new propellants on drug deposition and dissolution in the lungs, giving confidence in the performance of the reformulated product before embarking on any necessary clinical studies.

Dr. Jan de Backer, CEO of Fluidda, stated, “Fluidda has already demonstrated the applicability of its FRI platform to provide more objective data for evaluating and administering inhaled drug products accurately. Nanopharm’s unique SmartTrack™ platform provides us with clinically relevant input data without having to go into the clinic, which really adds another level of confidence to the models and provides an integrated perspective.

Guillaume Brouet, Vice President Analytical, Regulatory and Scientific Affairs at Aptar Pharma, commented, “Aptar Pharma is delighted to collaborate with Fluidda on this important development, which reinforces our mission to help customers derisk and accelerate their drug product development programs.”

About Fluidda

FLUIDDA, founded in 2005, is the world leader in the field of Functional Respiratory Imaging (FRI). This technique combines HRCT scans and Computational Fluid Dynamics technology (CFD), which offers vast improvements by making clinical trials shorter, faster and thus, more cost effective. FRI also helps patients and healthcare providers in offering a unique entry point in personalized medicine, by optimizing diagnosis, monitoring disease progression and the effects of therapy including accurate assessment of the deposition of inhalation medication. Fluidda's mission is to optimize treatment pathways, reduce healthcare costs and to limit the go-to-market time of respiratory drugs, pulmonology medical devices and therapies. Fluidda has offices in Belgium, the United States (New York and LA) and Portugal (Lisbon). For more information, please visit www.fluidda.com

About Aptar

Aptar Pharma is part of AptarGroup, Inc., a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing and active material science solutions and services. Aptar's innovative solutions and services serve a variety of end markets including pharmaceutical, beauty, personal care, home care, food and beverage. Aptar Pharma's analytical, laboratory and regulatory services add value at every stage of the drug development process, accelerating and de-risking the program along the way. Nanopharm, an Aptar Pharma company, is a leading provider of specialized analytical and product development services, with a focus on orally inhaled and nasal drug products. Aptar is headquartered in Crystal Lake, Illinois and has 13,000 dedicated employees in 20 countries. For more information, visit www.aptar.com.

This press release contains forward-looking statements. Expressions or future or conditional verbs such as "will" are intended to identify such forward-looking statements. Forward-looking statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are based on our beliefs as well as assumptions made by and information currently available to us. Accordingly, our actual results may differ materially from those expressed or implied in such forward-looking statements due to known or unknown risks and uncertainties that exist in our operations and business environment including, but not limited to: the successful integration of acquisitions; the regulatory environment; and competition, including technological advances. For additional information on these and other risks and uncertainties, please see our filings with the Securities and Exchange Commission, including the discussion under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-Ks and Form 10-Qs. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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