Vectura Group plc

FDA approves IND to support Vectura's wholly-owned programme VR647 in paediatric asthma

Chippenham, UK – 24 January 2017: Vectura Group plc (LSE: VEC) ("Vectura", "the Group"), an industry-leading device and formulation business for inhaled airways disease, has received an Investigational New Drug (IND) approval from the US Food and Drug Administration (FDA) to conduct a Phase 1 clinical trial with VR647.

VR647

Wholly-owned "smart" nebuliser programme in paediatric asthma

VR647 is a drug/device combination, using the AKITA® JET smart nebuliser, for the delivery of nebulised budesonide for maintenance treatment and prophylactic therapy of asthma in children (12 months to 8 years) for the US market. This wholly-owned pipeline programme seeks to significantly improve the currently available nebulised delivery of budesonide with a faster delivery time and better lung deposition where there is potential for reducing the dosage whilst maintaining similar efficacy, thereby reducing the risk of local and systemic side effects.

In June 2015 the FDA agreed with the Group's plan to rely on the 505(b)(2) pathway for the development programme with the aim of filing a New Drug Application (NDA). This approach requires a small number of clinical studies whose costs are within the Group's existing guidance for R&D investment. In line with its existing strategy to selectively build a specialist sales capability alongside the Group's continuing and proven partnering model, VR647 offers a further potentially significant source of recurring revenue. According to IMS, US sales of nebulised budesonide are approximately $830m[1] per year.

The Phase I pharmacokinetic study in adults is expected to be initiated in H1 2017 and will inform the doses to be explored in a Phase 2 study in children planned for H2 2017. These studies will be conducted to support initiation of a Phase III study in H2 2018 with the NDA filing anticipated in 2020.

James Ward-Lilley, Chief Executive Officer, commented:

"VR647 offers substantial potential harnessing of Vectura's innovative smart nebuliser technology for superior delivery of an existing drug with a proven track record in an established and significant US market. The FDA's approval is an important milestone allowing us to commence an accelerated clinical programme ahead of potential launch in 2021 as a self-commercialised asset."

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Enquiries

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About Vectura

Vectura, a FTSE250 company listed on the London Stock Exchange (LSE: VEC), is an industry-leading inhaled airways disease focused business with proprietary formulation and devices across DPI, pMDI and "smart" nebulisation platforms. With our extensive range of technologies, capabilities and collaborations, we believe we can become a leader in the development of inhalation products, increasing our ability to help patients suffering from respiratory diseases. In June 2016 Vectura completed a merger with Skyepharma PLC.

[1] IMS MIDAS Q3 2016 MAT

Vectura has seven inhaled, four non-inhaled and ten oral products marketed by partners with growing global royalty streams, and a portfolio of drugs in clinical development, a number of which have licence agreements with several global pharmaceutical and biotechnology companies including Hikma, Novartis, Sandoz, Mundipharma, Kyorin, Baxter, GSK, UCB, Ablynx, Grifols, Chiesi, Almirall, Janssen, and Tianjin KingYork.

For further information, please visit Vectura's website at www.vectura.com.

Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development and commercialisation of products. Various risks may cause Vectura's actual results to differ materially from those expressed or implied by the forward-looking statements, including: adverse results in clinical development programmes; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialise products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialisation activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.