



## **Mundipharma signs new deal with Vectura for global development and commercialization of inhaled triple therapy VR2076 for the treatment of asthma and COPD**

- *VR2076 is a novel inhaled triple ICS/LABA/LAMA therapy being developed for the treatment of asthma and COPD, available in an aerosol inhaler.*
- *Continues the growth of the global respiratory franchise for Mundipharma and the network of independent associated companies worldwide.*
- *Furtheres Mundipharma's partnership with Vectura following the successful development and launch of flutiform®.*

**CAMBRIDGE (UK) - 23 December 2016:** Mundipharma International Corporation Limited and a US independent associated company today announce that, following completion of formulation feasibility studies, they have exercised the option to license and assume full global responsibility from Vectura to develop and commercialize a new inhaled triple combination therapy (VR2076, formerly SKP-2076) of an inhaled corticosteroid (ICS), a long-acting beta2-adrenergic agonist (LABA), and a long-acting muscarinic antagonist (LAMA) in a single aerosol inhaler.

Concurrent treatment with an ICS, a LABA and a LAMA is already used to a large extent for COPD and asthma patients today, however, these three medicines are not currently available in a single device and are therefore administered separately via two or more inhalers. It is hoped that providing all three therapies in a single inhaler will offer more convenient dosing, improve compliance and reduce the risk of exacerbations. Triple therapies are anticipated to enter the market initially to provide additional treatment options for chronic obstructive pulmonary disease (COPD) with later launches for asthmatic populations who are poorly maintained on current therapies. Once the fixed-dose triple combination class is available, it is expected to grow into a class with a market size of \$3-5bn by 2025.<sup>1</sup>

Mundipharma is committed to developing new treatments to help patients better manage respiratory conditions. The initial development of VR2076 will be focussed on an asthma indication, but Mundipharma also has the option to continue development into COPD. The addition of this asset to the Mundipharma pipeline continues the growth of the global respiratory franchise for Mundipharma and the network of independent associated companies worldwide and builds on the successful launch of asthma treatment *flutiform* which was the basis for the first successful collaboration with Vectura.

Antony Mattessich, Managing Director, Mundipharma International Limited commented on the partnership, *"We're excited about the opportunity to realize the potential of VR2076"*

*which will form a key part of our growing respiratory pipeline. We're also pleased to expand our partnership with Vectura. This strategic collaboration leverages our companies' individual strengths. Our ability to bring medicines through the development and regulatory process, knowledge of the market and proven abilities to successfully commercialize respiratory medicines perfectly complements Vectura's expertise in innovative novel formulation and device development for inhaled airway-related diseases."*

The exercise of this option triggers a payment to Vectura of €1.5 million. Further total milestone payments up to €46.5 million are receivable linked to development, regulatory and launch progress of the program as well as royalties on any future net sales. The royalty rate for Vectura on this novel product development program, where Vectura has been responsible for the formulation development, is initially around a mid-single digit percentage but could increase depending on sales.

This agreement also includes the potential for further development of the triple combination treatment for chronic obstructive pulmonary disease (COPD). If Mundipharma decides to develop the program in COPD, Vectura is eligible for further potential milestones linked to the regulatory progress of the program up to €20.0 million as well as royalties payable on any future net sales of the product. The royalty rate on net sales for the COPD indication product would be the same as the asthma indication product.

In addition, Vectura will also receive one-off undisclosed sales milestones should net sales milestones of both the asthma and COPD products be achieved.

The respiratory market, worth over \$40 billion<sup>2</sup> in 2015, is expected to continue to grow, with current estimates up to 2025<sup>3</sup> predicting low single digit percentage growth. Within this, the dynamics of the classes of products are forecast to change significantly with further generic penetration of core classes such as ICS/LABA and LAMA and newer classes such as LAMA/LABA (dual bronchodilators), triple therapies and biologics expected to gain momentum. The first COPD triple (LABA/LAMA/ICS) is expected to launch in 2017<sup>4</sup> with the first asthma triple products expected to launch in 2019/20.

The first regulatory filings of VR2076 are planned in the EU for late 2022/early 2023.

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### **About Mundipharma International Corporation Limited**

Mundipharma International Corporation Limited and the network of independent associated companies are privately-owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of significant new treatment options in the core therapy areas of pain, respiratory, addiction, oncology and inflammatory conditions. Through innovation, design and acquisition, Mundipharma and the network deliver important treatments to meet the most pressing needs

of patients, healthcare professionals and health systems worldwide. For further information please visit: [www.mundipharma.com](http://www.mundipharma.com).

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**References:**

1. Forecast estimates from Decision resources Pharmacor Asthma (2016) COPD (2015) and select analyst reports Stifel Sept 2016, Leerink May 2016, JP Morgan March 2016, Citibank June 2016, N+1 Singer June 2016, Societe Generale Sep 2016
2. Source: Global Data 2016, market defined as Asthma, COPD, Allergic Rhinitis, IPF, CF, ARDS and RSV
3. Decision Resources Pharmacare Asthma & COPD 2015 (G7)
4. Based on press releases from GSK, Novartis, Chiesi, Clintrial.gov and applied standard timelines for approvals/fillings