VECTURA SIGNS GLOBAL AGREEMENT WITH HIKMA TO DEVELOP GENERIC VERSIONS OF GSK'S ELLIPTA® PORTFOLIO

On 8 November 2018, Vectura announced that it signed an agreement with Hikma Pharmaceuticals PLC for the global development and commercialisation of generic versions of GSK's Ellipta® portfolio, utilising Vectura's proprietary Open-Inhale-Close dry powder inhaler device.

By strengthening and expanding our partnership with Hikma, Vectura will develop a range of complex inhaled respiratory products that will deliver sustainable long-term growth. This presents a significant opportunity, with net sales for Ellipta® products in the US projected to be $4 billion by 2024 and approximately $5.5 billion globally.[1]

The inhaled generic respiratory market is a key area of pipeline focus for Vectura. This agreement leverages the investment already made and the experience both companies have gained through the generic Advair® Diskus® programme. The new Open-Inhale-Close (OIC) device is an evolution of Vectura's lever operated multi dose (LOMI) device used in the generic Advair programme which will enable accelerated development under this new agreement.

The Open-Inhale-Close dry powder inhaler programme includes the development of AB-rated substitutable generics of up to five GSK respiratory medicines. Vectura and Hikma have agreed to develop and commercialise at least three of the portfolio products. A substitutable generic version of Breo® Ellipta® (fluticasone furoate and vilanterol trifenatate) will be prioritised for the first wave of development. Pharmaceutical and device development work has progressed in parallel with partnering discussions.

More detailed product timings will be provided as development progresses

Summary

- Validates the utility of Vectura's market-leading formulation and DPI technology
- Provides significant short, medium and long-term revenue potential
- Upfront payment of US$15m
- Up to US$80m in development milestone payments
- Mid-teen percentage profit share arrangement for each portfolio product
- Net sales for Ellipta® products in the US projected to be $4 billion by 2024 and over $5.5bn globally[1]

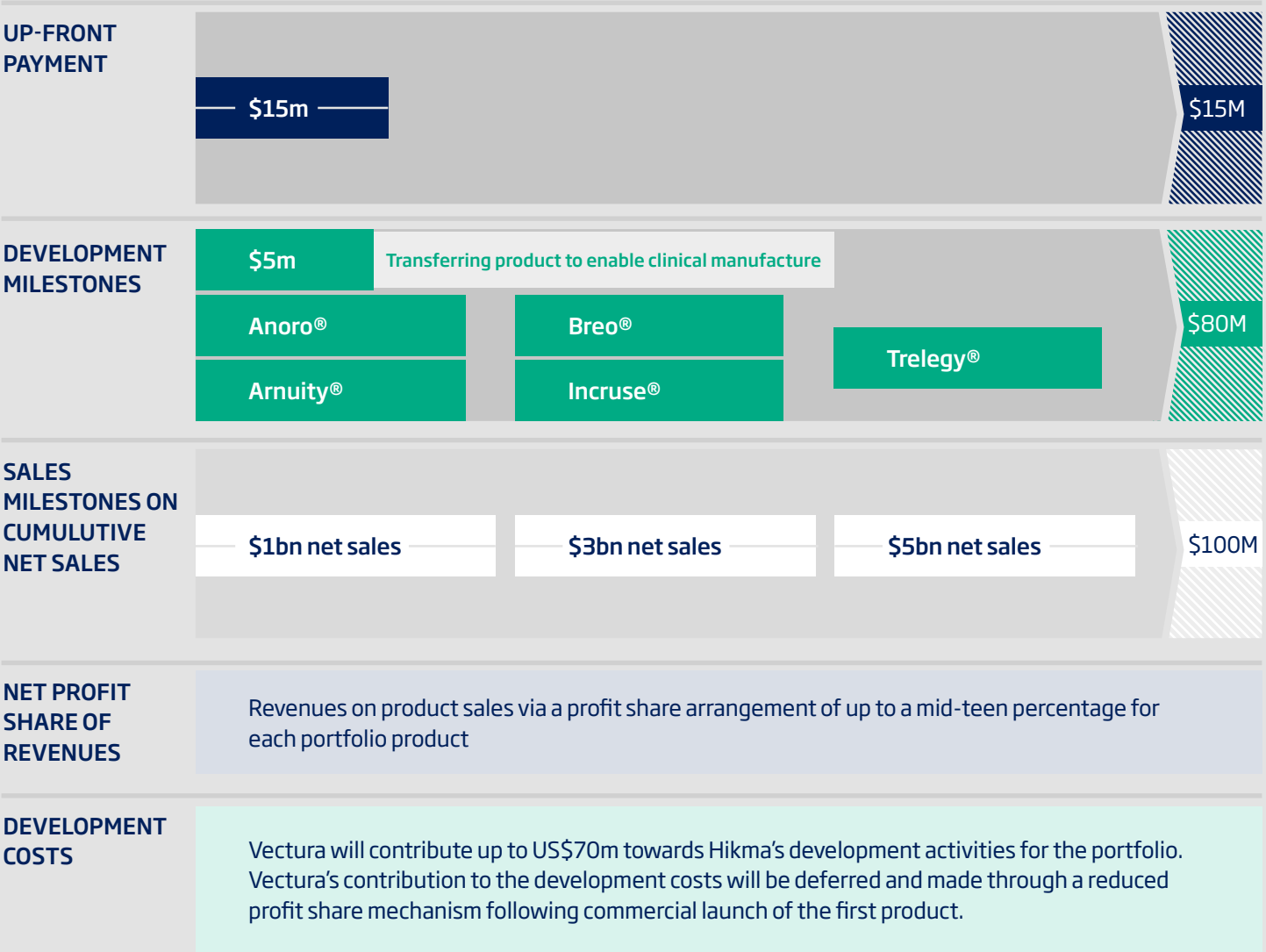
Financial Considerations

Upon signing, Vectura will receive an upfront payment of US$15m in 2018. Vectura will be responsible for, and fund, initial device and formulation development. Hikma will be responsible for clinical development, regulatory submission, manufacturing and commercialisation activities. Transfer of the first product to Hikma's manufacturing facility, to enable clinical manufacturing, will trigger a $5m milestone payment. Thereafter, Vectura will receive milestone payments of up to $75m upon achieving key development milestones, including the completion of PK studies and any required clinical trials, ANDA submissions and FDA approvals.

On approval, Vectura will receive a share of distributable net profit up to a mid-teen percentage for each portfolio product.

In the event of cumulative net global sales of the combined products reaching $1bn, $3bn and $5bn, Vectura is also eligible to receive milestone payments of $25m, $35m and $40m respectively. Vectura will contribute up to US$70m towards Hikma's development activities for the portfolio. Vectura's contribution to the development costs will be deferred and made through a reduced profit share mechanism following commercial launch of the first product. Vectura's investment in the programmes does not alter the company's R&D guidance for 2018 and 2019.

Agreement targets 5 products with global potential value of $5.6bn market by 2024



A significant commercial opportunity

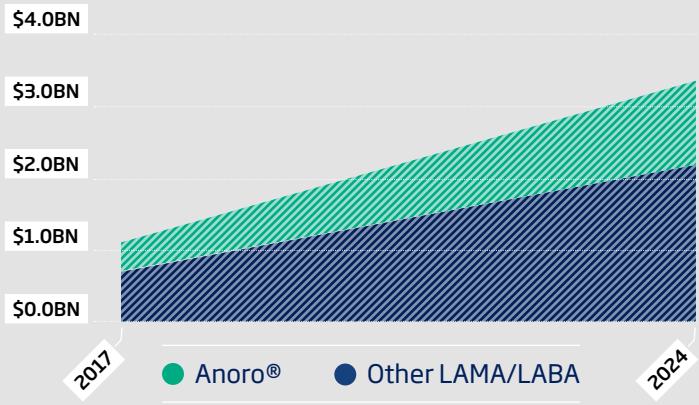
- $23bn US market size for inhaled products [2]
- More than 65m inhalants in key DPI/ pMDI maintenance classes [3]
- <1% generic conversion for key inhaled maintenance classes [4]

CLASS	PRODUCT	INDICATION(S)	2017 sales[1]	2024 forecast[1]
ICS / LABA	**Breo®/Relvar®** » fluticasone furoate; vilanterol trifenatate	Asthma & COPD	$1.3bn $775m US	$2.4bn $1.4bn US
LAMA / LABA	**Anoro®** » umeclidinium bromide; vilanterol trifenatate	COPD	$440m $301m US	$1.2bn $851m US
ICS / LABA / LAMA	**Trelegy®** » fluticasone furoate; umeclidinium; vilanterol trifenatate	COPD (approved) Asthma (pipeline)	$3m	$1.1bn
LAMA	**Incruse®** » umeclidinium bromide	COPD	$259m $173m US	$677m $452m US
ICS	**Arnuity®** » fluticasone furoate	Asthma	$45m $41m US	$173m $158m US

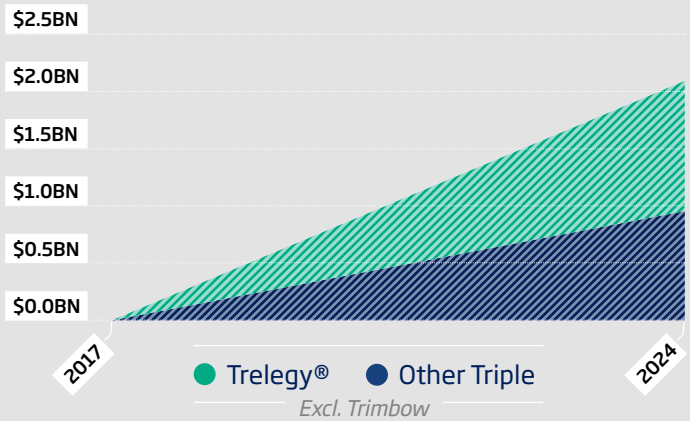
Total 2024 consensus forecast
$5.6bn
$4.0bn US

Growing global market for LAMA/LABA and triples[5]:

LAMA/LABA GLOBAL SALES CONSENSUS FORECAST



LAMA/LABA GLOBAL SALES CONSENSUS FORECAST



Excl. Trimbow

Regulatory environment:

Following recent interactions with the FDA, the Open-Inhale-Close dry powder inhaler device has the potential to be developed as an AB-rated substitutable drug-device combination for generic versions of the GSK Ellipta® portfolio.

Orange Book listed patent expiry dates (as of December 2018)	Molecule/Formulation	Device
Breo® Ellipta® (fluticasone furoate and vilanterol trifenatate)	2025	2030
Anoro® Ellipta® (vilanterol trifenatate and umeclidinium bromide)	2030	2030
Trelegy®Ellipta® (fluticasone furoate, umeclidinium bromide and vilanterol trifenatate)	2030	2030
Incruse® Ellipta® (umeclidinium bromide)	2027	2030
Arnuity® Ellipta® (fluticasone furoate)	2021	2030

OIC technology

This agreement leverages the investment already made and the experience both companies have gained through the generic Advair Diskus®programme. The new Open-Inhale-Close (OIC) device is an evolution of Vectura's lever operated multi dose (LOMI) device used in the generic Advair® programme which will enable accelerated development under this new agreement.

The Open-Inhale-Close dry powder inhaler leverages Vectura's proprietary technology from both the GyroHaler® device (marketed by Sandoz as Airflusal® Forspiro®) and the LOMI device (licensed to Hikma for VR315[US]). It has been developed to be a simple, cost effective, high volume device designed to provide therapeutically equivalent products to the Ellipta® products.

SANDOZ A Novartis Division
GyroHaler®

- Approved and marketed in > 70 Countries
- Validates core Vectura DPI blister technology

hikma.
LOMI

- VR315US under regulatory review
- Extensive real world data provides support for technology in the US market

hikma.
OIC

- Potential to be developed as an AB-rated substitutable drug-device combination for generic versions of GSK Ellipta® based products

References

[1] Global Data October 2018

[2] IQVIA SMART Q4 2017 data for inhaled classes in Asthma and COPD

[3] IQVIA SMART Q4 2017

[4] IQVIA SMART Q4 2017 – defined as pMDI and DPI ICS, ICS-LABA, LAMAs and LAMA/LABAs and LABAs and newly launched triple formulations

[5] Product forecasts sourced from Global Data October 2018 apart from Stiolto sourced from Evaluate Pharma October 2018. LABA/LAMA/ICS excludes Chiesi's Trimbow

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