

Mayne, Mithra bring novel oral contraception in the US

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Signed a 20-year exclusive supply and license agreement



Mayne Pharma, with two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA, is pleased to announce it has entered into an exclusive license and supply agreement with Belgium headquartered Mithra to commercialise E4/DRSP, a combined oral contraceptive, in the United States.

The product is expected to be launched in first half of calendar 2021, subject to US Food and Drug Administration (FDA) approval. On approval the product is expected to receive five-year New Chemical Entity (NCE) exclusivity from the FDA, with potential for patent protection beyond 2030.

E4/DRSP is a novel, next generation combined oral contraceptive composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Estetrol (E4) is a native estrogen produced by the human foetal liver during pregnancy. Following more than 20 years of research and development, Mithra can now produce Estetrol (E4) at scale through a complex plant-based production process.

Under the terms of the agreement, Mayne Pharma will pay up to \$295 million comprising \$8.75 million in cash and 4.95% of Mayne Pharma's ordinary shares at closing. Mayne Pharma will also pay \$11 million in cash and a further 4.65% of Mayne Pharma's ordinary shares following FDA approval (based on issued shares at closing), plus contingent payments based on reaching cumulative net sales targets. The total consideration of \$295 million would be paid if cumulative net sales of E4/DRSP exceed \$2.25 billion. In addition, there is a transfer price comprising fixed and variable component based on a percentage of net sales over the term of the license.