ASX Announcement

MAYNE PHARMA SIGNS EXCLUSIVE LICENSE AGREEMENT FOR THREE NOVEL WOMEN'S HEALTH PRODUCTS AND A RANGE OF PRENATAL VITAMINS IN THE US

5 December 2022, Adelaide, Australia:

- Mayne Pharma Group Limited (Mayne Pharma or Company) (ASX: MYX) has signed an exclusive license agreement with TherapeuticsMD, Inc. a NASDAQ listed company (TXMD or TherapeuticsMD) for three branded women's health products and a portfolio of prenatal vitamins in the US (License Agreement)
- ANNOVERA®, IMVEXXY® and BIJUVA® are highly novel complementary women's health products to NEXTSTELLIS® and will be marketed through Mayne Pharma's women's health team
- Significantly enhances Mayne Pharma's position in the US women's health market
- Consideration paid will include US$140m in cash along with potential sales-based milestone cash payments and sales-based royalties
- Mayne Pharma will fund the acquisition from a combination of cash, existing debt facilities and convertible notes
- Immediately additive to net profit after tax
- Orange Book listed patents until 2039 for ANNOVERA®, 2034 for IMEXXY® and 2032 for BIJUVA®
- Completion is expected by end of the calendar year 2022 pending satisfaction of customary closing conditions

Mayne Pharma is pleased to announce it has signed a transaction agreement and related license agreement for a portfolio of on-market women's health products from TherapeuticsMD, for US$140 million, a payment for acquired working capital and contingent payments based on achieving certain sales-based milestones and sales-based royalties.

Under the License Agreement the Company will exclusively license ANNOVERA®, IMVEXXY®, BIJUVA® and the BocaGreenMD® and vitaMedMD® lines of prenatal vitamins (the Products) and acquire selected assets including inventory and regulatory filings to support the operation and commercialisation of the portfolio.

ANNOVERA® (segesterone acetate/ethinyl estradiol), is a patent protected ring for birth control. It is the first and only patient-controlled, procedure free, reversible prescription birth control product to provide a full year of protection from pregnancy.

Mayne Pharma Group Limited
ABN 76 115 832 963
maynepharma.com
1538 Main North Road, Salisbury South, SA 5106 Australia

IMVEXXY® (estradiol) vaginal inserts are approved in the US for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

BIJUVA® (estradiol and progesterone) capsules are the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral daily capsule for the treatment of moderate-to-severe vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.

The Products' net revenue in the third calendar quarter 2022 were US$20.9m and gross profit was US$17.1m as reported by TherapeuticsMD[1]. Mayne Pharma will leverage its existing women's health sales team and add additional sales representatives into new territories not currently covered for Nextstellis®. Approximately, US$20m in additional annual operating expenses are expected to be provided by Mayne Pharma to support the Products.

Mayne Pharma's CEO Mr Shawn O'Brien said, "We are pleased to add these highly complementary and patent protected women's health products to our portfolio. The Products will be supported by our existing commercial capability across sales and marketing, customer service and medical affairs. Women's health is a core therapeutic area for the Company and this deal enables Mayne Pharma to accelerate and extend its position in this specialty."

"We are very attracted by the underlying fundamentals of the contraceptive and menopause market and these products provide a solid foundation to creating a market leadership position in the US women's health market.

Transaction details

Under the terms of the License Agreement, Mayne Pharma has potential one-time contingent payments to TherapeuticsMD based on reaching the following annual net revenue targets for the Products:

- US$100m in net revenue: US$5m milestone payment
- US$200m in net revenue: US$10m milestone payment
- US$300m in net revenue: US$15m milestone payment

In addition, during a 20-year royalty term, a royalty is payable to TherapeuticsMD at ~8% of net revenue which will reduce to 2% if certain events happen such as loss of exclusivity or the patent term expires. Mayne Pharma will receive a fully paid-up license following the royalty term. Mayne Pharma will pay TherapeuticsMD minimal annual royalties of US$3.0 million per year for 12 years, adjusted for inflation at an annual rate of 3%, subject to certain further adjustments including a reduction if certain events happen such as loss of exclusivity or the patent term expires for ANNOVERA®.

Mayne Pharma will also make a payment of approximately US$13.1m for the acquisition of net working capital, in exchange for inventory, accounts receivables and related liabilities, subject to certain adjustments.

[1] ANNOVERA® royalties payable by TherapeuticsMD to the Population Council in 2022 are 5% of annual net revenue up to US$50m; 10% of annual net revenue between US$50m and US$150m; and 15% of net revenue >US$150m

Mayne Pharma has an in principal agreement which is currently being finalised to pay a license fee of US$13m to the Population Council, owner of the ANNOVERA® IP in 2025. Under this agreement, Mayne Pharma may pay up to US$80m of additional contingent payments to the Population Council, owner of the ANNOVERA® IP, based on reaching cumulative net revenue targets for ANNOVERA®:

- US$400m in cumulative net revenue: US$40m
- US$1b in cumulative net revenue: US$40m
- Cumulative ANNOVERA® net revenues were US$101m from launch to 30 September 2022
- 3QCY22 ANNOVERA® net revenues were US$10.4m

ANNOVERA® royalties payable to the Population Council will be 10% of net revenue up to US$150m in annual net revenue and 15% of net revenue greater than US$150m. Mayne Pharma will provide a further update if there are any material changes to the above in principal agreement once it is finalised.

Completion of the transaction is subject to expiration of the applicable waiting period under the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Mayne Pharma expects to close the transaction on or prior to 30 December 2022.

Mayne Pharma will fund the initial US$140 million payment to TherapeuticsMD from cash and existing debt facilities and through a binding commitment from Rubric Capital Management LP (Rubric Capital) for approximately US$27.95m (face value) in the form of an unsecured senior convertible note at a price equal to 90% of the face value. The maximum number of shares issued to Rubric Capital will be the lesser of 178,863,974 shares (on a pre-share consolidation basis) and 9.61% of Mayne Pharma's issued capital. The conversion price on the convertible note will be $0.295, adjusted for certain events including dividends and capital return (a 23% premium over the closing price of Mayne Pharma shares on 2 December 2022). The interest rate on the convertible notes is 2.5% per annum on the unconverted value. The convertible note is exercisable by Rubric Capital between 6 to 48 months after the issue date of the convertible note, or earlier if a change of control event occurs in respect of Mayne Pharma. The convertible note terms will be set out further in definitive agreements and the convertible notes will be issued on completion of the License Agreement. This investment commitment by Rubric Capital, a current shareholder of TherapeuticsMD, represents a continued commitment and belief in these women's health assets.

For further information contact:
Shawn Patrick O'Brien +61 3 8614 7706
IR@maynepharma.com

Authorised for release to the ASX by the Chair

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.

About ANNOVERA®

The ANNOVERA® one-year contraceptive vaginal system combines a widely used estrogen (ethinyl estradiol) with a progestin segesterone acetate (NESTORONE®) into a single ring to prevent pregnancy for an entire year (13 cycles; used in repeated four-week cycles (remaining in place continuously for three weeks followed by removal for one week)). ANNOVERA represents the first and only long-lasting birth control product that is reversible and does not require a medical procedure for insertion or removal. The soft, flexible ring can be inserted and removed by the woman herself and without the help of a healthcare professional. The one-year vaginal system represents a new option for women, including nulliparous women (women who have not given birth) desiring long-lasting reversible contraception. The one-year contraceptive vaginal system does not require refrigeration.

About IMVEXXY®

IMVEXXY (estradiol vaginal inserts) is approved in the US for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. IMVEXXY is the only product in its therapeutic class to offer a 4mcg and 10mcg dose. The 4 mcg dose representing the lowest approved dose of vaginal estradiol available.

About BIJUVA®

BIJUVA is the first and only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule for the treatment of moderate-to-sever vasomotor symptoms (commonly known as hot flashes or flushes) due to menopause in women with a uterus.