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Mirum Pharmaceuticals Enters Agreement to Acquire Bile Acid Product Portfolio for the Treatment of Rare Liver Diseases from Travere Therapeutics

- *Mirum to acquire all of Travere's rights and assets related to Cholbam® and Chenodal®*
- *Travere to receive up to $445 million with $210 million upfront and up to $235 million in potential sales-based milestones*
- *Mirum announces concurrent private placement of $210 million, funding upfront payment*
- *Expands Mirum's leadership in rare liver disease with two commercial products and a near-term Phase 3 label expansion opportunity*
- *Advances Travere's strategy to deliver new treatment standards from its pipeline of innovative medicines for rare diseases and strengthens financial foundation*
- *Mirum to host conference call today, July 17, 2023, at 8:30 a.m. ET/5:30 a.m. PT*

July 17, 2023 08:00 AM Eastern Daylight Time

FOSTER CITY, Calif. & SAN DIEGO--(BUSINESS WIRE)--Mirum Pharmaceuticals, Inc. (NASDAQ: MIRM) and Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced that they have entered into a definitive agreement for the sale of Travere's bile acid product portfolio that includes Cholbam® (cholic acid) and Chenodal® (chenodiol), two medications addressing rare diseases in high-need settings.

Under the terms of the definitive agreement, Mirum will purchase Travere's bile acid product portfolio for $445 million, consisting of $210 million upfront and $235 million in potential sales-based milestone payments. Mirum will acquire Travere's rights to Cholbam®, indicated for the treatment of bile acid synthesis disorders due to single enzyme deficiencies and adjunctive treatment of peroxisomal disorders in patients who show signs or symptoms of liver disease, and Chenodal®, indicated for the treatment of radiolucent stones in the gallbladder, which is also under Phase 3 clinical evaluation for cerebrotendinous xanthomatosis (CTX).

Mirum has secured $210 million in funding from a syndicate of existing investors led by Frazier Life Sciences and other existing stockholders and new investors that include Avidity Partners, BVF Partners, Longitude Capital, Sofinnova Investments, Inc. and a healthcare investment fund to finance the upfront payment for the acquisition.

“The addition of the bile acid replacement therapies from Travere will strengthen our pipeline and offer an opportunity to leverage our unique expertise in the development and commercialization of treatments in rare and underserved liver diseases,” said Chris Peetz, president and chief executive officer at Mirum. “This synergistic acquisition of the bile acid portfolio along with the opportunity to sponsor the genetic testing program will help to reinforce our leadership position in pediatric hepatology. We look forward to building on the meaningful work initiated by the talented Travere team and delivering on our commitment to advancing research and bringing treatments to rare liver disease patients in need.”

“This agreement is an important step forward in Travere's strategy to deliver our pipeline of innovative medicines to patients living with rare disease,” said Eric Dube Ph.D., president and chief executive officer of Travere Therapeutics. “The sale of the bile acid portfolio will enable us to further focus our efforts on the ongoing, and successful launch of FILSPARI™ for IgA nephropathy, pursuing a potential regulatory path forward for sparsentan in FSGS, and the development of pegtibatinase for the treatment of classical homocystinuria, all of which we believe have the potential to be future treatment standards in their respective indications. This divestment will also strengthen our financial foundation by meaningfully extending our cash runway and allow us to maximize our growth potential. We look forward to working with Mirum to ensure a seamless transition and continuing the commitment to delivering these important medicines to patients in the rare liver disease community.”

Transaction Details

Per the terms of the agreement, Mirum will acquire Travere’s rights to the bile acid product portfolio consisting of Cholbam® and Chenodal®. Travere will receive an upfront payment of $210 million and be eligible for up to $235 million in sales-based milestone payments based on annual net sales thresholds tiered from $125 to $500 million. Travere has also agreed to provide certain transitional services. The transaction is expected to close in the third quarter of 2023, subject to regulatory clearance and customary closing conditions.

Concurrent with entering into the definitive agreement to acquire Travere’s bile acid portfolio, Mirum has also entered into a definitive agreement for the sale of common stock in a private placement. The private placement was oversubscribed and is expected to result in gross proceeds to Mirum of approximately $210 million before deducting placement agent and other offering expenses. The proceeds from the private placement are intended to fund the up-front payment for the acquisition of Travere’s bile acid portfolio.

For Travere, Lazard is acting as financial advisor and Cooley is acting as legal advisor. For Mirum, Evercore is advising on the acquisition and Gibson, Dunn & Crutcher is acting as legal advisor. Morgan Stanley and Evercore are serving as financial advisors on the accompanying equity financing, with Latham & Watkins advising the placement agents.

Mirum to Host Conference Call

Mirum will host a conference call today, July 17, 2023 at 8:30 a.m. ET/5:30 a.m. PT, to provide further details on the transaction. Join the call using the following information:

United States/Toll-free: 1-833-470-1428
International: 1-404-975-4839
Access code: 341495

You may also access the call via webcast by visiting the Events & Presentations section on Mirum’s website. A replay of this webcast will be available for 30 days.

About Cholbam® (cholic acid)

The FDA approved Cholbam® (cholic acid) capsules) in March 2015, the first FDA-approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects, and for adjunctive treatment of patients with peroxisome biogenesis disorder-Zellweger spectrum disorder. The effectiveness of Cholbam® has been demonstrated in clinical trials for bile acid synthesis disorders and the adjunctive treatment of peroxisomal disorders. An estimated 200 to 300 patients are current candidates for therapy.

CHOLBAM® (cholic acid) Indication

Cholbam is a bile acid indicated for

- Treatment of bile acid synthesis disorders due to single enzyme defects.
- Adjunctive treatment of peroxisomal disorders, including Zellweger spectrum disorders, in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

LIMITATIONS OF USE

The safety and effectiveness of CHOLBAM on extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects or peroxisomal disorders, including Zellweger spectrum disorders, have not been established.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS – Exacerbation of liver impairment

- Monitor liver function and discontinue CHOLBAM in patients who develop worsening of liver function while on treatment.
- Concurrent elevations of serum gamma glutamyltransferase (GGT) and alanine aminotransferase (ALT) may indicate CHOLBAM overdose.
- Discontinue treatment with CHOLBAM at any time if there are clinical or laboratory indicators of worsening liver function or cholestasis.

ADVERSE REACTIONS

- The most common adverse reactions (≥1%) are diarrhea, reflux esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy.

DRUG INTERACTIONS

- Inhibitors of Bile Acid Transporters: Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitoring of serum transaminases and bilirubin is recommended.
- Bile Acid Binding Resins: Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the efficacy of CHOLBAM. Take CHOLBAM at least 1 hour before or 4 to 6 hours (or at as great an interval as possible) after a bile acid binding resin.
- Aluminum-based Antacids: Aluminum-based antacids have been shown to adsorb bile acids *in vitro* and can reduce the bioavailability of CHOLBAM. Take CHOLBAM at least 1

hour before or 4 to 6 hours (or at as great an interval as possible) after an aluminum-based antacid.

PREGNANCY

No studies in pregnant women or animal reproduction studies have been conducted with CHOLBAM. Women who become pregnant during CHOLBAM treatment are encouraged to call 1-844-202-6262.

LACTATION

Endogenous cholic acid is present in human milk. Clinical lactation studies have not been conducted to assess the presence of CHOLBAM in human milk, the effects of CHOLBAM on the breastfed infant, or the effects of CHOLBAM on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CHOLBAM and any potential adverse effects on the breastfed infant from CHOLBAM or from the underlying maternal condition.

GERIATRIC USE

It is not known if elderly patients respond differently from younger patients.

HEPATIC IMPAIRMENT

- Discontinue treatment with CHOLBAM if liver function does not improve within 3 months of the start of treatment.
- Discontinue treatment with CHOLBAM at any time if there are clinical or laboratory indicators of worsening liver function or cholestasis. Continue to monitor laboratory parameters of liver function and consider restarting at a lower dose when the parameters return to baseline.

OVERDOSAGE

Concurrent elevations of serum GGT and serum ALT may indicate CHOLBAM overdose. In the event of overdose, the patient should be monitored and treated symptomatically. Continue to monitor laboratory parameters of liver function and consider restarting at a lower dose when the parameters return to baseline.

Please see full Prescribing Information for additional Important Safety Information.

About Chenodal® (chenodiol)

Chenodal® is a synthetic oral form of chenodeoxycholic acid ("CDCA"), a naturally occurring primary bile acid synthesized from cholesterol in the liver. The FDA approved Chenodal for the treatment of people with radiolucent stones in the gallbladder. In 2010, Chenodal was granted orphan drug designation for the treatment of cerebrotendinous xanthomatosis ("CTX"), a rare autosomal recessive lipid storage disease.

While Chenodal® is not currently labeled for CTX, it received a medical necessity determination in the US by the FDA and has been used as the standard of care for more than three decades. Travere is working to obtain FDA approval of Chenodal for the treatment of CTX and initiated a Phase 3 clinical trial for this indication in January 2020. The prevalence of CTX is estimated in the literature to be as high as 1 in 70,000 in the overall population.

About Mirum Pharmaceuticals, Inc.

Mirum Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to transforming the treatment of rare liver diseases. Mirum's approved medication is LIVMARLI® (maralixibat) oral solution which is approved in the U.S. for the treatment of cholestatic pruritus in patients with Alagille syndrome three months of age and older, and in Europe for the same indication in patients two months of age and older.

Mirum has also submitted LIVMARLI for approval in the U.S. in cholestatic pruritus in PFIC patients three months of age and older and in Europe in PFIC for patients two months of age and older.

Mirum's late-stage pipeline includes two investigational treatments for debilitating liver diseases affecting children and adults. LIVMARLI, an oral ileal bile acid transporter (IBAT) inhibitor, is currently being evaluated in clinical trials for pediatric liver diseases and includes the EMBARK Phase 2b clinical trial for patients with biliary atresia. In addition, Mirum has an expanded access program open across multiple countries for eligible patients with ALGS and PFIC.

Mirum's second investigational treatment, volixibat, an oral IBAT inhibitor, is being evaluated in two potentially registrational studies including the VISTAS Phase 2b clinical trial for adults with primary sclerosing cholangitis and the VANTAGE Phase 2b clinical trial for adults with primary biliary cholangitis.

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About Travere Therapeutics

At Travere Therapeutics, we are in rare for life. We are a biopharmaceutical company that comes together every day to help patients, families and caregivers of all backgrounds as they navigate life with a rare disease. On this path, we know the need for treatment options is urgent – that is why our global team works with the rare disease community to identify, develop and deliver life-changing therapies. In pursuit of this mission, we continuously seek to understand the diverse perspectives of rare patients and to courageously forge new paths to make a difference in their lives and provide hope – today and tomorrow. For more information, visit travere.com

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements, including those regarding the timing, and consummation and anticipated benefits of, the transactions described herein involve risks and uncertainties. The Company's experience and results may differ materially from the experience and results anticipated in such statements. The accuracy of such statements is subject to a number of risks, uncertainties and assumptions including, but are not limited to, the following factors: litigation relating to the transactions (the "Asset Purchase") discussed; risks that the Asset Purchase disrupts the current plans or operations of the Company; the ability of the Company to retain and hire key personnel; competitive responses to the Asset Purchase; unexpected costs, charges or expenses resulting from the Asset Purchase; potential adverse reactions or changes to relationships with customers, suppliers, distributors and other business partners resulting from the announcement or completion of the Asset Purchase; the Company's ability to achieve the synergies expected from the Asset Purchase, as well as delays, challenges and expenses associated with integrating the businesses; the impact of overall industry and general economic conditions, including inflation, interest rates and related monetary policy by governments in response to inflation; geopolitical events, and regulatory, economic and other risks associated therewith; and continued uncertainty resulting from broader macroeconomic conditions. Other factors that might cause such a difference include those discussed in the Company's filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Mirum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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