

## Anthera Pharmaceuticals Provides Business Update and Reports 2016 Fourth Quarter and Fiscal Year Financial Results

- SOLUTION study with Sollpura<sup>™</sup> missed non-inferiority endpoint by 1%, prompting new phase 3 study
- Data Monitoring Committee issued recommendation to continue SIMPLICITY study with Sollpura™
- Blisibimod for the treatment of IgA Nephropathy demonstrated positive trends at week 48
- Blisibimod for the treatment of systemic lupus terminated
- Craig Thompson appointed to serve as Chief Executive Officer and Director

HAYWARD, Calif., Feb. 27, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (Nasdaq:ANTH) today provided a business update and reported financial results for the 2016 fourth quarter and the fiscal year ending December 31, 2016.

#### **Recent Developments and Business Highlights:**

Sollpura™ (liprotamase) for the treatment of Exocrine Pancreatic Insufficiency ("EPI")

Phase 3 SOLUTION Clinical Study missed primary endpoint; additional study is needed
On December 27, 2016, we announced topline data from the SOLUTION phase 3 clinical study of Sollpura™ in
patients with EPI due to cystic fibrosis (CF), which showed the study narrowly missed (by 1%) the primary endpoint of
non-inferiority to porcine pancreatic enzyme replacement therapy based on the Coefficient of Fat Absorption (CFA) in
the modified Intent to Treat population ("mITT"). However, by additional pre-specified analyses of CFA (mITTBaseline Observation Carried Forward and Per Protocol), Sollpura™ met the non-inferiority criterion. Also, the fixed
ratio of the three enzymes in Sollpura™ demonstrated an appropriate response in the Coefficient of Nitrogen
Absorption ("CNA"). We expect to release data from the extension phase of the study around the end of the first
quarter of 2017.

Data from the SOLUTION study identified that, for some patients, higher doses may be necessary to compensate for the lower solubility of Sollpura™ under the acidic upper small intestinal conditions found in many patients with EPI due to CF. The upper small intestine plays a critical role in the digestion of lipids and other nutrients.

#### Phase 3 RESULT Clinical Study

Following the outcome of the SOLUTION study, we began preparations for a new phase 3 study, RESULT. Similar to SOLUTION, the RESULT study will be a randomized, open-label, non-inferiority, active-comparator study in approximately 150 CF patients who are porcine PERT responders. As in the SOLUTION study, the primary endpoint will be CFA at week 7. RESULT will incorporate key learnings from the SOLUTION study, especially with respect to the need for individual optimization of the lipase dose to achieve desired efficacy. Changes include a higher starting dose of Sollpura™, allowance for frequent dose adjustments as needed during the first six weeks, and a higher cap on the maximum allowable lipase dose. Topline data from the RESULT study is expected around the end of 2017 or early 2018.

#### SIMPLICITY Clinical Study

Part A of the SIMPLICITY study, which evaluated the efficacy and safety of Sollpura™ supplied as a powder for oral solution in 15 patients ≥7 years of age, was completed in the fourth quarter of 2016. An independent Data Monitoring Committee evaluated the data from Part A and unanimously determined that it is safe to enroll ~30 subjects younger than 7 years of age into Part B of the study. Based on the data from the SOLUTION study, we plan to amend the SIMPLICITY study to follow a similar dosing paradigm as the RESULT study. We expect to start enrolling patients in Part B of the SIMPLICITY study towards the end of the first quarter of 2017, with topline data expected in the fourth quarter of 2017. For more information on the study, please visit <a href="http://www.anthera.com/clinical-studies/simplicity-study/">http://www.anthera.com/clinical-studies/simplicity-study/</a>.

#### EASY Clinical Study

During the third quarter of 2016, we initiated the EASY study, which provides continued access to Sollpura<sup>™</sup> for patients who complete the SOLUTION study. The EASY study will also be offered to subjects completing the RESULT and SIMPLICITY studies. We plan to continue the EASY study until the Biologic License Application ("BLA") for Sollpura<sup>™</sup> is approved by the U.S. Food and Drug Administration ("FDA").

#### Manufacturing

Manufacturing efforts continue to be on track with the completion of tech transfer of all three active pharmaceutical ingredients ("APIs") at commercial scale and the initiation of process validation.

#### Blisibimod for the treatment of IgA Nephropathy

#### Longer-Term Evaluation Continues in Phase 2 BRIGHT-SC Clinical Study

On December 6, 2016, we announced positive trends from the week 48 data analysis of the Phase 2 BRIGHT-SC clinical study. The positive trend in lower proteinuria in blisibimod versus placebo treated patients was sustained in subjects treated for a least 48 weeks and up to 104 weeks, supporting continuation of the study until all patients have had the opportunity to complete two years of treatment. Data from the 2-year evaluation is expected at the end of this year or in early 2018. For more information about the BRIGHT-SC study, visit <a href="http://www.anthera.com/clinical-studies/bright-sc/">http://www.anthera.com/clinical-studies/bright-sc/</a>.

#### Blisibimod for the treatment of Systemic Lupus Erythematosus ("SLE")

### Phase 3 CHABLIS-SC1 Clinical Study Failed to Meet Primary Endpoint

On November 10, 2016, we announced the CHABLIS-SC1 clinical study with blisibimod for the treatment of SLE failed to meet its primary endpoint based upon the SLE Responder Index-6 (SRI-6) at 52 weeks. Although 47% of patients in the blisibimod arm versus 42% of patients in the placebo arm achieved this endpoint, the difference was not statistically significant. The SRI is a composite index comprised of SELENA-SLEDAI, BILAG and Physician Global Assessment (PGA) criteria. In addition to meeting BILAG and PGA criteria, a SRI-6 response requires a decrease of at least 6 points in SELENA-SLEDAI. Following careful analysis of the data, we decided to discontinue the development of blisibimod for SLE.

#### Phase 3 CHABLIS 7.5 Clinical Study Terminated

Following the outcome of the CHABLIS-SC1 clinical study, we halted enrollment in the Chablis 7.5 study and began close-out activities.

#### Management Update

- On December 6, 2016, Craig Thompson was promoted to Chief Executive Officer and appointed to serve as a member of the Board of Directors. Mr. Thompson joined Anthera at the beginning of 2016 with over 20 years of experience in the pharmaceutical and healthcare industries.
- On December 2, 2016, Paul Truex stepped down as Chief Executive Officer and was appointed to serve as the Executive Chairman of the Board. In conjunction with the transition, Dr. Christopher Henney stepped down as Chairman of the Board, and continues to serve as a member of our Board of Directors.

#### **Summary of Financial Results**

- Cash Position. We ended the fourth quarter of 2016 with cash and cash equivalents totaling \$20.8 million, compared to \$47.0 million as of December 31, 2015. The decrease in cash is mainly attributable to \$48.9 million used to fund our clinical development programs in 2016, offset by approximately \$16.8 million and \$6.4 million in net proceeds received from the sale of convertible preferred stock through a registered direct offering and common stock through an at-the-market equity offering program, respectively.
- R&D Expense. Research and development expenses for the three months and year ended December 31, 2016 totaled \$10.8 million and \$46.5 million, respectively, compared to \$8.6 million and \$33.5 million for the corresponding periods in 2015. The increase in 2016 from 2015 is primarily due to costs associated with acceleration of the manufacturing scale-up timeline, including the production of demonstration and registration batches at commercial launch scale for Sollpura™. Additionally, clinical development expense increased from the prior year due to the initiation of three new clinical studies, namely the CHABLIS-7.5 study with blisibimod in severe lupus patients, the SIMPLICITY study with Sollpura™ in sachet formulation and the EASY study which provides continued access to Sollpura™ for patients who rolled off the SOLUTION clinical study.
- **G&A Expense**. General and administrative expenses for the three months and year ended December 31, 2016 totaled \$3.8 million and \$11.1 million, respectively, compared to \$1.9 million and \$7.6 million for the corresponding periods in 2015. The increase is primarily due to higher non-cash stock-based compensation expense recognized in 2016 and higher expense related to professional services to support the Company.
- Net Loss. Net loss for the three months and year ended December 31, 2016 was \$13.0 million and \$55.5 million, respectively, compared to \$7.3 million and \$35.2 million for the corresponding periods in 2015. The increase in net loss is mainly attributable to the increase in manufacturing expense for Sollpura™ and clinical study expense for both

Sollpura<sup>™</sup> and blisibimod in 2016.

Net Loss Applicable to Common Stockholders. In connection with the September 2016 registered direct offering of convertible preferred stock, warrants and options to purchase future shares of convertible preferred stock, there is an in-the-money conversion feature (beneficial conversion feature, or BCF). The BCF required separate financial statement recognition and recorded as a discount to the preferred shares and was immediately accreted as a deemed dividend because the shares were contingently redeemable. For the quarter and year ended December 31, 2016, we recorded a deemed dividend of \$2.1 million and \$10.9 million, respectively.

#### **About Anthera Pharmaceuticals**

Anthera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing and commercializing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency and IgA nephropathy. Additional information on the Company can be found at <a href="https://www.anthera.com">www.anthera.com</a>.

#### Safe Harbor Statement

Any statements contained in this press release that refer to future events or other non-historical matters, including statements that are preceded by, followed by, or that include such words as "estimate," "intend," "anticipate," "believe," "plan," "goal," "expect," "project," or similar statements, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are based on Anthera's expectations as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including but not limited to those set forth in Anthera's public filings with the SEC, including Anthera's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. Anthera disclaims any intent or obligation to update any forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

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# ANTHERA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except share and per share data) (unaudited)

	Three months ended December 31,			Year ended December 31,				
		2016		2015		2016		2015
Revenues:								
License fee revenue	\$	_	\$	1,819	\$	139	\$	2,562
Collaborative revenue				99		6		623
Total revenues				1,918		145		3,185
Operating expenses:								
Research and development	\$	10,825	\$	8,605	\$	46,512	\$	33,498
General and administrative		3,754		1,874		11,071		7,568
Research award				(1,171)		(261)		(2,638)
Total operating expenses		14,579		9,308		57,322		38,428
Loss from operations		(14,579)		(7,390)		(57,177)		(35,243)
Other income (expense):								
Other income (expense)	\$	19	\$	51	\$	(90)	\$	23
Change in fair value of warrant liability		1,575				1,744		<u> </u>
Net loss		(12,985)		(7,339)		(55,523)		(35,220)
Deemed dividends attributable to preferred stock		(2,107)				(10,914)		
Net loss applicable to common stockholders	\$	(15,092)		(7,339)	\$	(66,437)		(35,220)
Net loss per share—basic and diluted	\$	(0.36)	\$	(0.18)	\$	(1.61)	\$	(0.99)
Weighted-average number of shares used in								

# ANTHERA PHARMACEUTICALS, INC. BALANCE SHEET DATA (in thousands, except share data) (unaudited)

	Dec	ember 31, 2016	December 31, 2015		
Cash and cash equivalents	\$	20,843	\$	46,951	
Accounts receivable	\$	_	\$	326	
Total assets	\$	23,471	\$	48,125	
Total deferred revenue	\$	_	\$	138	
Total liabilities, excludes deferred revenue	\$	10,624	\$	8,330	
Series X contingently redeemable convertible preferred stock	\$	377	\$	_	
Series X convertible preferred stock	\$	8,614	\$	_	
Common Stock and additional paid-in capital	\$	411,410	\$	391,688	
Accumulated deficit	\$	(407,554)	\$	(352,031)	
Total shareholders' equity	\$	12,470	\$	39,657	
Common shares outstanding	4	15,964,286		40,004,037	
Series X convertible preferred shares outstanding		9,499		_	

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