

Aytu BioPharma Announces Approval of the Cotempla XR-ODT® Manufacturing Site Transfer Prior Approval Supplement

***U.S. Food & Drug Administration Approval of the Prior Approval Supplement (PAS)
Enables Transfer of Cotempla Production to Contract Manufacturer***

Upon Completion of Manufacturing Transfer of Adzenys XR-ODT and Cotempla XR-ODT, Company Expects to Report Enhanced ADHD Product Margins

DENVER, CO / October 26, 2023 / Aytu BioPharma, Inc. (the Company or “Aytu”) (NASDAQ:AYTU), a pharmaceutical company focused on commercializing novel therapeutics, announced receipt of U.S. Food & Drug Administration (FDA) approval of the Cotempla XR-ODT® (“Cotempla”) Prior Approval Supplement (PAS). This approval enables the transfer of manufacturing of Cotempla to the Company’s third-party manufacturer and follows a similar achievement for Adzenys XR-ODT® (“Adzenys”) which received PAS approval in April 2023.

“I’m pleased to report this important milestone as we work to lower our overhead costs and improve the margins of our ADHD products by transferring the production of our ADHD brands to a contract manufacturer,” remarked Josh Disbrow, Aytu’s Chief Executive Officer. “Our team has worked diligently and performed a tremendous job in advancing the site transfer of these flagship ADHD brands. I am appreciative of the team’s multi-year effort in running bioequivalence studies, securing strong contract manufacturing and packaging partners, and successfully navigating the regulatory process involved in this transfer.”

Aytu is committed to a consistent and orderly transition of production to the new manufacturing facility in the coming months to ensure adequate inventory is available to meet the recent surge in prescription growth experienced for both Adzenys and Cotempla.

Disbrow expanded, “With both Adzenys and Cotempla PAS approvals now achieved, we have greater visibility into the timing of the site transfer process and expect to begin the initial ramp-up of contract manufacturing of Adzenys and Cotempla in late calendar 2023. Production of Adzenys at the contract manufacturer is already underway. The transfer of production to our contract manufacturer, coupled with the exiting of operations at the Grand Prairie, Texas manufacturing facility, will allow us to realize enhanced margin improvement in these ADHD products beginning in calendar 2024.”

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company commercializing a portfolio of commercial prescription therapeutics. The Company’s prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including

Boxed WARNING) for the treatment of attention deficit hyperactivity disorder (ADHD), Karbinal® ER (carbinoxamine maleate), an extended-release antihistamine suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines available in various formulations for infants and children with fluoride deficiency. To learn more, please visit aytubio.com.

Forward-Looking Statement

This press release includes 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, or the Exchange Act. All statements other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. All statements other than statements of historical facts contained in this press release, are forward-looking statements. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others, risks associated with the Company's ability to realize cost savings and to transfer manufacturing of its ADHD products to a third-party contract manufacturer and the timing associated with these. We also refer you to (i) the risks described in 'Risk Factors' in Part I, Item 1A of Aytu's most recent Annual Report on Form 10-K and in the other reports and documents it files with the Securities and Exchange Commission.

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