

Aytu BioPharma Announces Approval of Adzenys XR-ODT® Manufacturing Site Transfer

U.S. Food & Drug Administration Approval of Prior Approval Supplement Enables Transfer of Adzenys Production to Contract Manufacturer in 2023

Upon Completion of Manufacturing Transfer of Adzenys XR-ODT and Cotelpla XR-ODT, Company Expects to Improve ADHD Product Margins by an Estimated 15%

ENGLEWOOD, CO / April 27, 2023 / Aytu BioPharma, Inc. (the “Company” or “Aytu”) (NASDAQ:AYTU), a commercial stage pharmaceutical and consumer health company providing pediatric-focused prescription drugs and cost-effective consumer health solutions, received U.S. Food & Drug Administration (“FDA”) approval of the Adzenys XR-ODT® (“Adzenys”) Prior Approval Supplement (“PAS”). This approval enables the transfer of manufacturing of Adzenys to the Company’s third-party manufacturer.

Additionally, the Cotelpla XR-ODT® (“Cotelpla”) bioequivalence study has been successfully completed. Accordingly, the Company expects to submit the Cotelpla site transfer PAS to the FDA in the middle of calendar 2023, with approval expected thereafter. The Company expects a six-month review of the PAS, which would enable FDA approval by late calendar 2023 or early calendar 2024.

“I’m pleased to report these two important milestones as we work to improve the margins of our ADHD products by transferring the manufacturing of our ADHD brands to a contract manufacturer,” commented Josh Disbrow, Aytu’s Chief Executive Officer. “Our team has done a tremendous job in advancing the site transfer of these important ADHD brands, and I am grateful for the team’s efforts throughout this extensive operational and regulatory process. With both milestones now achieved, we have greater visibility into the timing of the site transfer and expect to begin manufacturing Adzenys and Cotelpla at the contract manufacturer’s site in late 2023 and early 2024, respectively. Thus, we expect to begin realizing margin improvement for the ADHD brands starting in early calendar 2024. As we have communicated, upon the completion of the site transfers of both products and exiting the Grand Prairie, Texas facility, we expect to realize an estimated 15% margin improvement of the ADHD brands.”

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company commercializing a portfolio of commercial prescription therapeutics and consumer health products. The Company’s prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotelpla 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. Aytu's consumer health segment markets a range of over-the-counter medicines, personal care products, and dietary supplements addressing a range of common conditions including diabetes, allergy, hair regrowth, and gastrointestinal conditions. 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, gain margin improvement and to transfer manufacturing of its ADHD products to a third-party contract manufacturer. 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.

Contacts for Investors:

Mark Oki, Chief Financial Officer
Aytu BioPharma, Inc.
moki@aytubio.com

Robert Blum or Roger Weiss
Lytham Partners
AYTU@lythampartners.com

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