

## **Aytu BioPharma Announces Submission of Cotempla XR-ODT® Manufacturing Site Transfer Prior Approval Supplement**

***Company Expects a Six-Month Review of the Prior Approval Supplement Submission by the U.S. Food & Drug Administration Which, if Approved, Enables the Transfer of Cotempla Production to Contract Manufacturer***

***Upon Completion of Manufacturing Transfer of Adzenys XR-ODT and Cotempla XR-ODT, Company Expects to Improve ADHD Product Margins by an Estimated Fifteen Percent***

**ENGLEWOOD, CO / July 10, 2023** / Aytu BioPharma, Inc. (the Company or “Aytu”) (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, has submitted the Cotempla XR-ODT® (“Cotempla”) Prior Approval Supplement (PAS) to the U.S. Food & Drug Administration (FDA). If approved, the PAS would enable Aytu to transfer the production of Cotempla to the Company’s third-party manufacturer. The Company expects a six-month review of the PAS submission, which would enable FDA approval by late calendar 2023 or early calendar 2024. The Company previously announced the FDA approval of the Adzenys XR-ODT® (“Adzenys”) site transfer PAS and has begun shifting Adzenys production to the Company’s contract manufacturer.

“I’m pleased to report this additional milestone as we work to increase the profitability of our products by reducing the cost of goods sold and the expenses associated with the production of our ADHD products by leveraging the operating efficiencies of our contract manufacturer,” commented Josh Disbrow, Aytu’s Chief Executive Officer. “With this additional step now achieved, we have even greater visibility into the timing of the site transfer and expect to begin outsourced manufacturing of Adzenys and Cotempla by late 2023 or early 2024. Importantly, we have already begun shifting production of Adzenys to Aytu’s contract manufacturer. Thus, we expect to start realizing margin improvements for the ADHD brands in early calendar 2024. As we have previously communicated, upon the completion of the site transfers of both products and exiting the former Neos Therapeutics Grand Prairie, Texas facility, we expect to realize an estimated fifteen percent margin improvement of the ADHD brands. I am grateful for our team’s tremendous effort and applaud their hard work in advancing the site transfer of these important 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 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. Aytu's consumer health segment markets a range of over-the-counter medicines and consumer health products addressing a range of common conditions including diabetes, allergy, hair regrowth, and gastrointestinal conditions. To learn more, please visit [aytubio.com](http://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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