Aytu BioPharma Announces Patent Term Extension for EXXUA™

DENVER, CO / ACCESS Newswire / October 28, 2025 / Aytu BioPharma, Inc. (the "Company" or "Aytu") (Nasdaq:AYTU), a pharmaceutical company focused on advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients, today announced that the method of use patent (U.S. Patent No. 7,538,116) for EXXUA™ (gepirone) extended-release tablets ("EXXUA") has been extended through September 2, 2030 under 35 U.S.C. 156. The patent extension further expands upon the new chemical entity ("NCE") exclusivity period granted by the United States Food and Drug Administration ("FDA"). Gepirone is an NCE, and EXXUA is the first-in-class selective serotonin 5HT1a receptor agonist approved by the FDA for the treatment of major depressive disorder ("MDD") in adults.

"We are very pleased that the EXXUA patent has been granted this five year extension which adds to the exclusivity beyond that normally provided by the NCE approval," commented Josh Disbrow, Chief Executive Officer of Aytu. "Further, we continue to engage in discussions with our partner to expand upon the existing intellectual property through various potential life cycle management approaches, which may extend exclusivity beyond 2030."

"EXXUA is on track to be commercially launched in 2025. Its novel product profile is expected to be an important treatment option to help address the unmet needs of the estimated 21 million Americans affected by MDD."

"Although progress has been made in depression treatments, challenges like treatment-related sexual dysfunction and weight gain remain significant drawbacks for many MDD therapies," Disbrow continued. "We believe EXXUA will be a crucial option for doctors treating the millions of patients with MDD in the United States," Disbrow concluded.

About Aytu BioPharma

Aytu is a pharmaceutical company focused on advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients. The Company's prescription products include EXXUA™ (gepirone) extended-release tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of major depressive disorder (MDD), 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), and a line of legacy products, including Karbinal® ER (carbinoxamine maleate), Poly-Vi-Flor® and Tri-Vi-Flor®. To learn more, please visit aytubio.com.

About EXXUA

EXXUA is a novel oral selective serotonin 5HT1a receptor agonist indicated for the treatment of major depressive disorder (MDD) in adults. EXXUA is also being developed for other psychiatric disorders.

INDICATIONS and IMPORTANT SAFETY INFORMATION for EXXUA

INDICATIONS

EXXUA is indicated for the treatment of major depressive disorder (MDD) in adults.

IMPORTANT SAFETY INFORMATION

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors.

EXXUA is not approved for use in pediatric patients.

Do not take EXXUA if you:

- are allergic to EXXUA or any of the ingredients in EXXUA.
- have a prolonged QTc interval greater than 450 msec or congenital long QT syndrome.
- are taking medicines known as strong CYP3A4 inhibitors. Ask your healthcare provider if you are not sure if you are taking one of these medicines.
- have severe liver problems.
- are taking, or have stopped taking within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue. Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 14 days after you have stopped treatment with EXXUA.

EXXUA may cause serious side effects, including:

Changes in the electrical activity of your heart called QT prolongation. QT prolongation can cause irregular heartbeats that can be life-threatening. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and will also do blood tests to check your levels of body salts (electrolytes) before and during treatment with EXXUA. Your healthcare provider may check your electrolytes more often during treatment if you have heart failure, a slow heart rate, abnormal levels of electrolytes in your blood, or if you take other medications that can prolong the QT interval of your heartbeat.

A potentially life-threatening problem called serotonin syndrome can happen when EXXUA is taken with certain other medicines.

Manic episodes may happen in people with bipolar disorder who take EXXUA.

Please read FULL PRESCRIBING INFORMATION for EXXUA.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (“Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (“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 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 overall financial and operational performance, potential adverse changes to the Company’s financial position or our business, the results of operations, strategy and plans, changes in capital markets and the ability of the Company to finance operations in the manner expected, risks relating to gaining market acceptance of our products, our partners performing their required activities, our anticipated future cash position, regulatory and compliance challenges and future events under current and potential future collaborations. We also refer you to (i) the risks described in “Risk Factors” in Part I, Item 1A of our most recent Annual Report on Form 10 K and in the other reports and documents we file with the United States Securities and Exchange Commission.

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SOURCE: Aytu BioPharma, Inc.