Aytu BioPharma Announces Commercial Availability of EXXUA™ (gepirone) Extended-Release Tablets, the First and Only 5HT1a Agonist Indicated for the Treatment of Major Depressive Disorder in Adults

EXXUA is now available through Aytu RxConnect® pharmacies to ensure optimal access and availability

EXXUA has demonstrated significant improvement in depression symptoms in clinical trials involving more than 5,000 patients and, notably, has no warnings or adverse events related to sexual dysfunction and no clinically significant weight gain compared to placebo

DENVER, CO / ACCESS Newswire / December 15, 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 the commercial availability of EXXUA in the United States. EXXUA is the first and only 5HT1a agonist approved by the United States Food and Drug Administration for the treatment of major depressive disorder ("MDD"), representing a new way to treat MDD.

The immediate availability of EXXUA through participating Aytu RxConnect pharmacies enables patients and prescribers the ability to access EXXUA through Aytu's best-in-class patient access program, Aytu RxConnect. In parallel, distribution through all major United States wholesalers is progressing to enable nationwide availability across all pharmacy retailers in the coming weeks. Product information and Aytu RxConnect pharmacy availability can be found at EXXUA.com.

"We are thrilled to have achieved this significant milestone with EXXUA now officially available in the United States as a new treatment option for the estimated 21 million Americans suffering from major depressive disorder," commented Josh Disbrow, Chief Executive Officer of Aytu. "EXXUA represents a truly unique approach to treating MDD, offering a novel mechanism of action and distinctive clinical profile – including the absence of reported sexual side effects in clinical trials. We are excited to see EXXUA entering the commercial channel across the United States, supported by full integration into Aytu RxConnect patient platform. Ensuring that patients who need EXXUA can access it remains our top priority, and we are committed to making this important therapy both affordable and widely available," Disbrow concluded.

To learn more about EXXUA, please visit EXXUA.com.

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), and treatments for attention deficit-hyperactivity disorder (ADHD). Aytu is committed to delivering the Company's medications through best-in-class patient access programs that help to enable optimal patient outcomes. For more information, please visit aytubio.com or follow us on LinkedIn.

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 are described in “Risk Factors” in Part I, Item 1A of the Company’s most recent Annual Report on Form 10 K and in the other reports and documents it files with the United States Securities and Exchange Commission.

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