Aytu BioPharma Announces Exclusive Agreement with Fabre-Kramer Pharmaceuticals to Commercialize First-in-Class Antidepressant EXXUA™ (gepirone) Extended-Release Tablets in the United States

Aytu enters the over $22 billion United States prescription major depressive disorder ("MDD") market with the first-in-class oral selective serotonin 5HT1a receptor agonist for adults with MDD.

EXXUA has demonstrated significant improvement in depression symptoms in clinical trials involving more than 5,000 patients and, notably, the incidence of sexual side effects experienced with EXXUA was comparable to placebo.

EXXUA is expected to serve as a major growth catalyst as Aytu continues to build value for shareholders; the Company anticipates launching EXXUA in the fourth calendar quarter of 2025 as a centerpiece of its commercial efforts.

EXXUA transaction financed by long-term, healthcare-focused institutional investors, including Aytu's largest shareholder Nantahala Capital Management, Stonepine Capital Management, Aytu management, and new institutional shareholders.

DENVER, CO / ACCESS Newswire / June 6, 2025 / Aytu BioPharma, Inc. (the "Company" or "Aytu") (NASDAQ:AYTU), a pharmaceutical company focused on commercializing novel therapeutics, announced the signing of an exclusive agreement to commercialize EXXUA™ (gepirone) extended-release tablets ("EXXUA") in the United States. Gepirone is a new chemical entity, and EXXUA is the first-in-class selective serotonin 5HT1a receptor agonist approved by the United States Food and Drug Administration ("FDA") for the treatment of MDD in adults.

EXXUA has been extensively studied in over 5,000 patients and represents a new class of therapeutics to compete in the over $22 billion United States prescription MDD market. Importantly, EXXUA is the only antidepressant acting on serotonin receptors that does not carry label warnings about the risk of sexual dysfunction. The mechanism of the antidepressant effect of EXXUA is believed to be related to its modulation of serotonin activity and, specifically, its exclusive and strong binding affinity for 5HT1a receptors, which are key regulators of mood and emotion. EXXUA is not a selective serotonin reuptake inhibitor ("SSRI") and has no reuptake inhibition activity. EXXUA also exhibits no significant adverse effects on weight, blood pressure, heart rate or liver function.

Dr. Stephen Stahl, Professor of Psychiatry, University of California and founder of the Neuroscience Education Institute, a recognized expert neuropsychopharmacologist said "EXXUA is the first truly selective agonist of the serotonin 1a receptor that has been

consistently linked to mediation of mood disorders and suicide risk. It's an important addition to the armamentarium to treat depression."

Josh Disbrow, Chief Executive Officer of Aytu, stated, "We are thrilled to be the exclusive commercialization partner for EXXUA in the United States and to be partnering with Fabre-Kramer Pharmaceuticals on this exciting opportunity. We believe that the licensing of EXXUA represents a transformative milestone for Aytu and a significant advancement for patients suffering from major depressive disorder."

"Over the past two years, Aytu has undergone a planned, strategic pivot to focus on our core prescription business while seeking to acquire differentiated, branded CNS products that complement our portfolio and focus. We believe that EXXUA is a perfect strategic fit and will be a centerpiece of Aytu's commercial efforts going forward considering the significant commercial potential, uniqueness of the product, our sales force's CNS focus and alignment with our proprietary Aytu RxConnect patient access platform," Disbrow continued.

"More importantly, given the compelling and novel product profile of EXXUA and the unmet needs of MDD patients, we believe EXXUA can become a very important treatment option for the over 21 million Americans affected by MDD. Over 340 million antidepressant prescriptions were written in 2024 in the United States, yet significant unmet needs remain considering the unacceptable side effects associated with current therapeutics. Aytu is well positioned to realize the significant market potential of EXXUA while positively impacting the lives of MDD patients. We look forward to launching EXXUA later this year and to our exciting partnership with Fabre-Kramer Pharmaceuticals," Disbrow concluded.

Stephen Kramer, M.D., Co-Founder and Chief Executive Officer of Fabre-Kramer Pharmaceuticals said, "We are very pleased to be partnering with Aytu to bring EXXUA to the United States market. We developed EXXUA to address important unmet needs that I witnessed first-hand managing MDD patients for decades as a practicing psychiatrist. While therapeutic advancements have been made, issues such as treatment emergent sexual dysfunction and weight gain persist as problematic side effects of many MDD treatments. We believe EXXUA will be a very important addition to physicians managing the millions of patients with depression in the United States and worldwide."

Under the terms of the agreement, upon closing Aytu paid Fabre-Kramer Pharmaceuticals an upfront payment and will pay an additional fixed payment at the one-year anniversary of the EXXUA launch date.

In addition, Aytu will pay royalties on net revenue as defined in the definitive agreement, along with a product transfer price. Aytu will also make variable, performance-based milestone payments to Fabre-Kramer Pharmaceuticals upon the achievement of various net revenue thresholds over the term of the agreement.

The EXXUA transaction is being funded by cash on hand along with a financing led by long-term, healthcare-focused institutional investors, including Aytu's largest shareholder Nantahala Capital Management, Stonepine Capital Management, Aytu management, and new institutional shareholders.

Aytu is actively preparing to launch EXXUA in the United States as soon as possible and currently anticipates pharmacy and patient availability in the fourth calendar quarter of 2025. For more information and updates, please visit aytubio.com.

About Aytu BioPharma

Aytu is a pharmaceutical company focused on commercializing novel therapeutics. 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.

Contacts for Investors

Ryan Selhorn, Chief Financial Officer
Aytu BioPharma, Inc.
rselhorn@aytubio.com

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

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