



PRESS RELEASE – October 9, 2026 – 1:00 pm – Montpellier, France – Euronext: MEDCL

Medincell Achieves Major Milestone with U.S. FDA Approval of WELTRUZA™ (olanzapine)

Medincell will host Investor webcast today to discuss the implications of the approval for the Company and answer questions from analysts.

Webcast Details

- Date: Friday, October 9, 2026
- Time: 4:00 p.m. CEST / 10:00 a.m. ET
- Webcast: <https://www.medincell.com/investor-webcast-oct-9-2026/>

A replay of the webcast will be available on Medincell's website following the event.

Medincell (Euronext: MEDCL) achieves major milestone with the announcement by its partner Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd, of the U.S. Food and Drug Administration (FDA) approval of WELTRUZA™ (olanzapine) for extended-release injectable suspension, as the first and only once-monthly subcutaneous long-acting injectable (LAI) formulation of olanzapine for adults with schizophrenia that can help support stabilization for people living with schizophrenia.

WELTRUZA™ does not require loading doses or oral supplementation at treatment initiation and eliminates the need for post-injection monitoring, addressing a major, long-standing gap in schizophrenia care.

The approval of WELTRUZA™ marks the second FDA-approved medicine utilizing Medincell's long-acting injectable technology, following UZEDY® (risperidone) in 2023.

Teva Pharmaceuticals plans to make WELTRUZA™ available in the United States in the coming weeks.

Medincell is entitled to mid- to high-single digit royalties on worldwide net sales of WELTRUZA™. Medincell is also eligible to receive up to \$112 million in development and commercial milestones, including a \$4 million payment upon U.S. approval and up to \$105 million in sales-based commercial milestones upon achievement of specified sales thresholds.

Christophe Douat, CEO of Medincell, said: *"Beyond its clinical significance, the FDA approval of WELTRUZA™ represents a major milestone in the execution of Medincell's Shift to Growth strategy, with the emergence of a second significant growth engine for the Company. This approval provides further validation of our technology and demonstrates our ability to transform innovation into differentiated medicines that create long-term value for patients, partners and shareholders."*

For additional information regarding WELTRUZA™, please refer to Teva Pharmaceuticals' press release: <https://ir.tevapharm.com/news-and-events/press-releases/default.aspx>

About Medincell

Medincell is a clinical- and commercial-stage innovation-driven biopharmaceutical company developing and licensing long-acting injectable treatments across multiple therapeutic areas. Our innovative treatments are designed to ensure adherence to medical prescriptions, enhance the effectiveness and accessibility of medicines, and reduce their environmental impact.

These treatments combine active pharmaceutical ingredients with our proprietary BEPO® / BEPO® Star technologies, which enable controlled drug delivery at therapeutic levels for several days, weeks, or months following a subcutaneous or local injection of a small, fully bioresorbable depot.

Risperidone LAI was the first treatment based on BEPO® technology to receive FDA approval, initially for schizophrenia in April 2023 (one- and two-month dosing), and subsequently for Bipolar I Disorder in October 2025 (one-month dosing). It is marketed in the United States by Teva under the brand name UZEDY®.

Olanzapine LAI as a once-monthly treatment for schizophrenia in adults received FDA approval in October 2026 with launch in the United States by Teva under the brand name WELTRUZA™ planned in Q4 2026. A European Marketing Authorization Application (MAA) for Olanzapine LAI was also accepted by EMA in May 2026.

Medincell's investigational pipeline includes numerous innovative therapeutic candidates in various stages of development, from formulation to Phase 3 clinical trials. We collaborate with leading pharmaceutical companies and foundations to advance global health through new treatment options.

Headquartered in Montpellier, France, Medincell employs over 150 people representing more than 27 nationalities.

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This press release contains forward-looking statements, including statements regarding Company's expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) its ability to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its future product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this press release relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company's control and the Company's financial capabilities.

These statements may include, but are not limited to, any statement beginning with, followed by or including words or phrases such as "objective", "believe", "anticipate", "expect", "foresee", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "probably", "potential", "should", "could" and other words and phrases of the same meaning or used in negative form. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the "AMF") pursuant to its regulatory obligations, including the Company's universal registration document, filed with the AMF on July 29, 2025, under number D. 25-0580 (the "Universal Registration Document"), as well as in the documents and reports to be published subsequently by the Company. In particular, readers' attention is drawn to the section entitled "Facteurs de Risques" on page 30 *et seq.* 26 of the Registration Document.

Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company's update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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