Baird Medical and Alpmed Announce FDA 510(k) and EU CE Submissions for Irreversible Electroporation (IRE) System

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510(k) Application to U.S. Food and Drug Administration and Application for European Union Certification Submitted in Fourth Quarter 2026

NEW YORK, Nov. 05, 2026 (GLOBE NEWSWIRE) -- Baird Medical Investment Holdings Limited (NASDAQ: BDMD) ("Baird Medical" or the "Company"), a global leader in microwave ablation (MWA) technology, today announced that its strategic partner, Tianjin Yuanshan Medical Technology Co., Ltd. ("Alpmed"), has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) and an application for CE conformity assessment in the European Union for an irreversible electroporation (IRE) system. The system is designed for soft tissue ablation, with the potential to be used to treat a range of tumor types, and is being advanced under the companies' previously announced partnership.

IRE is an advanced, minimally-invasive, non-thermal ablation technology that uses high-voltage electrical pulses to disrupt cell membranes and induce cell death. This mechanism may offer advantages when treating tissue near sensitive anatomical structures.

Under the partnership with Alpmed, Baird Medical is leading global regulatory interactions during the respective review processes, and holds worldwide commercial rights for the IRE system. The companies are targeting potential U.S. FDA 510(k) clearance and EU CE marking in 2027, subject to the outcome of the respective regulatory review processes.

"The U.S. 510(k) submission and EU CE conformity assessment application represent two significant milestones as we continue working to expand our portfolio of minimally-invasive ablation platforms beyond our core MWA technology. If cleared, adding IRE to our portfolio could create additional opportunities to address indications for which thermal ablation may not be the optimal solution," said Haimei Wu, Chairwoman and CEO of Baird Medical. "That these submissions were completed less than three months after the signing of the cooperation agreement with Alpmed is a testament to the capabilities and commitment of our teams as well as the broader potential of this strategic partnership. We look forward to productive interactions with the regulators in the U.S. and EU during the respective review processes, and to providing updates on our progress, as appropriate."

About Baird Medical

Baird Medical is a global, pioneering medical device company specializing in minimally invasive ablation technologies for a range of solid tumors. The Company's lead product, a microwave ablation (MWA) system, is FDA-cleared for soft tissue ablation and is being launched in the U.S. primarily for the treatment of benign thyroid nodules. In addition, the Company is expanding its minimally invasive technology portfolio, including IRE-based products and an AI-powered robotic ablation system.

Baird Medical's MWA solutions have been adopted by a growing number of leading U.S. institutions and private practice groups, including the Mayo Clinic, Columbia University Medical Center, and The George Washington University Hospital. The company is rapidly expanding its global commercial footprint, with sales now reaching markets across multiple continents.

About Alpmed

Alpmed is a member company of Saixiang Group and is under common control with Tianjin Saixiang Technology Co., Ltd. (SZSE: 002337), a publicly listed company. Alpmed focuses on the research, development, and innovation of IRE technology and is an early mover and one of the leading companies in the field. The company has established an IRE technology portfolio across four areas: tumor ablation, cardiac electrophysiology, peripheral vascular intervention, and interventional pulmonology.

In oncology, Alpmed has commercialized China's first domestically developed IRE ablation product for malignant liver and pancreatic tumors. The company is also advancing applications of its technology in prostate, thyroid, breast, and other solid tumor indications.

Forward-Looking Statements

This press release includes certain statements that are not historical facts but are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Baird Medical's future financial or operating performance. In some cases, you can identify forward-looking statements by terminology such as "may", "could", "should", "expect", "intend", "might", "will", "estimate", "anticipate", "believe", "budget", "forecast", "intend", "plan", "potential", "predict", or "continue", or the negatives of these terms or variations of them or similar terminology. Forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Baird Medical and its management, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict

all risks and uncertainties. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Baird Medical does not undertake any duty to update these forward-looking statements.

Actual results may vary materially from those expressed or implied by forward-looking statements based on a number of factors, including, without limitation: (1) the risk that Baird Medical may not be successful in expanding its business in China or the United States; (2) changes in general economic conditions; (3) regulatory conditions and developments; (4) changes in applicable laws or regulations; (5) the nature, cost and outcome of pending and future litigation and other legal proceedings instituted against Baird Medical or others; and (6) other risks and uncertainties from time to time described in the Registration Statement relating to the Business Combination and the transition report, including those listed under the sections titled "Risk Factors" therein, and in ExcelFin's other filings with the SEC.

The foregoing list of factors is not exclusive. Additional information concerning certain of these, and other risk factors is contained in ExcelFin's most recent filings with the SEC and in the Registration Statement described above filed by Baird Medical in connection with its business combination with ExcelFin. All subsequent written and oral forward-looking statements concerning Baird Medical, the business combination described herein, or other matters attributable to Baird Medical or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements above. Readers are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Baird Medical expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

Contact:

Lee Roth
Burns McClellan for Baird Medical
Lroth@burnsmc.com

Baird Medical