Immunome To Acquire AL102, A Phase 3 Asset for the Treatment of Desmoid Tumors, From Ayala Pharmaceuticals

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AL102 is a small molecule gamma secretase inhibitor with a differentiated clinical profile

BOTHELL, Wash. and MONMOUTH JUNCTION, N.J., Feb. 06, 2024 (GLOBE NEWSWIRE) -- Immunome, Inc. (Nasdaq: IMNM), a biotechnology company dedicated to developing first-in-class and best-in-class targeted cancer therapies, today announced that it entered into a definitive asset purchase agreement with Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, to acquire AL102 and related drug candidate AL101 from Ayala. Based on the terms of the agreement, Immunome will pay Ayala $20 million in cash and $30 million in Immunome common stock (valued at 30-day VWAP as of February 1, 2024) at the closing and will pay up to an additional $37.5 million in development and commercial milestone payments. Completion of the transaction is subject to customary conditions including Ayala obtaining the requisite stockholder approval.

AL102 is an investigational small molecule gamma secretase inhibitor currently being evaluated in the randomized Phase 3 RINGSIDE international trial for the treatment of desmoid tumors – a debilitating soft tissue malignancy. AL102 is a potential once-daily oral treatment for desmoid tumors. Data from clinical trials have shown AL102 may be more effective in treating desmoid tumors than OGSIVEO™ (nirogacestat), which recently became the first treatment approved for desmoid tumors by the U.S. Food and Drug Administration (FDA) in November 2023.

The Phase 2 portion of the RINGSIDE study demonstrated clinically meaningful anti-tumor activity across multiple parameters. The data showed high objective response rates, including 75% of evaluable patients (and 64% of intent-to-treat patients) in the 1.2 mg once daily arm, the dose being evaluated in the current Phase 3 trial. Furthermore, patients receiving the 1.2 mg daily dose experienced a median best reduction in tumor volume of 88% as measured by serial MRI exams, as of the previously reported July 5, 2023 data cut-off, and also demonstrated improvement in other radiographic parameters.

“Immunome is committed to advancing therapies with best-in-class potential. We are especially optimistic about the rapidity and depth of the tumor responses observed in the Phase 2 portion of RINGSIDE,” said Clay B. Siegall, Ph.D., President and Chief Executive Officer of Immunome. “AL102 will complement our existing portfolio of targeted cancer agents that are approaching Phase 1 trials. As we complete the work required to advance AL102 to NDA submission, our goal is to bring clinical benefit to an underserved patient population while generating substantial value for stockholders. We also plan to investigate other populations of cancer patients that could benefit from treatment with AL102.”

Ken Berlin, CEO of Ayala Pharmaceuticals, stated, “We are pleased that this exciting molecule will be advanced by Immunome and its team of highly-experienced drug developers which, we believe, maximizes the ability to conclude the RINGSIDE study and bring our lead asset to commercialization. I am proud of the work Ayala has done over the last several years to assemble compelling clinical data and reach this point.”

It is estimated that as many as 1,650 people in the U.S. are diagnosed annually with desmoid tumors, also known as aggressive fibromatosis, and the population prevalence is much higher. Desmoid tumors, which occur predominantly in young adults, can cause significant pain and disability. Available non-pharmacologic therapies such as surgery or radiation are often ineffective and can lead to long term complications, and unapproved targeted therapies lack long-term potency. In November 2023, AL102 was granted Orphan Drug Designation by the FDA.

A.G.P./Alliance Global Partners is acting as strategic advisor to Ayala Pharmaceuticals, Inc. in connection with the transaction.

About Immunome, Inc.
Immunome is a biotechnology company dedicated to developing first-in-class and best-in-class targeted cancer therapies. Our portfolio pursues each target with a modality appropriate to its biology, including immunotherapies, radioligand therapies and ADCs. We believe that pursuing underexplored targets with appropriate drug modalities leads to transformative therapies. Our proprietary memory B cell hybridoma technology allows for the rapid screening and functional characterization of novel antibodies and targets.

For more information, visit www.immunome.com or follow us on Twitter and LinkedIn.

About Ayala Pharmaceuticals, Inc.
Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company primarily focused on developing and commercializing small molecule therapeutics for people living with rare tumors and aggressive cancers. The Company’s lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors, and aspacytarabine (BST-236), a novel proprietary anti-metabolite for first line treatment in unfit acute myeloid leukemia (AML). AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 segment of a pivotal study for patients with desmoid tumors (RINGSIDE). For more information, visit www.ayalapharma.com.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this communication regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). We use words such as “may,” “could,” “potential,” “will,” “plan,” “believe,” “goal,” “optimistic,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. These forward-looking statements include, but are not limited to, statements regarding Immunome’s expectation that the purchase of assets from Ayala will close and, if closed, will complement Immunome’s

development pipeline, as well as assessments of the clinical efficacy and potential commercial success of the AL102 program; Immunome plans to evaluate other populations of cancer patients that may benefit from AL102; the expected benefits of the Ayala transaction; and other statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Such forward-looking statements are based on Immunome's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, the risk that the transaction with Ayala will not be completed; potential litigation relating to the proposed transaction that could be instituted against Immunome, Ayala or their respective directors; possible disruptions from the proposed transaction that could harm Immunome's and/or Ayala's respective businesses; Immunome's ability to grow and successfully execute on its business plan, including the development and commercialization of its pipeline; changes in the applicable laws or regulations; the possibility that Immunome may be adversely affected by other economic, business, and/or competitive factors; the risk that regulatory approvals for Immunome's programs and product candidates are not obtained, are delayed or are subject to unanticipated conditions; the risk that pre-clinical data may not be predictive of clinical data; the risk that interim results of a clinical trial do not necessarily predict final results; potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; the complexity of numerous regulatory and legal requirements that Immunome needs to comply with to operate its business; the reliance on Immunome's management; the prior experience and successes of the Immunome's management team not being indicative of any future success; uncertainties related to Immunome's capital requirements and Immunome's expected cash runway; the failure to obtain, adequately protect, maintain or enforce Immunome's intellectual property rights; and other risks and uncertainties indicated from time to time described in Immunome's Annual Report on Form 10-K for the year ended December 31, 2022 filed with Securities and Exchange Commission ("SEC") on March 16, 2023, Immunome's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 9, 2023, and in Immunome's other filings with the SEC. Immunome cautions that the foregoing list of factors is not exclusive and not to place undue reliance upon any forward-looking statements which speak only as of the date made. Moreover, Immunome operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Except as required by law, Immunome does not undertake any obligation to update publicly any forward-looking statements for any reason after the date of this press release to conform these statements to actual results or to changes in their expectations.

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