IDEAYA Biosciences Enters Exclusive License with Hengrui Pharma for SHR-4849, a Novel Phase 1 DLL3 Topo-I-Payload ADC Targeting SCLC and NET Solid Tumors

- Exclusive global license outside of Greater China for SHR-4849, a Phase 1 DLL3-targeting Topo-I-payload antibody drug conjugate (ADC)
- DLL3 highly expressed in Small Cell Lung Cancer (SCLC) and Neuroendocrine Tumors (NETs), respectively 85% and 20-40%
- Rational combination opportunities with IDEAYA's DNA Damage Repair (DDR) clinical pipeline, including Phase 1 PARG inhibitor IDE161
- Targeting US IND filing for SHR-4849 in H1 2025

SOUTH SAN FRANCISCO, Calif. and SHANGHAI, Dec. 29, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced that it has entered into an exclusive license agreement for SHR-4849, a novel DLL3-targeting Topo-I-payload ADC program with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma, SHA: 600276), an innovative global pharmaceutical company headquartered in China focused on unmet clinical needs. Under the terms of the agreement, IDEAYA will develop and commercialize SHR-4849 worldwide outside of Greater China.

"There is significant unmet medical need in DLL3-expressing solid tumors, and we are excited by the opportunity to develop SHR-4849, which has monotherapy potential in SCLC and NETs. SHR-4849 is competitively well positioned with first-in-class potential in the DLL3 topo-I-payload ADC field, a therapeutic area that has demonstrated preliminary monotherapy clinical validation in SCLC," said Yujiro S. Hata, Chief Executive Officer and Founder, IDEAYA Biosciences. "In addition, SHR-4849 accelerates IDEAYA's strategic objective to develop rational clinical combinations of topo-payload based ADCs with our PARG inhibitor IDE161, where we observe enhanced preclinical combination efficacy versus evaluated topo-payload ADCs alone," said Daniel A. Simon, Chief Business Officer, IDEAYA Biosciences.

Frank Jiang, Chief Strategy Officer and Board Director, Hengrui Pharma, said "SHR-4849 is a novel DLL3 targeting ADC showing encouraging early clinical signals in small-cell lung cancer with a manageable safety profile. We are delighted to partner with IDEAYA to support the development of this ADC globally, which furthers our goal of delivering innovative medicines for the benefit of patients around the world."

SHR-4849 has shown promising antitumor activity in preclinical studies, including tumor regression as a monotherapy in multiple models. This drug is currently being evaluated in a Phase 1 clinical trial for advanced solid tumors in China (NCT06443489). In the ongoing Phase 1 dose escalation, SHR-4849 has reached therapeutic dose levels where multiple partial responses have been observed as of the data cut-off date of December 10, 2024. Among 11 evaluable small cell lung cancer (SCLC) subjects treated at therapeutic dose levels, 8 partial responses by RECIST 1.1 were observed, resulting in an overall response rate of ~73% (including both confirmed and unconfirmed responses, all unconfirmed responses were pending further evaluation). As of the data cut-off date, treatment related adverse events (TRAEs) were predominantly Grade 1 or 2, and the Phase 1 dose escalation is ongoing with no reported drug-related discontinuations, and the maximum tolerated dose has not yet been reached. The most common TRAEs observed were white blood cell count decreased, anemia, neutrophil count decreased, nausea and platelet count decreased.

IDEAYA is targeting to file a US IND for SHR-4849 in the first half of 2025.

DLL3 has been reported to be expressed in multiple solid tumor types, including in SCLC and Neuroendocrine Tumors at approximately 85% and 20-40%, respectively, based on the Human Protein Atlas database. DLL3 has limited extracellular expression in normal tissues, making it a promising therapeutic target in these tumor types, for which there remains significant unmet medical need.

Under the terms of the agreement, Hengrui Pharma is eligible to receive upfront and milestone payments totaling $1.045 billion, including a $75m upfront fee, up to $200m in development and regulatory milestone payments, plus commercial success-based milestones. Hengrui is also eligible to receive mid-single to low-double digit royalties on net sales outside of Greater China. The upfront and projected research and development costs, including potential milestone payments, does not change the earlier provided IDEAYA guided cash out runway of at least 2028.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its early research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

About Hengrui Pharma

Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma) is an innovative global pharmaceutical company focused on unmet clinical needs, with a strong track record of scientific and technological innovation. Since its first innovative drug approval in 2011, Hengrui Pharma has invested more than $5.4 billion in R&D and set up 14 R&D centers in Lianyungang, Shanghai, the U.S., and Europe. It has 9 major manufacturing sites and a global R&D team of more than 5,000 professionals. Hengrui Pharma has independently established a number of leading technology platforms such as its ADC platform, proteolysis targeting chimera (PROTAC), molecular gels, bi/multi-specific antibodies, and AI molecular design, which provide a strong foundation for innovative R&D. Hengrui strives for continued innovation and collaboration with global partners to serve a healthy China and benefit patients around the world.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) the timing of a potential IND filing, (ii) potential development strategies, (iii) the estimated potential addressable market and (iv) the potential therapeutic benefits of IDEAYA therapeutics. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's Annual Report on Form 10-K dated February 20, 2024 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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