IDEAYA Announces Development Candidate Nomination of IDE034, a Potential First-in-Class B7H3/PTK7 Topo-I-Payload Bispecific ADC and Option Exercise with Biocytogen

- Nominated IDE034 (BCG034) as a development candidate, a potential first-in-class B7H3/PTK7 topo-I-payload bispecific antibody drug conjugate (BsADC)
- Option exercised for an exclusive worldwide license for IDE034 from Biocytogen
- Targeting an IND-filing for IDE034 in 2025 to enable first-in-human clinical evaluation of B7H3/PTK7 topo-I-payload BsADC program
- IDE034 has the potential to be developed as a monotherapy and in combination with IDEAYA's PARG inhibitor IDE161
- B7H3/PTK7 co-expression in lung, colorectal, and head and neck cancer, has been reported at approximately 30%, 46% and 27%, respectively

SOUTH SAN FRANCISCO, Calif. and BEIJING, Nov. 11, 2024 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced the selection of IDE034, a potential first-in-class B7H3/PTK7 topo-I-payload BsADC, as a development candidate and the exercise of its option for an exclusive worldwide license from Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen, HKEX: 02315) for potential first-in-class B7H3/PTK7 BsADC program.

"We are pleased to nominate development candidate IDE034, a promising potential first-in class B7H3/PTK7 topo-I-payload bispecific ADC, which has demonstrated robust monotherapy tumor regressions in multiple preclinical models. The co-expression of B7H3/PTK7 in several solid tumors, including double-digit percent prevalence in lung, colorectal, and head and neck cancers, highlights the potential addressable market, both as monotherapy and in combination with PARG inhibitor IDE161," said Michael White, Ph.D., Chief Scientific Officer of IDEAYA Biosciences. "We are excited to nominate our 6th development candidate in IDE034 and this program achieves several strategic objectives for IDEAYA, including the potential for monotherapy activity, application in multiple priority solid tumor types of lung and colorectal cancer, and the ability to enable wholly-owned rational combinations with our internal pipeline," said Yujiro S. Hata, Chief Executive Officer and Founder, IDEAYA Biosciences.

"We are excited to have IDEAYA exercise their option to license the worldwide rights to our B7H3/PTK7 BsADC IDE034 with a proprietary topoisomerase linker-payload. This important milestone in our partnership further validates Biocytogen's RenLite® platform and brings us one step closer to making an impact on patients with solid tumors. We look forward to our continued partnership with IDEAYA as they advance this program to the clinic," added Dr. Yuelei Shen, President and CEO of Biocytogen.

IDEAYA is targeting an Investigational New Drug (IND) submission to the U.S. Food and Drug Administration (FDA) in 2025 for IDE034, subject to satisfactory completion of ongoing preclinical and IND-enabling studies, to enable first-in-human study initiation.

The option was exercised for an exclusive worldwide license from Biocytogen pursuant to the option and license agreement between IDEAYA and Biocytogen. IDEAYA will pay Biocytogen upfront and option exercise fees, along with additional development and regulatory milestone payments, commercial milestone payments, and royalties on net sales, totaling $406.5 million, including up to $100 million in development and regulatory milestone payments.

B7H3/PTK7 has been reported to be co-expressed in multiple solid tumor types, including in lung, colorectal, and head and neck cancers at approximately 30%, 46% and 27%, respectively, based on the Human Protein Atlas database.

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 research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

About Biocytogen

Biocytogen (HKEX: 02315) is a global biotechnology company that drives the research and development of novel antibody-based drugs with innovative technologies. Founded on gene editing technology, Biocytogen leverages genetically engineered proprietary RenMice® (RenMab™/ RenLite®/ RenNano®/ RenTCR-mimic™) platforms for fully human monoclonal/bispecific/multispecific antibody discovery, bispecific antibody-drug conjugate discovery, nanobody discovery and TCR-mimic antibody discovery, and has established a sub-brand, RenBiologics™, to explore global partnerships for an off-the-shelf library of >400,000 fully human antibody sequences against approximately 1000 targets for worldwide collaboration. As of June 30, 2024, approximately 150 therapeutic antibody and multiple clinical asset co-development/out-licensing/transfer agreements and nearly 50 target-nominated RenMice® licensing projects have been established with over 60 global pharmaceutical and biotech companies, including several partnerships with multinational pharmaceutical companies (MNCs). Biocytogen pioneered the generation of drug target knock-in humanized models for preclinical research, and currently provides a few thousand off-the-shelf animal and cell models under the company's sub-brand, BioMice™, along with preclinical pharmacology and gene-editing services for clients worldwide. Headquartered in Beijing, Biocytogen has branches in China (Haimen Jiangsu, Shanghai), USA (Boston, San Francisco), and Germany (Heidelberg). For more information, please visit http://en.biocytogen.com.cn.

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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