IDEAYA Receives Authorization to Proceed with Phase 1/2 Tissue-Type Agnostic Basket Trial to Treat Patients with Tumors Harboring GNAQ/11 Mutations and PKC Fusions

SOUTH SAN FRANCISCO, Calif., May 8, 2019 /PRNewswire/ -- IDEAYA Biosciences, Inc., an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics to treat cancer, announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for the development of IDE196 as a treatment for metastatic uveal melanoma and other solid tumors harboring *GNAQ* or *GNA11* (*GNAQ*/*11*) mutations and PKC fusions. "IDEAYA is excited to initiate its Phase 1/2 tissue-type agnostic basket trial in the second or third quarter of this year to evaluate IDE196 in patients with solid tumors harboring *GNAQ*/*11* mutations or PKC fusions, including, but not limited to, metastatic uveal melanoma (UM), cutaneous melanoma, and colorectal cancer," noted Dr. Julie Hambleton, M.D., Senior Vice President, Chief Medical Officer and Head of Development at IDEAYA.

IDE196 is a potent small molecule protein kinase C (PKC) inhibitor demonstrating early clinical activity and tolerability in an ongoing Phase 1 trial of IDE196 in patients with metastatic UM. IDE196 is active across the classical and novel PKC isoforms and is highly selective relative to other kinases. Approximately 90% of uveal melanoma patients harbor activating mutations in *GNA11* or *GNAQ*. Metastatic UM is a rare disease of high unmet medical need with no FDA approved therapies.

"Patients with metastatic UM generally have a poor prognosis, with historic clinical response rates generally ranging from 0% to 10% and median overall survival of 10 months. In light of this significant patient need and the promising activity seen in the initial IDE196 clinical study, we are excited for continued development of IDE196 to further evaluate its clinical potential," said Dr. Matteo Carlino, Medical Oncologist, Blacktown and Westmead Hospitals, Clinical Associate Professor, University of Sydney, and IDE196 clinical investigator.

Mutations in *GNAQ* or *GNA11* have also been observed across other solid tumors, such as cutaneous melanoma, colorectal, pancreatic, stomach, cervical, lung adenocarcinoma and bladder. The initial clinical focus of IDEAYA's Phase 1/2 basket trial will be on treatment of patients having tumors with likely pathogenic "hotspot" mutations, which are known to activate the PKC signaling pathway.

Dr. Johanna Bendell, M.D., Chief Development Officer and Director, Drug Development Unit, Nashville, Tennessee, Sarah Cannon Research Institute, observed that, "IDEAYA's tissue-type agnostic basket trial offers a unique clinical opportunity based on a genetic biomarker rationale to treat patients that harbor *GNAQ* or *GNA11* mutations across multiple solid tumors, who at the moment do not have any *GNAQ* or *GNA11*-specific targeted therapies available."

About IDEAYA Biosciences

IDEAYA is an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. Our approach integrates capabilities in identifying and validating translational biomarkers with small molecule drug discovery to select patient populations most likely to benefit from the targeted therapies we are developing. We are applying these capabilities across multiple classes of precision medicine, including direct targeting of oncogenic pathways and synthetic lethality – which represents an emerging class of precision medicine targets. For additional information, please visit www.ideayabio.com.

Forward-Looking Statements

This press release contains forward-looking statements. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's 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 pharmaceutical drug and medical device development processes, including regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing pharmaceutical drug and medical device products, IDEAYA's ability to raise sufficient capital to fund its development programs, and other matters that could affect the sufficiency of existing cash to fund operations and the availability or commercial potential of IDEAYA's product candidates. 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 Registration Statement on Form S-1 and any subsequent current and periodic reports filed with the U.S. Securities and Exchange Commission.

SOURCE IDEAYA Biosciences, Inc.

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