IDEAYA Biosciences Announces First Patient Dosing of PKC inhibitor IDE196 in Phase 1/2 Tissue-Type Agnostic Basket Trial for Solid Tumors Harboring GNAQ or GNA11 Mutations

SOUTH SAN FRANCISCO, Calif., July 11, 2019 /PRNewswire/ -- IDEAYA Biosciences, Inc., an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics to treat cancer, announces initiation of its Phase 1/2 study evaluating IDE196 in Patients with Solid Tumors Harboring GNAQ/11 Mutations or PRKC Fusions (ClinicalTrials.gov Identifier: NCT03947385). The first patient dosing was in June 2019 and clinical trial sites are now enrolling in the U.S. and Australia.

IDEAYA previously announced that the U.S. Food and Drug Administration (FDA) cleared the 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. "IDEAYA's tissue-type agnostic strategy provides a genetic biomarker driven approach to treat patients whose tumors harbor *GNAQ* or *GNA11* hotspot mutations across multiple solid tumors, including uveal melanoma, cutaneous melanoma, and colorectal cancer," said Meredith McKean, MD, MPH, Melanoma and Skin Cancer Research Program, Sarah Cannon Research Institute.

"We are delighted to announce our first patient dosing for IDE196 in our tissue type agnostic *GNAQ* and *GNA11* basket trial, and the opportunity to advance IDE196 in its dose escalation with the goal of enabling the optimal dose selection for the Phase 2 portion of the trial," said Julie Hambleton, M.D., Chief Medical Officer, Head of Development at IDEAYA Biosciences.

IDE196 is a potent small molecule protein kinase C (PKC) inhibitor demonstrating clinical activity and tolerability in a separate ongoing Phase 1 trial of IDE196 in patients with Metastatic Uveal Melanoma (MUM). Approximately 90% of uveal melanoma patients harbor activating mutations in *GNAQ* or *GNA11* (*GNAQ/11*). Mutations in *GNAQ/11* have also been observed in other solid tumors, such as cutaneous melanoma, colorectal, pancreatic, stomach, cervical, lung adenocarcinoma and bladder. The clinical focus of IDEAYA's Phase 1/2 basket trial will be on treatment of patients having tumors with likely pathogenic *GNAQ/11* hotspot mutations, which are known to activate the PKC signaling pathway. *GNAQ/11* hotspot mutations are not generally known to overlap with other oncogenic driver mutations, such as *BRAF* and *NRAS* mutations, in certain solid tumors.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

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. IDEAYA's 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 IDEAYA is developing. IDEAYA is 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.

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tumors-harboring-gnaq-or-gna11-mutations-300882971.html

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