IDEAYA Biosciences Reports End-of-Phase 1 Meeting with FDA for IDE196 Confirms Acceptability of Single-Arm Trial Design for Potential Phase 2 Registration-Enabling Study in Metastatic Uveal Melanoma

- FDA feedback from End-of-Phase 1 meeting indicates IDEAYA's proposed single-arm Phase 2 clinical trial may be adequate to support an NDA seeking Accelerated Approval for IDE196 monotherapy in metastatic uveal melanoma (MUM)
- Phase 2 dose selection and initiation of the potentially registration-enabling single-arm Phase 2 clinical trial anticipated in Q4 2019
- Confirmed Complete Response observed in one patient previously reported with confirmed Partial Response in the ongoing IDE196 monotherapy clinical trial

SOUTH SAN FRANCISCO, Calif., Oct. 31, 2019 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics, provided a regulatory and clinical update on IDE196 following receipt of meeting minutes from an End-of-Phase 1 (EOP1) meeting with the FDA. IDE196 is being evaluated for the treatment of MUM and other solid tumors harboring activating GNAQ or GNA11 (GNAQ/11) mutations in its ongoing Phase 1/2 clinical trial entitled "Patients with Solid Tumors Harboring GNAQ/11 Mutations or PRKC Fusions" (ClinicalTrials.gov Identifier: NCT03947385).

"Following FDA feedback from the EOP1 meeting, we plan to initiate the Phase 2 single-arm, potentially registration-enabling clinical trial of IDE196 monotherapy. This arm of our clinical trial will target enrollment of 60 evaluable MUM patients with blinded independent central review (BICR)-determined overall response rate (ORR) as the primary endpoint," said Bao Truong, Vice President, Head of Regulatory Affairs at IDEAYA Biosciences. "We look forward to the continued clinical advancement of IDE196 in MUM and in our broader tissue-type agnostic basket trial to treat other solid tumors that harbor activating GNAQ/11 mutations, including in cutaneous melanoma and colorectal cancer," said Julie Hambleton, M.D., Chief Medical Officer and Senior Vice President at IDEAYA Biosciences.

Regulatory and Clinical Program Highlights for IDE196:

- FDA EOP1 meeting minutes indicate that the proposed single-arm Phase 2 IDE196 clinical trial may be adequate to support a new drug application (NDA) seeking Accelerated Approval of IDE196 monotherapy for the treatment of MUM
- Phase 2 dose selection, and the single-arm, potentially registration-enabling Phase 2 part of the Phase 1/2 clinical trial is anticipated to be initiated in Q4 2019
- This Phase 2 clinical trial will target enrollment of 60 evaluable MUM patients with the primary endpoint of overall response rate (ORR) as determined by blinded independent central review (BICR), supported by BICR-determined duration of response (DOR) as a secondary endpoint
- The 13-week GLP-compliant toxicology studies in 2 species is scheduled to initiate in November 2019, in support of FDA requirement that results of these studies be submitted prior to enrollment of more than approximately 50 patients in the investigational arm of the clinical trial that will support a marketing application
- An immediate release tablet formulation for IDE196 is on-track for introduction in the clinic in Q1 2020, as a potential registration and commercial formulation
- Interim data for GNAQ/11 Phase 1/2 basket trial expected in Q2/Q3 2020
- Confirmed Complete Response observed at month 31 in one patient previously reported with confirmed Partial Response in the ongoing IDE196 monotherapy clinical trial conducted by Novartis (ClinicalTrials.gov Identifier: NCT02601378)

"We are grateful for the regulatory feedback from the FDA on our single-arm trial design, providing an opportunity for a potential Accelerated Approval path for IDE196 monotherapy in MUM, a high unmet medical need and a solid tumor indication where there are no FDA approved therapies. We are also encouraged to see continued progress in our tissue-type agnostic GNAQ/11 Phase 1/2 basket trial to treat solid tumor patients beyond MUM," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) initiation of the IDE196 Phase 2 trial, (ii) initiation and timing of the 13-week GLP-compliant toxicology studies, (iii) release of interim data for the IDE196 Phase 1/2 basket trial, and (iv) introduction of an immediate release tablet formulation for IDE196. 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 recent Quarterly Report on Form 10-Q filed on August 12, 2019 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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SOURCE IDEAYA Biosciences, Inc.

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