Phase 1/2 Clinical Trial Data for IDE196 Presented at Society for Melanoma Research Congress

- Robust enrollment, with 27 total patients enrolled in the Phase 1 dose escalation portion, including 12 patients in MUM DLT cohorts, 14 patients in MUM overflow cohort, and 1 GNA11 cutaneous melanoma patient in non-MUM GNAQ/11 cohort
- All 12 patients in DLT cohorts remained on therapy with Duration of Treatment ranging from 1.3 to 4.0 months as of October 28, 2019 data cut-off
- No dose limiting toxicities were reported in MUM DLT cohorts and no adverse events > Grade 3 were reported in any patients
- On-track for Phase 2 dose-selection and expansion into the potential registration-enabling portion of the trial for MUM in December 2019

SOUTH SAN FRANCISCO, Calif., Nov. 20, 2019 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics to treat cancer, announced it has presented data from an ongoing Phase 1/2 clinical trial entitled "A Phase 1/2 Study in Patients with Solid Tumors Harboring GNAQ/11 Mutations or PRKC Fusions" (ClinicalTrials.gov Identifier: NCT03947385). This clinical trial is evaluating the tolerability and preliminary clinical activity of IDE196 for the treatment of Metastatic Uveal Melanoma (MUM) and other solid tumors harboring GNAQ or GNA11 (GNAQ/11) mutations activating the PKC signaling pathway.

Data was presented by Dr. Matteo Carlino, Medical Oncologist, Westmead Hospital and University of Australia, Westmead, Australia at the 16th International Congress for the Society for Melanoma Research (SMR Congress) at the Grand America Hotel in Salt Lake City, Utah, on November 20, 2019.

"We are evaluating IDE196 at two dose regimens of 300 mg BID and 400 mg BID following a 200mg BID run-in for the first seven days of dosing. Our hypothesis is that the run-in approach, which was has not been previously tested in a monotherapy setting, may improve tolerability and potentially increase exposure," said Dr. Matteo Carlino, Medical Oncologist, Westmead Hospital and University of Australia, Westmead, Australia.

"There is need for more effective therapies for patients facing Metastatic Uveal Melanoma. We are pleased to see the preliminary safety and tolerability of IDE196 in Phase 1 of the clinical trial, which may enable a duration of treatment that may be impactful," said Dr. Meredith McKean, MD, MPH, Investigator, Melanoma Research Program at Sarah Cannon Research Institute, Nashville, TN.

Key highlights as of October 28, 2019 data cut-off include:

- Dosing schema: Cohort 1 patients (n=6) received 300mg BID, and Cohort 2 patients (n=6) received 200mg BID for the first 7-days (run-in) and then 400mg BID for all subsequent doses

- Run-in dosing schema utilized in Cohort 2 with objective to enhance exposure and improve tolerability

- 27 total patients enrolled in the Phase 1 dose escalation portion including:

    - 12 patients in the two MUM DLT cohorts (6 patients at 300mg BID, and 6 patients using run-in to 400 mg BID)
    - 14 patients in a MUM overflow cohort (6 patients at 300mg BID, and 8 patients using run-in to 400 mg BID)
    - 1 cutaneous melanoma patient having a tumor with a GNA11 mutation (GNA11 patient) in a non-MUM GNAQ/11 cohort

- All 12 patients in the two DLT cohorts remained on therapy with Duration of Treatment ranging from 1.3 to 4.0

months, as of the October 28, 2019 data cut-off

- No dose limiting toxicities were reported in the two MUM DLT cohorts; no adverse events ≥ Grade 3 and no patient discontinuations due to AEs were reported in any patients

- Additional Phase 1 patients enrolled in this ongoing trial post-October 28, 2019 to better characterize tolerability and pharmacokinetics for Phase 2 dose selection

- On-track for Phase 2 dose-selection and expansion into the potential registration-enabling portion of the trial for MUM in December 2019

- Interim data with efficacy for GNAQ/11 Phase 1/2 basket trial expected in Q2/Q3 2020

"We have achieved several key milestones for IDE196 monotherapy, including completing enrollment ahead of schedule in the Phase 1 dose escalation portion of our Phase 1/2 clinical trial, the first confirmed Complete Response in a MUM patient at month 31, and receiving FDA feedback on the proposed single arm trial design for evaluating IDE196 in MUM as a potential registration-enabling Phase 2 expansion portion of this clinical trial," said Julie Hambleton, M.D., Chief Medical Officer and Senior Vice President at IDEAYA Biosciences.

"We are excited for the opportunity to advance the targeted agent IDE196 to its next stage of development for patients with MUM and other solid tumors with GNAQ/GNA11 mutations. There is a high unmet medical need in MUM, where there are no FDA approved therapies. We look forward to our continued collaboration with our clinical investigators, the FDA and the patient community," 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) Phase 2 dose selection and expansion into the IDE196 Phase 2 portion of the Phase 1/2 clinical trial, (ii) potential of the dosing schema of 400 mg BID following a 200mg BID run-in for the first seven days to improve tolerability and potentially increase exposure of IDE196, and (iii) release of interim data for the IDE196 Phase 1/2 basket trial. 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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