IDEAYA Biosciences Announces IDE196 Monotherapy Phase 2 Dose Selection and Clinical Program Update

SOUTH SAN FRANCISCO, Calif., March 18, 2020 /PRNewswire/ -- IDEAYA Biosciences, Inc. (NASDAQ: IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics to treat cancer, announces an update for IDE196, a Protein Kinase C (PKC) inhibitor, in its 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).

IDEAYA is pursuing both a monotherapy and combination approach for IDE196 in Metastatic Uveal Melanoma and GNAQ/GNA11 hotspot mutation solid tumors, including Cutaneous Melanoma and Colorectal Cancer. The company selected a Phase 2 monotherapy dose of 400mg BID (with one-week 200mg BID run-in) and achieved first-patient-in (FPI) for the GNAQ/GNA11 non-MUM basket trial. IDEAYA also announced plans to evaluate the clinical combination of IDE196 and binimetinib, a MEK inhibitor. IDEAYA anticipates initiating this clinical combination in mid-2020 as part of its ongoing Phase 1/2 clinical trial.

Key IDE196 program updates as of March 15, 2020 include:

- 53 patients enrolled in Phase 1/2 monotherapy study, including 49 in MUM and 4 in Cutaneous Melanoma, from earlier-reported 40 patients in December 2019
- Selected 400mg BID (with one-week 200 mg BID run-in) as Phase 2 monotherapy dose; observed approximately 44% higher average steady state exposure of free IDE196 (AUC_{free}) and approximately 40% higher trough concentration of IDE196 (C_{min}) at the higher 400 mg BID run-in dose relative to the 300 mg BID dose
- Initiated Phase 2 monotherapy expansion for GNAQ/GNA11 non-MUM basket trial
- Phase 1 sub-study evaluation of pharmacokinetic profile for tablet formulation demonstrates targeted equivalence of pharmacokinetic properties with powder-in-capsule (PIC) formulation; 11 MUM patients dosed with the tablet formulation
- Targeting initiation of IDE196 and binimetinib combination clinical trial in mid-2020
- Interim data from IDE196 monotherapy Phase 1/2 clinical study targeted for second half of 2020
- Design and initiation of potential registration-enabling study in MUM will be evaluated based on results of the ongoing Phase 1/2 monotherapy arm and the IDE196 and binimetinib combination arm of the clinical trial, at which time we will provide guidance on potential NDA timing
- Cash currently anticipated to be sufficient to fund planned operations into end of 2021 to early 2022, which is an extension from the earlier guided third quarter 2021

"We continue to see robust enrollment of MUM patients in our Phase 1/2 monotherapy study and look forward to providing the interim data update in the second half of 2020," said Julie Hambleton, M.D., Chief Medical Officer and Senior Vice President at IDEAYA Biosciences. "We have made significant progress in the IDE196 clinical

program, including selecting the Phase 2 monotherapy dose, initiating Phase 2 monotherapy expansion for the basket trial for non-MUM patients, and introducing the tablet formulation. In addition, we plan to evaluate a combination strategy targeting multiple nodes of the MAP-Kinase pathway, which we believe may inform the optimal registrational path for MUM."

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 a combination clinical trial of IDE196 plus a MEK inhibitor in mid-2020, (ii) timing of release of interim monotherapy data for the IDE196 Phase 1/2 basket trial, (iii) timing of evaluation of initiation and design of potential registration-enabling study in MUM, and (iv) sufficiency of cash to fund planned operations into the end of 2021 or early 2022. 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 November 13, 2019 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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