IDE196 Program Updates: Targeting Initiation of Potentially Registration-Enabling Phase 2 Single-Arm Monotherapy Trial in MUM and Introduction of Tablet Formulation in Q1 2020

- Targeting initiation of Phase 2 single-arm potentially registration-enabling clinical trial in MUM in Q1 2020, potentially coinciding with Phase 2 introduction of tablet formulation
- Pharmacokinetic Phase 1 clinical sub-study with immediate release tablet formulation of IDE196 scheduled to initiate in January 2020
- Initiated 13-week GLP-compliant toxicology studies in two species in November 2019, in support of FDA requirement for registration-enabling clinical trial
- Total of 40 patients enrolled in the Phase 1 portion of the Phase 1/2 GNAQ/11 basket trial as of December 6, 2019, including 38 MUM and 2 non-MUM patients
- On track to present interim clinical data from the GNAQ/11 Phase 1/2 monotherapy basket trial in Q2/Q3 2020

SOUTH SAN FRANCISCO, Calif., Dec. 9, 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 further progress on key elements of 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). 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.

"The pharmacokinetic clinical sub-study for the tablet formulation is on-track to start in January 2020. This may enable the initiation of the Phase 2 expansion to coincide with potential introduction of the tablet in Q1 2020. We also continue to evaluate the Phase 1 dose escalation data, including pharmacokinetic and tolerability data, as we target to advance IDE196 into the potentially registration-enabling study for MUM," said Julie Hambleton, M.D., Chief Medical Officer and Senior Vice President at IDEAYA Biosciences.

Key updates include:

- Initiated 13-week GLP-compliant toxicology studies in 2 species in November 2019, in support of registration-enabling FDA requirement to submit study results prior to enrollment of more than approximately 50 patients in the investigational arm of the clinical trial that will support a marketing application
- Pharmacokinetic Phase 1 clinical sub-study with immediate release tablet formulation of IDE196 scheduled to initiate in January 2020, in support of potential introduction of the tablet in the Phase 2 clinical trial in Q1 2020
- Targeting initiation of Phase 2 single-arm potentially registration-enabling clinical trial in MUM in Q1 2020, which we anticipate may coincide with introduction of tablet formulation
- Targeting initiation of combination clinical trial of IDE196 plus a MEK inhibitor in H1 2020, accelerated from earlier guidance. Preclinical evaluation of potential additional combinations ongoing
- Total of 40 patients enrolled in the Phase 1 portion of the Phase 1/2 GNAQ/11 basket trial as of as of December 6, 2019, including 38 MUM patients, for which dose escalation is complete, and 2 non-MUM patients, for which enrollment is ongoing
- Launching the IDEAYA Genomics Profiling Initiative (IDEAYA GPI). IDEAYA GPI is a company initiative leveraging various Next Generation Sequencing (NGS) platforms, including in partnership, to identify patients having tumors with specific mutations, such as tumors with activating GNAQ/11 mutations for potential enrollment in our IDE196 basket trial
- On track to present interim clinical data from the GNAQ/11 Phase 1/2 monotherapy basket trial in Q2/Q3 2020

"We are excited for the opportunity to initiate the single-arm Phase 2 monotherapy expansion, which is potentially

registration-enabling for MUM. We also look forward to advancing the clinical combination of IDE196 with MEK, as well as the GNAQ/11 basket trial to evaluate the clinical activity of IDE196 in non-MUM patients, including in skin melanoma," 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 initiation of the IDE196 Phase 2 portion of the Phase 1/2 clinical trial, (ii) potential introduction of the tablet formulation in the Phase 2 clinical trial, (iii) pharmacokinetic Phase 1 clinical sub-study with immediate release tablet formulation of IDE196, (iv) potential for IDEAYA Genomics Profiling Initiative (IDEAYA GPI) to identify patients having tumors with specific mutations, such as tumors with activating GNAQ/11 mutations for potential enrollment in our IDE196 basket trial, (v) initiation of a combination clinical trial of IDE196 plus a MEK inhibitor in Q2 2020, and (vi) 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 November 13, 2019 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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